7 Introduction to the Concepts and Methods of Uncertainty Analysis

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Introduction

Uncertainty is present in virtually all parts of risk assessment; risk analysts are almost certain to encounter it when identifying potential adverse effects, when estimating parameters that predict the probability of adverse effects and when interpreting terms such as 'adverse effects'. The key to any reliable risk assessment is to recognize and treat (i.e. analyse, eliminate or propagate through the risk assessment) the various sources of uncertainty. Burgman (2005) defines an 'honest' risk assessment as one that: (i) is faithful to assumptions and the kinds of uncertainty embedded in it; (ii) carries these uncertainties through chains of calculations and judgements; and (iii) represents and communicates them in a reliable and transparent manner. Thus, uncertainty analysis is crucial to the scientific credibility, accuracy and 'honesty' of a risk assessment.

This chapter provides a non-technical introduction to uncertainty and uncertainty analysis. It aims to help risk analysts complete an 'honest' risk assessment and policy advisers to correctly interpret the results of a risk assessment. The chapter discusses the three main types of uncertainty commonly encountered in environmental risk assessment, and identifies techniques to address them. It also briefly highlights a number of practical analysis issues. Since the theory and methodology of uncertainty analysis are broad and continue to develop, this chapter highlights only the most relevant methods for risk assessment of transgenic fish, and it directs readers to other literature sources for more detailed information.

Types of Uncertainty

The different kinds of uncertainty in environmental risk assessment, and methods for their treatment, are summarized in a variety of ways (Baybutt, 1989;

Morgan and Henrion, 1990; Haimes, 1998; Cullen and Frey, 1999; Regan *et al.*, 2002a; Regan *et al.*, 2003). This chapter distinguishes between three main types of uncertainty: linguistic uncertainty, variability and incertitude. These distinctions are important because each type arises from very different mechanisms, and risk analysts must use different approaches to represent, propagate and communicate these uncertainties (Ferson, 1996; Ferson and Ginzburg, 1996; Regan *et al.*, 2002a). The most important reason for this distinction, however, is that some sources of uncertainty can be eliminated through appropriate treatment (e.g. some sources of linguistic uncertainty), others can be reduced by further data collection (e.g. incertitude), while still others can neither be reduced nor eliminated and can only be better represented and understood (e.g. variability).

Linguistic Uncertainty

Linguistic uncertainty occurs in environmental risk assessment because the language used to describe events and processes is sometimes ambiguous, context-dependent, underspecified and vague. Linguistic uncertainty is present in all types of risk assessment, but it is particularly prevalent in qualitative risk assessment (Chapter 1, this volume). It also occurs in policy advice, management decisions and stakeholder deliberations because interpretations of institutional directives and broadly defined scientific terms can influence decisions about what to assess and how to interpret the results of assessments. It is therefore important to identify the relevant sources of linguistic uncertainty at the outset of any risk assessment, to apply appropriate treatments if it cannot be eliminated and to be aware of the possible consequences of linguistic uncertainty when it cannot be eliminated or treated.

Ambiguity

Ambiguity arises when words have more than one meaning, and it is not clear which one is meant. For example, the term 'genetically modified' could encompass organisms modified by traditional breeding methods. However, it is more generally used to refer to organisms modified in ways that do not occur naturally from mating and natural recombination (EU, 2001), and the term reflects important differences associated with modern genetic techniques relevant for a risk assessment (Regal, 1994). This source of linguistic uncertainty is relatively simple to address and clearly defines the term to remove its ambiguity. Although simple to remove, ambiguity can often be a resilient source of uncertainty if there is strong disagreement about the working definition of terms.[1]

Context Dependence

Context dependence is uncertainty caused by a failure to specify the context in which a term is to be understood. A clear way to deal with context dependence

[1] The PFOA process (Chapter 2, this volume) provides a mechanism to identify and resolve these types of disagreements.

is to ensure that the context is stated explicitly. Issues of context dependence can occur in risk assessments of transgenic fish. For example, 'large-scale' escapes of transgenic fish (Chapter 5, this volume) can mean many different things depending on the size and intensity of the production facility.

Underspecificity

Underspecificity occurs when there is unwanted generality; the statement in question does not provide the degree of specificity required in order to proceed with an assessment or decision. Statements relevant for risk assessment can be underspecified with respect to location, time, species, methods, etc. For example, the following statement is underspecified with respect to species and method: '... in a small percentage (generally <10%) of founder fish, foreign DNA is integrated into the host genome and thus permanently retained in the transgenic fish ...' (Chapter 4, this volume). In reality, the success rate of transgenic methods for integrating foreign (exogenous) DNA into the genome of a fish varies markedly and depends on the method, the fish species and the skill of the technician involved (see Chapter 3, this volume). Underspecificity is minimized by providing all relevant contextual data, thereby ensuring the narrowest possible bounds on the statement in question.

Vagueness

Vagueness arises because terms used in environmental risk assessment, such as categorical descriptions (high, medium and low) of consequence and likelihood, sometimes allow borderline cases. Vagueness is particularly prevalent in qualitative risk assessments. This is because such risk assessments often differentiate impacts spatially and temporally, assigning, for example, the same level of risk to 'local, long-term' and 'widespread, short-term' impacts. Words such as 'local', 'widespread', 'short-term' and 'long-term' are vague because some impacts may be borderline cases, i.e. neither local nor widespread, and neither short- nor long-term. It is important to note that these terms are also context-dependent, but the vagueness still persists after the context is defined. A common treatment for vagueness is to substitute potentially vague terms with precise definitions. For example, the term 'local' might be defined as less than 10 km from an initial release site, 'widespread' defined as 'greater than 10 km', 'short-term' defined as 'less than 5 years' and 'long-term' defined as 'greater than 5 years'.

It is important to realize that precise definitions may not always honour the spirit in which the words are intended to be used. For instance, in the previous example, a distribution of 11 km would be considered widespread, whereas a distribution of 9 km would not. Vague terms operate along a continuum where there is a degree to which a statement is satisfied, and as such they are a source of uncertainty that is not always desirable to eliminate with precise definitions. Perhaps the most widely applied treatment of vagueness in scientific applications is fuzzy sets (e.g. Fig. 7.1) and fuzzy logic (Zadeh, 1978). Other treatments include supervaluations, rough sets, three-valued logic and other logic systems (see Regan *et al.*, 2002a, and references therein).

Conventional statements relevant to the risk assessment of transgenic organisms which are subject to considerable linguistic uncertainty include terms

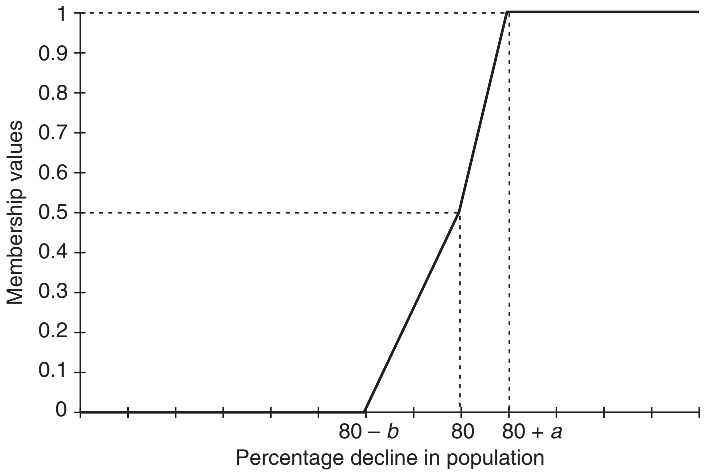

Fig. 7.1. The membership function for a fuzzy set that maps the percentage decline in a species population (*x*-axis) to the probability that it belongs to the set 'critically endangered' (*y*-axis). In this example, *a* and *b* are positive real numbers used to define the upper and lower bounds of the set, i.e. the percentage decline in a species population such that it is definitely endangered and definitely not endangered. Fuzzy sets are commonly used to eliminate vagueness from terms such as 'critically endangered'. (Reprinted from Regan *et al.*, 2000, with permission from Elsevier.)

like 'familiarity' (Van Dommelen, 1998; OECD, 2000). Consider the following statement found in a proposed risk assessment framework for genetically modified organisms:

> When the familiarity standard for a plant or micro-organism has been satisfied such that reasonable assurance exists that the organism and the other conditions of an introduction are essentially similar to known introductions . . . the introduction is assumed suitable for field testing.
>
> (National Research Council, 1989)

Terms such as 'familiarity', 'essentially similar' and 'reasonable assurance' are vague ('reasonable assurance' permits borderline cases), context-dependent ('conditions of an introduction' vary dramatically between species, locations and over time) and underspecific ('other conditions' do not specify how many and what type of conditions must be considered). Hence, statements can be subject to multiple sources of linguistic uncertainty. These sources of linguistic uncertainty may be further compounded by variability and incertitude, as discussed below.

Variability

Variability is the uncertainty caused by fluctuations or differences in a quantity or process. Variability can occur because a parameter naturally fluctuates over time (e.g. water temperature in a given location), with location (e.g. average rainfall at different locations in April) or within a group (e.g. survival rates within a metapopulation). Parameters which vary through time and space in this manner are common in environmental risk assessment. Risk assessment parameters may also depend on other variables in ways that are difficult to quantify. Variation is therefore pervasive in all environmental risk assessments, and the term 'risk' is sometimes invoked to reflect this fact (Regan *et al.*, 2003).

Variability cannot be reduced by gathering additional data, but it can often be represented more accurately and communicated better with additional data. For example, structured population dynamics are essential elements of most models that predict fish population changes. Devlin *et al.* (Chapter 6, this volume) identify abundance, age structure and survival as key determinants of population behaviour. However, age- or stage-specific survivorship and fecundity are buffeted by unpredictable changes in environmental conditions, mitigated by temperature, currents, nutrients and trophic chain dynamics, all of which are inherently variable. Fortunately, there are a variety of mathematical methods available to characterize variability and propagate it through models (Box 7.1). Monte Carlo methods are the most common treatments of variability used in environmental risk assessment. These methods involve assigning probability distributions to parameters, then propagating the variability due to these multiple

Box 7.1. Mathematical methods for variability analysis.

First-order moment propagation

First-order moment propagation uses the rules of probability to estimate the means and variances of sums, products, differences and quotients based on the means and variances of the input variables. This method is useful when the means and variances of the variable parameters of a risk assessment model are known (or can be estimated) but their statistical distribution is not. The mean and variance of an uncertain parameter can be estimated from data or elicited based on subjective expert judgement. Although this approach has been widely used in conservation biology and traditional fisheries science (it is sometimes called the 'delta method': Seber, 1973), examples of first-order moment propagation in environmental risk assessment are rare. The authors are unaware of any examples relevant to transgenic fish.

Monte Carlo simulation

Monte Carlo simulation takes repeated random samples from statistical distributions specified for each variable parameter in the risk assessment, evaluates the risk algorithm many times and builds risk curves from the results (Fig. 7.2; Cullen and Frey, 1999). This method is useful when variable parameters in a risk assessment model can be represented by a statistical distribution. These statistical distributions may be based either on the probabilistic properties of the process being modelled, the empirical distribution of data, expert judgement or any information on the expected distribution of system behaviour (Gardner and O'Neill, 1983; Burgman, 2005). There are some ecological risk assessments relevant to transgenic fish that use or recommend Monte Carlo simulation to represent variability. Notable references include Murray (2002), Vose (2000) and Bartell and Nair (2003). It is important to note that Monte Carlo simulation analysis usually assumes that input parameters are independent or, at best, linearly dependent in a known manner. These assumptions, however, are rarely explored or supported by empirical data.

parameters through mathematical equations using random or stratified sampling techniques (Fig. 7.2). One or more of these methods could be applied, for example, to the variability associated with age- or stage-specific survivorship, growth rate, longevity, length or most traits identified in Chapter 6 that influence potential ecological impacts of transgenic fish. However, it is important to note that risk assessments based on Monte Carlo simulations typically make a

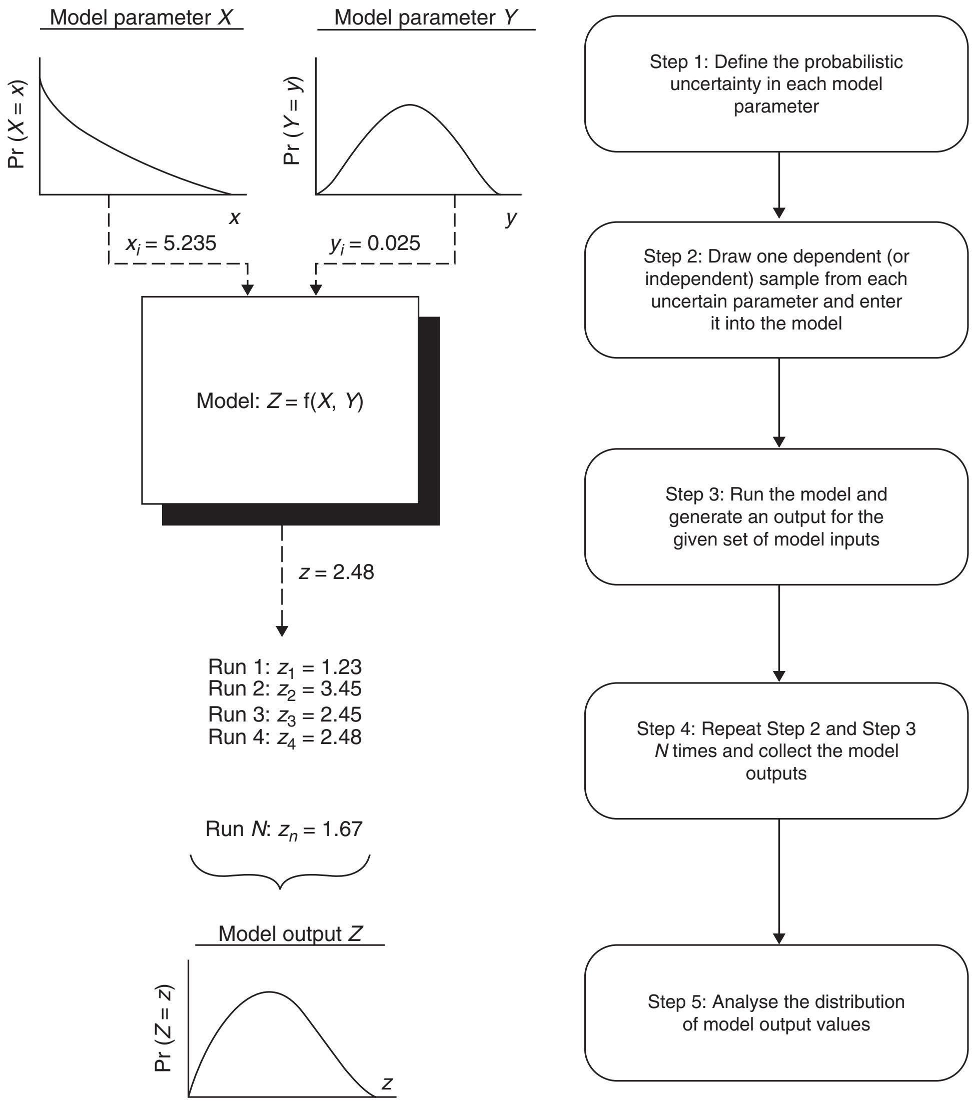

Fig. 7.2. Schematic and flowchart of a first-order Monte Carlo simulation. Monte Carlo simulation methods are commonly used to characterize the variability in model inputs parameters (*X* and *Y*) and explore the effect of this variability on the model output (*Z*). (Reprinted from Cullen and Frey, 1999, with permission of Springer Science and Business Media.)

number of often unwarranted assumptions that must be treated carefully in order to avoid overly optimistic results (see section on Dependence between Random Variables, this chapter).

Incertitude

Incertitude is uncertainty caused by measurement error, systematic bias, missing data, censoring, use of surrogates, incomplete descriptions of a mechanism or process and other limitations of scientific knowledge. It is sometimes described in the literature as epistemic, subjective or Type I uncertainty, as well as knowledge uncertainty. The large number of sources of incertitude is partially responsible for its broad taxonomy. Its key defining criterion, however, is that it can be reduced by gathering additional data.

Measurement Error

Measurement error occurs because observers and their equipment are imperfect. Measurement error can appear as random variation around a presumed true value and as systematic bias from this value. Random variation can be represented through simple intervals, confidence intervals or probability distributions (Edwards, 1996; Ferson, 2002). Systematic bias occurs through a variety of mechanisms: deliberate or accidental exclusion of certain data (censoring), poor calibration of measuring devices, non-random or poorly stratified field surveys, reference class problems[2] and extrapolation of surrogate information gathered at one site, or for one species, to other sites or species (Regan *et al.*, 2002a). Systematic bias is notoriously difficult to identify a priori and is best eliminated or minimized by careful study design and by validating predictions with independent data sets.

Model Uncertainty

In a risk assessment, our understanding of ecological systems can be expressed by qualitative, statistical or mechanistic models of the system in question (Levins, 1974). Incomplete understanding of these systems is reflected in the assessment as 'model uncertainty', and this is a particularly important source of incertitude in quantitative environmental risk assessment. Model uncertainty occurs where variables and processes are omitted (via abstraction and simplification of complex realities) and because of the variety of ways mathematical equations can be used to represent ecological processes. Model results are also subject to compounding effects of uncertainty and variability in parameter estimates. Although complex models may be more realistic and relevant to the system under investigation (Bartell *et al.*, 2003), they usually involve many uncertain parameters. Hence, minimization of uncertainty in model results will often involve a trade-off between model complexity and parameter uncertainty. Simpler models will usually be subject to greater model uncertainty but contain

[2] Reference class problems occur because there is often no 'natural' or unique class of events that underlie a frequency probability. The event class is more usually the subjective choice of the analyst. For example, there is often no obvious way to group data into discrete categories when constructing a histogram.

few uncertain parameters, while more complex models will usually contain more realism but rely on a greater number of uncertain parameters.

Some subjective judgement is usually required when an analyst chooses which model to use in a risk assessment. The literature provides guidance on how to measure important ecological processes (see Chapters 6 and 9, this volume, for some examples), represent these processes mathematically (Crawford-Brown, 2001) and choose optimally complex models (Jackson *et al.*, 2000; Pastorok *et al.*, 2002; Bartell *et al.*, 2003). Furthermore, there are a variety of techniques that can help analysts make more objective model choices. These techniques help the analyst explore alternative model specifications, identify important interactions in complex systems, distinguish genuine incertitude from variability, choose the most parsimonious model from a range of possible models and identify at what point uncertainty may change a risk-based decision (Box 7.2).

Incertitude arises in transgenic fish risk assessment, for example, through the extrapolation of data from unmodified surrogates to genetically modified fish and through problems associated with genotype-by-environment (G × E) interactions (see Chapter 6, this volume). The presence of G × E interactions implies that the statistical characteristics of important phenotypic properties of

Box 7.2. Mathematical methods for incertitude analysis.

Sensitivity analysis

Sensitivity analysis explores the effect of different modelling decisions and assumptions on the results of the risk assessment (e.g. different parameter values, alternative model structures, statistical models or dependence between parameters). This method is useful because all risk assessment models include assumptions and inherent modelling decisions. There are usually many possible combinations of parameter values, model structures and dependence relations that could be explored. In practice, analysts usually select only two or three, representing worst, anticipated and best case scenarios (if it is possible to discern them all). Figure 7.3, for example, shows the results of a sensitivity analysis applied to two out of six parameters of a net fitness model for transgenic fish (Muir and Howard, 2002). There are a variety of ways to perform sensitivity analyses, depending on the model and decision context (Morgan and Henrion, 1990; Helton and Davis, 2002; Burgman, 2005).

Interval analysis

Interval analysis (Dwyer, 1951; Moore, 1966; Alefield and Herzberger, 1983; Neumaier, 1990) is one of the simplest ways to represent and propagate incertitude in quantitative and semi-quantitative risk assessment. This method is useful in data-poor situations when the bounds (max/min or best estimate ± some error) of uncertain model parameters can be expressed as an interval. Arithmetic operations on intervals are defined so that the results enclose the true value with certainty, given the input intervals (Ferson, 2002). The interval for a parameter may be calculated from data, estimated based on expert judgement, or simply reflect optimistic and pessimistic model assumptions. There are a few examples that employ interval analysis in ways relevant to risk assessment of transgenic fish, including Brown and Patil (1986), Hayes *et al.* (2005) and Nyberg and Wallentinus (2005). While interval analysis is most often used to deal with incertitude alone, it can also be applied to compound variability and incertitude (see Box 7.3).

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Box 7.2. *Continued*

Qualitative modelling

Qualitative modelling is an extension of loop analysis (Puccia and Levins, 1985) that can address incertitude associated with the structure of the 'community matrix' (see the right-hand side of Fig. 7.4). It is a useful way to explore the effect of different models of the community's structure, or different interactions within a structure, on the community's response to sustained stress (Fig. 7.4). Qualitative modelling focuses on the sign (positive or negative) of the interaction between species and their physical resources within a community matrix, but it ignores the strength (magnitude) of this interaction. By ignoring the strength of the interaction, analysts can focus on the structural uncertainty in the community matrix and quickly explore the direction of change (increase, decrease or no change) of any particular component of any community structure (Dambacher *et al.*, 2002, 2003; Ramsey and Veltman, 2005). Importantly, qualitative modelling can be extended to examine the incertitude found in any structured set of interactions so long as the system in question is in, or close to, dynamic equilibrium (Dambacher *et al.*, in review; see also Chapter 6, this volume).

Aikake Information Criteria (AIC)

The Aikake Information Criteria (AIC) provides an objective way of determining the most prudent model from a range of possible models. It measures the parsimony (conciseness) of the model and is therefore useful when the analyst must choose from among a selection of plausible risk assessment models. The AIC combines a measure of the model likelihood (given the data) with a penalty for number of model parameters that must be estimated. By itself, the AIC for a given data set has no meaning. It is only useful when the AIC of a series of specified models are compared. The model with the lowest AIC is regarded as the 'best' of those considered. The AIC does not, however, reduce the uncertainty of any particular model.

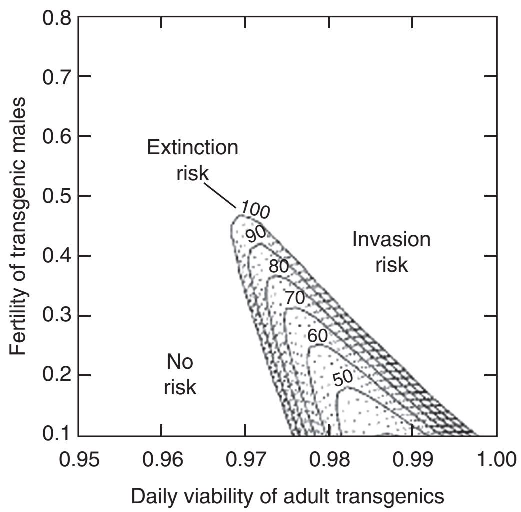
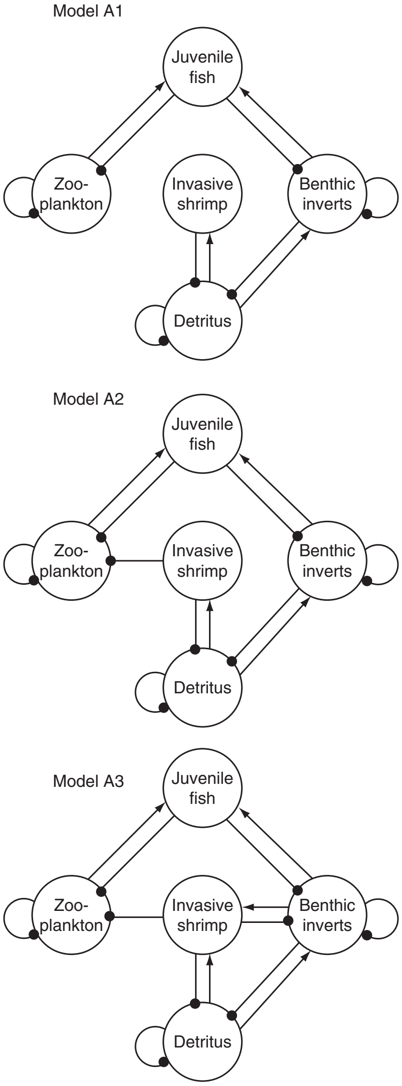


Fig. 7.3. Results of a sensitivity analysis highlighting the effect of varying the values of two model parameters (daily viability of adult transgenic fish and fertility of male transgenic fish) of a net fitness model for transgenic fish. (Reprinted from Muir and Howard, 2002, with permission from Springer Science and Business Media.) Refer to Chapter 5 for further discussion of this model.



$$A1 = \begin{vmatrix} -1 & 0 & -1 & -1 & 0 \\ 0 & -1 & 0 & 0 & -1 \\ 1 & 0 & 0 & 0 & 0 \\ 1 & 0 & 0 & -1 & -1 \\ 0 & 1 & 0 & 1 & 0 \end{vmatrix}$$

$$A2 = \begin{vmatrix} -1 & 0 & -1 & -1 & 0 \\ 0 & -1 & 0 & 0 & -1 \\ 1 & 0 & 0 & 1 & 0 \\ 1 & 0 & -1 & -1 & -1 \\ 0 & 1 & 0 & 1 & 0 \end{vmatrix}$$

$$A3 = \begin{vmatrix} -1 & 0 & -1 & -1 & 0 \\ 0 & -1 & -1 & 0 & -1 \\ 1 & 0 & 0 & 1 & 0 \\ 1 & 0 & -1 & -1 & -1 \\ 0 & 1 & 0 & 1 & 0 \end{vmatrix}$$

Fig. 7.4. Three hypothetical qualitative models (left) and the equivalent community matrix (right) showing possible interactions between a non-native, invasive shrimp and four components of the invaded ecosystem: detritus, zooplankton, benthic invertebrates and juvenile fish. Lines with arrows indicate positive effects, and those with filled circles denote negative effects. Self-effects are shown by lines that start and end at the same node (see Dambacher *et al*. [2003] for guidance on computing the community matrix). The different models are used to explore three different hypotheses: Model A1 – the shrimp feeds only on detritus; Model A2 – the shrimp feeds on detritus and competitively interferes with zooplankton; and Model A3 – the shrimp feeds on detritus, benthic invertebrates and competitively interferes with zooplankton. By analysing the sign of the interaction terms in the community matrices the analyst can predict the (in this case indirect) effect of the shrimp on juvenile fish. (From J. Dambacher, CSIRO, Australia, 2006, personal communication.)

transgenic fish in the wild (such as feeding rates, growth rates, predator avoidance, fecundity, etc.) may be substantially different from those measured in the laboratory. Therefore, there is both variability in, and incertitude about, these phenotypic properties.

Treatments for Variability and Incertitude

In practice, the distinction between variability and incertitude is not always clear and may be context-dependent. Moreover, most risk assessment problems must deal with both types of uncertainty. This is particularly true for transgenic fish because there is limited empirical information available to inform critical components of a risk assessment. Fortunately, there are a variety of mathematical tools that can accommodate both types of uncertainty, and there are a few that are specifically designed to handle both simultaneously (Box 7.3). Probability bounds analysis (Fig. 7.6; Ferson, 2002), interval analysis (Moore, 1966) and information gap decision theory (Ben-Haim, 2001) entail the least number of assumptions, and for this reason they are probably the most promising mathematical approaches. Probability bounds analysis and information gap theory are relatively new methods, and although there are some ecological applications available, the authors are unaware of any pertaining to transgenic fish.

Practical Issues when Dealing with Uncertainty

Data Types and Requirements

There are two general categories of data typically used in environmental risk assessment: (i) empirical observations of relevant parameters; and (ii) expert and stakeholder opinion. Empirical observations of relevant parameters are often considered to be 'objective' sources of data, although in reality experimental observations and measurements often incorporate important subjective decisions (Berger and Berry, 1988). Expert and stakeholder opinion may be based on their (sometimes different) interpretation of empirical measurements or on their accumulated experience and beliefs. As such, they are often labelled as 'subjective' sources of data.

The most appropriate representation of empirical variability depends on the quantity of observations available. Sample or empirical distribution functions (Gardner and O'Neill, 1983) are simple, do not require large amounts of data (e.g. 20 or more observations) and let the data speak for themselves. These functions assume that the data are collected randomly and are representative of the variable in question. Cullen and Frey (1999) reviewed strategies for computing empirical distributions from data. It has been found that kernel density estimates (Epanechnikov, 1969; Silverman, 1986) can be applied to small (e.g. at least 20 observations) data sets, but they require further assumptions, most notably about the maximum and minimum values that the variable can

Box 7.3. Mathematical methods that simultaneously treat variability and incertitude.

Two-dimensional Monte Carlo simulation
Two-dimensional (or second-order) Monte Carlo simulation nests one Monte Carlo simulation within another. This method is useful to simultaneously explore the effects of uncertainty and variability in a risk assessment model, while retaining a separate measure of the effect of each source of uncertainty on the risk assessment results. The inner simulation typically represents the natural variability in the physical or biological parameters of a risk assessment model. The outer simulation typically represents the analyst's incertitude about the parameters used to specify inputs to the inner simulation (Fig. 7.5). Each replication of the outer layer entails an entire Monte Carlo simulation. Two-dimensional Monte Carlo methods have been championed for use in risk analysis by Hoffman and Hammonds (1994), among others. Cullen and Frey (1999) give a good introduction to the technique. Wu and Tsang (2004) use this technique to explore the effects of incertitude in gravel-bed characteristics, and variability in the amount of sand accumulated in the bed surface, on the survival rate of salmonid embryos.

Probability bounds analysis
Probability bounds analysis computes the results of arithmetic operations using only the bounds of statistical distributions used to represent variable input parameters (Frank *et al.*, 1987; Williamson and Downs, 1990; Ferson and Long, 1995; Berleant and Goodman-Strauss, 1998; Ferson, 2002). This method is useful because it can represent variability and incertitude in both data-poor and data-rich situations. If there are enough empirical data to estimate the statistical distribution of uncertain model parameters and the dependence between them, the bounds on the resulting arithmetic operation will approximate the distribution resulting from a Monte Carlo simulation. When there is very little information about these distributions and the dependence between them, the resulting bounds tend to be much wider, representing weaker confidence about the results of the arithmetic operation (Fig. 7.6). Probability bounds analysis reliably propagates uncertainty about dependence between random variables through a risk assessment. It is more comprehensive than sensitivity analysis and computationally less demanding and often easier to interpret than two-dimensional Monte Carlo methods. See Regan *et al.* (2002b,c) for examples of probability bounds analysis applied to environmental risk assessment.

Information gap theory
Information gap theory asks how wrong a model and its parameters can be before jeopardizing the quality of decisions made on the basis of this model (Ben-Haim, 2001, 2005; Takewaki and Ben-Haim, 2005). Information gap theory does not use probability theory to represent uncertainty and variability, and it is therefore a useful way to address the 'robustness' of decision making in situations where it is difficult to apply probability theory, such as extremely data-poor situations. Information gap theory requires: (i) a model of the system in question; (ii) a non-probabilistic description of parametric and model structure uncertainty; and (iii) decision criteria. Information gap theory helps the analyst to explore the effects of unbounded, non-probabilistic measures of parameter or model uncertainty on the results of the model and the resulting decisions. For example, the analyst may increase the fractional error of important model parameters, recording the point at which a decision threshold is crossed. Examples relevant to environmental risk assessment include Regan *et al.* (2005) and Fox *et al.* (in press).

Fuzzy sets and arithmetic
Fuzzy sets simultaneously specify the range of an uncertain variable and the plausibility or possibility of intermediate values. The level of 'presumption' for any number of values on the

Continued

Box 7.3. *Continued*

range describes the level of possibility of these values being between 0 and 1 (Fig. 7.1; Kaufmann and Gupta, 1985). Often, fuzzy sets are triangular or trapezoidal in shape. More complicated forms can be constructed by stacking a series of interval estimates or specifying three or more intervening values (and their associated level of presumption) on the interval range. Fuzzy arithmetic is simply arithmetic (e.g. risk calculations) with fuzzy sets. Fuzzy sets are useful because they can help to eliminate vagueness from risk assessment terms such as 'high', 'medium' or 'low'. Fuzzy arithmetic is useful because it can simultaneously yield 'worst-case' and 'best-estimate' risk assessment results in data-poor situations (Ferson, 2002). However, fuzzy arithmetic becomes cumbersome, with repeated variables, and it cannot use knowledge of correlations to tighten the risk bounds (Ferson *et al.*, 2001).

Hierarchical Bayesian analysis

Hierarchical Bayesian analysis is essentially a Bayesian version of two-dimensional Monte Carlo analysis wherein the moments (e.g. mean and variance) of variable input distributions are themselves allowed to vary in a parametric fashion. It is a very powerful (but computationally intensive) method that is useful when variable and uncertain parameters in a risk assessment model can be represented by a statistical distribution. The computations associated with hierarchical Bayesian analysis were, until recently, prohibitively complex. However, recent numerical computation advances make the analysis much more tractable. Link *et al.* (2002) provide a general introduction to this subject matter.

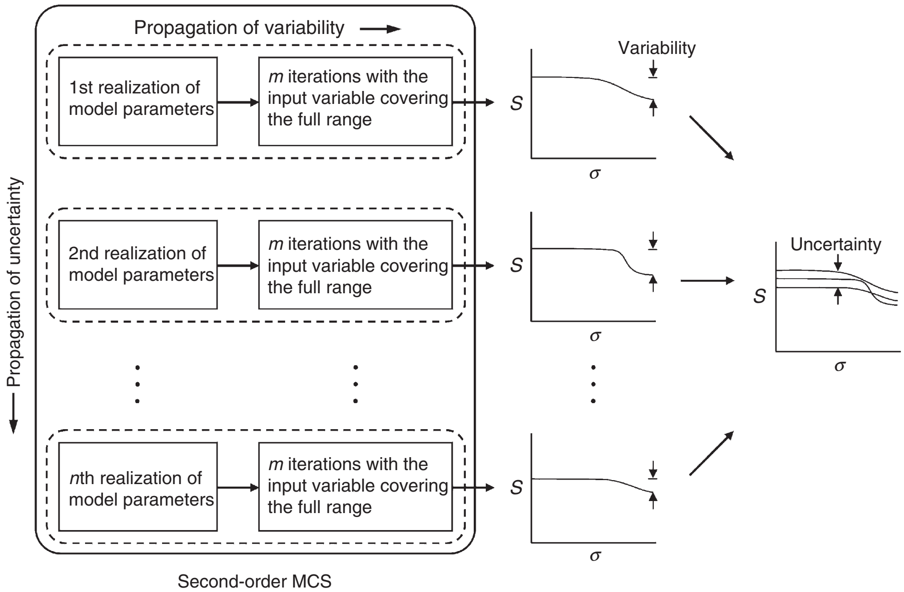


Fig. 7.5. Schematic showing the procedure and output of a second-order Monte Carlo simulation. In this example the salmonid embryo survival rate (S) is modelled as a function of the uncertain characteristics of the salmonid spawning nest and the variable sand composition (σ) of the stream bed. The m iterations of variability represent a first-order Monte Carlo simulation (refer to Fig. 7.2) in which S is calculated for a single value of each uncertain habitat parameter (drawn from triangular distributions) over the entire range of plausible values for σ. This procedure is repeated n times, drawing different values from the uncertain habitat characteristics each time. (Reprinted from Wu and Tsang, 2004, with permission from Elsevier.)

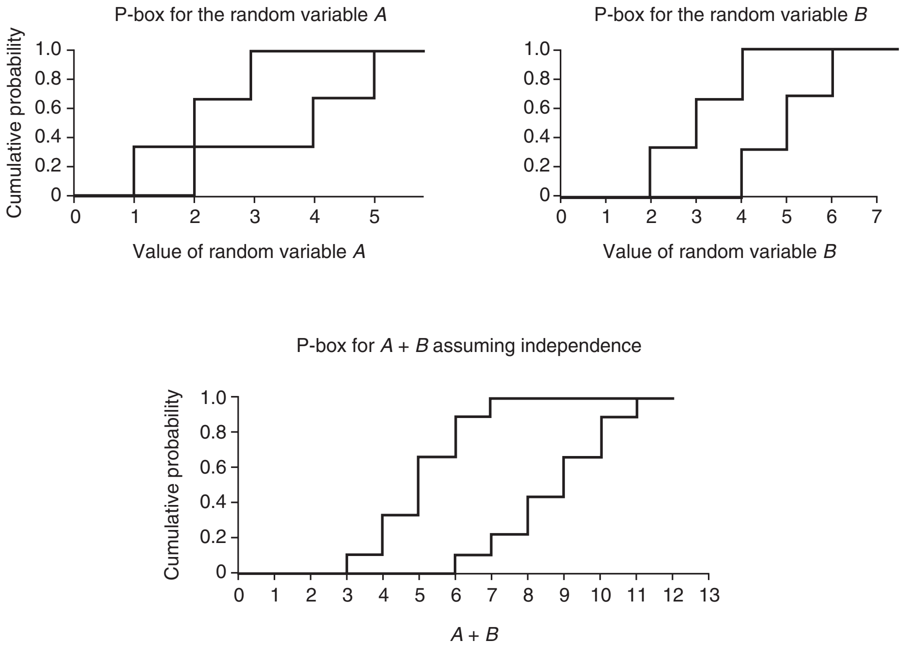


Fig. 7.6. Probability bounds analysis showing the result of the arithmetic operation *A* + *B* when the inputs *A* and *B* are variable and uncertain (and assumed to be independent). Variability in *A*, for example, is reflected by the cumulative probability of it taking any particular value on the range [0,5]. Uncertainty in *A* is reflected in the upper and lower bounds of the cumulative probability. Note that a different result for *A* + *B* would occur if no assumption were made about the dependence between these variables. (Reprinted from Burgman, 2005, with permission from Scott Ferson.)

take. Parametric approaches based on discrete or continuous population distributions require larger data sets (e.g. at least 30 observations), and they must fit the most likely of a range of possible distributions using a variety of techniques and statistical tests (Palisade Corporation, 1996; Ferson *et al*., 2001). Moore (1996) discusses some of the problems associated with parametric distribution choice in Monte Carlo simulations and makes a number of useful recommendations. Probability bounds analysis deals with uncertainty in a range of assumptions, including distribution shape, values of the mean, standard deviation and specified percentiles.

Subjective estimates of variation can be informally or formally elicited from experts using a variety of techniques (Morgan and Henrion, 1990). Informal probability estimates should be avoided wherever possible because of the 'psychological frailties' (such as overconfidence and insensitivity to sample size) discussed in Chapter 1. Burgman (2005), Vose (2000) and Cullen and Frey (1999) provide general summaries of formal elicitation and aggregation techniques, together with their advantages and potential pitfalls. However, these formal procedures are time consuming and are rarely employed in environmental risk assessment. To date, the authors are unaware of any examples relevant to transgenic fish.

Dependence Between Random Variables

The preceding sections of this chapter emphasize the uncertainty associated with environmental risk assessment models and input variables. Risk assessments that acknowledge uncertain input parameters will inevitably entail arithmetic operations performed on random variables. It is important to recognize that the results of these operations, and hence the results of the risk assessment, are sensitive to the dependence (if any) between variables (see, e.g. Ferson and Burgman, 1995). Most probabilistic risk assessments assume independence among random variables, but this is not always a reasonable assumption. For instance, it is highly implausible that fish body size at maturity and fecundity are independent of one another (Jobling, 1995). The existence of dependent input variables can be checked by measuring their correlation and covariance using standard statistical techniques. However, it is important to note that correlation coefficients do not fully specify the dependence structure of two random variables, and zero correlations do not generally guarantee independence (Ferson *et al*., 2004).

Dependence problems can be avoided by restructuring a risk assessment model to include only independent variables or by stratifying the entire assessment for subgroups of relatively homogenous input variables. The first approach re-specifies dependent input functions as functions of other related input variables. For example, a variable representing fish fecundity could be replaced with an allometric relationship using fish body mass that includes an independent (by construction) random error term reflecting the residual uncertainty in fecundity remaining after body mass is accounted for. Unfortunately, predictable relationships such as those between fish body mass and fecundity are relatively rare. The second approach stratifies populations into relevant subgroups (e.g. by age, stage or gender), making assumptions about independence between variables more plausible. This approach, however, makes the risk assessment more complex and cumbersome because it has to be repeated for each subgroup.

Monte Carlo simulation can account for linear dependence between input variables by using correlation coefficients (see, e.g. Vose, 2000), but this approach can only model one out of the many possible dependence structures. If this approach is adopted, the analyst must ensure that the matrix of adopted correlation coefficients is feasible; for example, one variable cannot be strongly positively correlated with each of two variables that are themselves strongly negatively correlated. This assurance can be achieved by checking the mathematical properties of the correlation matrix (Iman and Davenport, 1982). A more comprehensive simulation approach based on copulas is available (Haas, 1999; Clemen and Reilly, 1999). Copulas provide a way to study and measure dependence between random variables (Nelsen, 1999). In practice, linear correlation is often used to measure dependence. Linear correlation, however, can be misleading and should not be taken as a general measure of dependence (see Ferson *et al*., 2004). The advantage of copulas is that they provide a formal way of dealing with the full spectrum of possible dependence between variables. The disadvantage of copulas is that they can be difficult to construct if there is little or no empirical information on the dependence in question. By contrast, probability bounds analysis (Box 7.3; Fig. 7.6) does not require a priori information on the strength of dependence between input variables, and it provides reliable results for all types of dependence. Interested readers should refer to Ferson and Long (1995) for further discussion about the problems associated with dependence between input variables, Monte Carlo analysis and the advantages of probability bounds analysis.

Resources for Capacity Building in Uncertainty Analysis

There are a variety of mathematical methods that, when carefully implemented, provide a comprehensive and honest account of uncertainty within quantitative risk assessment frameworks. These approaches range from relatively simple to very complex, and they all require some combination of training and practice to master. The Society for Risk Analysis (SRA) (available at: http://www.sra.org/) and the Society for Environmental Toxicology and Chemistry (SETAC) (available at: http://www.setac.org/) occasionally run uncertainty analysis seminars and workshops, and there are a small (but growing) number of universities offering courses on environmental risk assessment.

There are many free and commercially available software packages for dealing with uncertainty in calculations (Table 7.1). Ferson (2002) provides a comprehensive package that can perform risk assessment calculations using intervals and probability bounds. Statool also performs dependence bounds convolutions and probability bounds analysis (Berleant *et al*., 2003). Crystal Ball and @Risk (Palisade Corporation, 1996; Vose, 2000) enable first- and second-order Monte Carlo simulations within a Microsoft Excel spreadsheet environment. Qualitative modelling can easily be done using Maple. Information gap analysis, while conceptually quite complex, can be performed analytically and numerically using a variety of standard mathematical and statistical software packages, including spreadsheet packages. R, for example, is an excellent, and freely available, package capable of performing a variety of uncertainty

Table 7.1. Web sites for uncertainty analysis software.

Method	Software	Web site
Qualitative modelling	Maple	http://www.maplesoft.com/
Statistical modelling	R	http://www.r-project.org/
Bayesian modelling	WinBUGS	http://www.mrc-bsu.cam.ac.uk/bugs
Monte Carlo simulation	@RISK	http://www.palisade.com.au/risk/default.asp
Monte Carlo simulation	Crystal Ball	http://www.decisioneering.com/
Interval and probability bounds analysis	Risk Calc	http://www.ramas.com/riskcalc.htm
Probability bounds analysis	Statool	http://class.ee.iastate.edu/berleant/home/Research/Pdfs/versions/statool/distribution/index.htm

analyses, including information gap theory, sensitivity analysis, Aikake Information Criteria (AIC) calculations and hierarchical Bayesian analysis. WinBUGS is similar to R, but is specifically designed for Bayesian analysis.

Chapter Summary

Uncertainty is a pervasive phenomenon in biology that should be addressed in any environmental risk assessment. This chapter identifies three main types of uncertainty: linguistic uncertainty, variability and incertitude. Qualitative risk assessment is fraught with linguistic uncertainty and does not adequately deal with incertitude and variability. Although quantitative risk assessments are not immune from linguistic uncertainty, they are able to provide an 'honest' account of variability and incertitude through a variety of mathematical methods. This chapter provides an introduction to such methods (Table 7.2), as well as resources and citations for further study.

Wherever possible, this chapter identifies examples of the application of quantitative uncertainty analysis techniques to environmental risks. There are, however, very few examples specific to transgenic fish from which practitioners can draw guidance. This statement, however, is true for virtually all forms of

Table 7.2. A summary of the various sources of uncertainty in environmental risk assessment, together with treatments identified in this chapter.

Source of uncertainty	Treatments identified in this chapter
Linguistic uncertainty	
Ambiguity	Clarify and agree on meaning (via PFOA, Chapter 2, this volume)
Context dependence	Clearly specify context
Underspecificity	Specify all available contextual data and provide narrowest possible bounds
Vagueness (non-numerical)	Construct numerical measures, then treat as numerical vagueness
Vagueness (numerical)	Fuzzy sets, supervaluations, rough sets, three-valued logic
Variability	
	First-order moment propagation, first-order Monte Carlo simulations
Incertitude	
Measurement error (random)	Standard statistical techniques, interval analysis
Measurement error (systematic)	Careful study design and validation of predictions with independent data
Model uncertainty	Sensitivity analysis, model validation, Aikake Information Criteria, qualitative modelling
Variability and incertitude	
	Second-order Monte Carlo simulation, probability bounds analysis, information gap theory, fuzzy sets and arithmetic, hierarchical Bayesian analysis.

quantitative risk assessment for genetically modified organisms. Future efforts to provide tools to assess and manage biosafety of transgenic fish should not only include developing strategies to identify and treat key sources of uncertainty, but also to build the capacity within regulatory programmes to address uncertainty. Moreover, future risk assessment research should aim to reduce these uncertainties or, at the very least, to increase the understanding of the consequences of uncertainty for decision making.

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Author Queries:

[AU1] Please update Dambacher et al, in review.

[AU2] Please update and cite Fox et al., in press.