Editorial

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This Special Issue contains several diverse papers that span a variety of disciplines and use theoretical and empirical findings that attempt to provide useful methodological examples to those concerned with making choices by accounting for uncertainty. The authors have not attempted to use decision-theoretic methods directly: this type of work is outside the domain of the Special Issue. Rather, they provide different approaches, some probabilistic and some deterministic, to assess uncertain events and to choose the optimal action from a set of actions while accounting for the potential effect of events that the decision-maker cannot control.

For example, the assessment of thermal loads resulting in heat stress to workers in a foundry uses a deterministic simulation modelling to represent the physics of the problem and to justify occupational managerial options regarding the minimisation of dangerous exposures. In another occupational context, a paper studies various activities involving handling heavy objects that may cause musculoskeletal disorders from improper postures. Using a biomechanical approach to evaluate the work posture and provide a safe working environment, this paper highlights the results that will help managers to select the optimal working environment, for a set of anthropometric data of a worker, and work posture of a typical grinding operation in a fettling shop. A simulation assesses the stress distribution in the human body and identifies excessive stress intensity in workers' current work posture and load carrying condition, thus suggesting ergonomically correct alternative work postures.

Another paper uses a deterministic model to study how to increase the ecological efficiency of pollution reduction for 32 paper mills. Yet another paper resorts to an integer linear programming algorithm to study multi-period and multi-objective optimisation of waste disposal activities. The assessment of potentially optimal choices is exemplified, using heuristic approaches, such as the 'balanced scorecard' method, within a medical diagnostic imaging problem. At the other end of the spectrum of potential issues that arise in making decisions that are affected by uncertainty, another paper investigates the desiderata of any communication of risky information to those interested or affected by potential exposure, and their trust in governmental decisions regarding environmental problems. This paper uses Meyer's five-item (i.e. fairness, bias, data presentation, accuracy, trust) five-choice index to identify issues of high priority in the design of the risk communication programmes. Because the interface between law and management is often murky and can defy practical modelling, another paper studies the implementation of a comprehensive water pollution control programme for distilleries than must comply with the national regulations and that can be very costly to those companies. If a company opts for on-compliance, this action can also be costly because of the large penalties mandated by the national Clean Water Act. The manager of the distillery thus faces two sources of potential economic loss; this paper includes a case study to exemplify the effect of these alternatives on the eventual choice.

The combination of deterministic and probabilistic models is shown in a paper in which the effect of exposure to lead is studied. Specifically, risk assessment methods are used to assess the operations of the secondary lead smelter, which result in soil, dust, air and water pollution. This paper combines epidemiological analyses, i.e. toxicological analysis within an integrated exposure assessment model to assess the risk profiles associated with those operations. The last study in this Special Issue deals with the interpretation of human biomonitoring results for policy-making. A major challenge addressed in this paper concerns the use of human biomonitoring data to examine policy options. The paper also includes the first pilot on DDE measurements (a metabolite of DDT) which was in two Flemish regions; the DDE results are further investigated and discussed as a basis for policy measures.

The implicit context of this Special Issue suggests technical ways to deal with uncertain events and policy postulates, such as the precautionary principle, that generally stand for the proposition that *when there are threats of serious or irreversible damage to the environment, scientific uncertainty should not prevent prudent actions to prevent potentially large or irreversible damage*. This foundational basis for the precautionary principle in many conventions and treaties, as well as pronunciations by a number of entities, requires differentiating them between legally binding forms (e.g. Title XVI, Art. 130r of the Maastricht Treaty on European Union (1992); the Delaney Clause to the US FFDCA) and not binding ones (as in a convention that has not been ratified). Perhaps the best known enunciation of the precautionary principle is the Rio Declaration on Environment and Development of 1992, which states that:

> *"In order to protect the environment, the Precautionary Approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."*

Precautionary principles tend to place the burden of proof about who causes the hazardous situation leading to risk on those who market or develop a product. An example of such a shift (Commission of the European Communities, 2001) is that the *[r]esponsibility to generate knowledge about chemicals should be placed on industry. Industry should also ensure that only chemicals that are safe for the intended purposes are produced*. The EC's Commentary also states that:

> *"A scientific evaluation of the potential adverse effects should be undertaken based on the available data … [T]his requires reliable scientific data and logical reasoning, leading to a conclusion which expresses the possibility of occurrence and the severity of a hazard's impact on the environment, or health of a given population …"*

The Commentary then concludes that precautionary measures must not be applied to address conjectured risks.

The Canadian government proposed guiding principles for risk analysis include the precautionary principles (Government of Canada, 2001) which are as follows:

1 Follow-up scientific activities, including further research and scientific monitoring, are a key part of the application of the precautionary approach. …

2 'Sufficiently sound information base' should be interpreted as sound and reasonable scientific information, including uncertainties that, through evaluation … [t]hat is, while scientific information would not need to demonstrate definitively the cause-and-effect relationship between risk and serious harm, it would demonstrate that such a risk exists. …

3 Generally, the responsibility for providing the scientific information base (the burden of proof) should rest with the party who is taking an action associated with potential or serious harm. …

An important issue that often goes unstated is Canadian (Government of Canada, 2001). Specifically:

… it is impossible to prove a negative (e.g. to prove categorically that something will cause no harm, or to prove with absolute certainty that something bad might not happen or to prove that something is not harmful), but possible to demonstrate that 'reasonable testing' was done with no evidence of harm … The real and potential impacts of making a precautionary decision (whether to act or not to act), including social, economic and other relevant factors, should be assessed. …As the precautionary approach is, by definition, an evolutionary process, precautionary measures should be monitored on an ongoing basis so that new scientific data that alters cost-effectiveness considerations can be incorporated (including performance monitoring results).

US law contains several variants of precautionary principles; some of those are quoted below:

- In the case of threshold effects, an additional ten-fold margin of safety for the pesticide chemical residue shall be applied for infants and children … (Federal Food, Drugs, and Cosmetics Act, §408 (b)(2)(C)(b)).
- The Administrator shall, specify, to the extent practicable: (1) each population addressed by any estimate of public health effects, (2) the expected risk or central estimate of risk for the specific populations, (3) each appropriate upper-bound or lower-bound estimate of risk … (Safe Drinking Water Act, §300g-1(b)(3)).
- Provide an ample margin of safety to protect public health or to prevent an adverse environmental effect (Clean Air Act, §112(f)).
- To assure chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment (Toxic Substances Control Act, TSCA §2(b)(3)).
- Necessary to protect human health and the environment (Resources Conservation and Recovery Act, RCRA §3005 as amended).
- Adequate to protect public health and the environment from any reasonably anticipated adverse effects (Clean Water Act, CWA §405(d)(2)(D)).

Clearly, when the magnitude of the consequences is large and the probabilities are also large, quick action becomes imperative. Precautionary principles argue for both circumspection and prevention when the magnitude of the potential adverse event is large or severe but its probability is relatively small (Enquette Kommission, 1994). Arguing for costly action when the causes of the adverse event are either poorly understood or conjectural is unlikely to result in an equitable distribution of risks and benefits, if an action developed on such basis is taken. When the *expected loss* of a choice is small (e.g. a fractional average cancer), some can argue *against* taking immediate precautionary action if the magnitude of the expected value is smaller than some legal minimum (in legal terms, it is no longer *de minimis*). Others look at the magnitude and severity of the probable outcome, but keep probability and magnitude separate and do not multiply them, thus arguing for action even when the probability is small but the magnitude of the adverse consequences is large. These alternative situations reinforce the suggestions that, regardless of their wording, the enunciation of the precautionary principle should contain specific guidance on the strength of the scientific evidence and the explicit recognition of time-dependent changes in the scientific information.

1 Uncertain events, outcomes and choices

Uncertainty and causation are inevitable aspects of risky decisions; yet, some forms or interpretations of the precautionary principle – such as political will – either dismiss or ignore this tenet in favour of actions that are guided by qualitative (and often not verifiable) assumptions and conjectures. To avoid costly mistakes, even if made in good faith, suggests achieving a convergence between legal principles and their practical application in a socially efficient way. Some of the salient characteristics of decision-making, in the context of both public and private decision-making are as follows:

- *Outcomes* for which there is no past experience thus requiring great attention to the measures of uncertainty used and the way choices are made because the axioms of choice may be violated (as they are for more traditional forms of decision-making under risk or uncertainty)
- *Deterministic representations* where the formal description of physical processes (e.g. a system of ordinary or partial differential equations) gives the illusion of complete and certain knowledge of future outcomes and their magnitude (given initial and boundary conditions)
- *Sensitivity to initial and boundary conditions* for certain types of differential equations used to describe a causal process over time and space
- *Need for sensitivity analysis*, when scenarios are used to describe seemingly plausible cause-and-effect relationships
- *Scientific defaults* that are pragmatically imposed when the scientific evidence is contradictory and causation is uncertain
- *Misspecified models* that exclude essential risk factors, and wrongly or incompletely formulate the causal relations between those factors and responses
- *Statistical uncertainties* that combine estimation and inference with the variability of data (e.g. sampling variability), heterogeneities, confounders, measurement errors and missing data.

In legal proceedings dealing with precautionary regulations, the question is: What is the factual basis of the issue or dispute to be resolved via precautionary measures? For prospective actions, whosoever bears the burden of proof (or, perhaps more appropriately, the burden of persuasion) must have enough evidence to satisfy a judge. This should ensure that the magnitude, probability and distribution of risks and benefits are correctly stated, analysed and that the proposed action can be shown to be socially more beneficial than harmful. Specifically, this accounting links:

- *Temporal and spatial dimensions*: the evolution (possibly stochastic) of each adverse consequence, by its hazardous source
- *Limits*: legal values (e.g. environmental standards, guidelines, etc.) that trigger legal or public management action to either study or to act
- *Source of risk*: the hazardous condition (such as an emission rate of a pollutants from a point source)
- *Exposures*: the events that, originating from the source of risk (the hazard or hazards), result in concentration or dose rates and can place individuals or populations at risk
- *Magnitude*: the numbers that characterise the counts of adverse outcomes (e.g. deaths, morbidities and other) for those at risk

- *Severity*: increases in the quantity of harm suffered (e.g. number of first degree burns, second degree, prompt deaths and so on) for those at risk
- *Risk-based results*: these include emissions, concentrations, exposures, doses, responses and models coupling emissions to responses in a causal network that accounts for the type of individuals at risk and those other risk factors that contribute to the potentially bad outcome of concern
- *Socioeconomic results*: the costs of controlling emissions, discount rates, economic analysis of direct, indirect and intangible net benefits (including impacts on the local economy) and so on
- *Net discounted social benefits*: the sum of the differences of the net direct, indirect, tangible and intangible monetised benefits and costs, discounted to account for the effect of time on the value of money
- *Equity of the risk and benefits*: Lorenz curves and Gini's coefficients may be sufficient to characterise the impacts of each precautionary or preventive action being assessed
- *Uncertainty*: the random elements of the decisional process. Thus, for example, time (as the arrival of a failure), thresholds, severity, magnitude, costs and benefits are all characterised by distribution functions. In general, the decision-maker has control over the actions that s/he is assessing, but other events (technically called the states-of-nature) cannot be controlled and thus require probabilities to be assigned to them. If probabilities cannot be assigned, then other measures of uncertainty can be used or the decision-maker may operate under complete uncertainty.

The social decision-maker empowered by a precautionary principle *weighs* the evidence probabilistically, using prior probabilities or distributions and likelihoods, to obtain posterior probabilities or distributions, via Bayes' theorem, if appropriate. If that aggregate belief in the balancing of the risks, costs and benefits is greater than a suitable number (e.g. 0.51), then the action could be socially tolerable, given the inferior alternatives.

Kriebel et al. (2001) state that the term precautionary principle has the advantage that it provides an overarching framework that links environmental science and public health. They also summarise some of the oppositions to the precautionary principle:

1 current regulatory procedures are already precautionary; for example the safety factors used in risk assessment …

2 the precautionary principle is not scientifically sound because it advocates making decisions without adequate scientific justification …

3 the precautionary principle would stifle innovation …

Those objections are red herrings. More intuitive forms of decision-making could appear to be as plausible as those that we have discussed. We do not dismiss alternative rationalities. However, societal allocations can benefit some but disbenefit others. If elected officials make a choice that is different from that shown to be optimal, then, at least, there is a basis for comparison and possible recourse and adjustment.

In general, the preferable choice, given the set of alternative choices, is one that is insensitive to different magnitudes, severities, costs, benefits, and where uncertainty is represented by probabilities (Kuhn, 1962). This is a small price to pay for a method suited to deal with incomplete and evolving information. Moreover, probabilities, unlike other measures of uncertainty such as possibilities or fuzzy numbers, are accepted in legal arguments and permeate legal reasoning. Finally, the language of the statutes that deal with precautionary actions and precautionary principle-based actions calls for the rationale we developed in this essay. Thus, we take probabilistic reasoning as the appropriate way to inform practical applications of any form of precautionary or preventive approaches of decision-making. We provide two accounts, among many others, of why this is the case.

1.1 Error rates

There are two complementary errors that are committed when setting up research, testable hypotheses. These are the following:

- Type I: rejecting the statistical null hypothesis, when it is in fact true
- Type II: accepting the null hypothesis, when it is in fact false.

A basis for rejecting the null hypothesis is the small probability that it has occurred because of chance alone. This probability is the level of *significance*; it is a probability most often stated as α ($\alpha = 0.05$, for instance). The implication of the Type I error is that the researcher mistakenly finds an association, when there is none. Hence, s/he wants to keep α low. β is the probability of making the Type II error: accepting an hypothesis (generally, the null hypothesis), when it is false. The *power* of the test is determined by subtracting from Type I the probability of committing a Type II error $(1 - \beta)$: power is the probability of rejecting the null hypothesis when it is false. To exemplify, consider the 2×2 contingency table (Table 1).

Table 1 The framework for assessing false positives, false negatives, sensitivity and specificity of statistical tests (discussed in the text)

		Disease is present		
		Yes	*No*	*Total*
Result	Positive	$a = 10$	$b = 20$	$a + c = 30$
	Negative	$c = 20$	$d = 30$	$c + d = 50$
	Total	$a + c = 30$	$b + d = 50$	$a + b + c + d = 80$

We let π be a proportion. The *sensitivity* of the test, π *positive/*(*disease is present*), is $[a/(a + c)]$. The sensitivity of the test measures the proportion of true positives. The *specificity* of the test, π *positive/(disease is absent)*, is $[b/(b + d)]$. Specificity measures the proportion of false positives. Using the numbers in the table, we obtain a sensitivity of 0.33 and a specificity of 0.40. In the context of precautionary decisions, for example, the trade-off between false positive and false negative errors suggests focusing on policy (and managerial) choices that minimise false negatives. What matters is that those at risk are correctly identified (at least in terms of their numbers): the language of precautionary principles can be interpreted as attempting to minimise the false positive error rate. At time t, one opts to minimise the Type I error. However, by adopting a resilient policy that allows updating the initial decision with new information and reassessing the risks, at time $t + k$, uncertainty is generally reduced: *both* probabilities of error change and have to be assessed as new information becomes available.

1.2 Cause and effect

Probabilistic reasoning provides a formal and coherent method (not accepting a gamble that surely leads to loss and that, on average, more is preferred to less) for describing uncertain knowledge and for updating it with new data, while accounting for variability. Probability distributions, in contrast to deterministic numbers, indicate the variability in quantities that may be essential for stating and evaluating data-driven causal arguments (Shafer, 1996). If a researcher can express his/her prior knowledge or belief as a prior probability distribution function, then the likelihood function for the data (i.e. its probability expressed as a function of model parameter values or assumptions) can be used to update this prior in light of the data. The key concepts are as follows:

1 *Knowledge is represented by probabilities.* Prior specific knowledge, information and judgements are represented by *prior probability distributions* for explanatory variables, and by *conditional probability distributions* for response variables under stringent requirements.

2 *Likelihoods formally represent empirical evidence that updates prior knowledge.* The sample, survey or other empirical data is the second element of the information used in Bayesian analysis.

3 *Prior beliefs are updated by conditioning on observed evidence.* Given the prior beliefs about uncertain quantities and the evidence, measurements, model and data, the posterior distribution of one or more parameters is computed by Bayesian inference. Algorithms, such as Gibbs sampling, other Markov Chain Monte Carlo (MCMC) methods, and special-purpose graph algorithms for factoring high-dimensional joint distributions, now make practical the computations required for Bayesian inference (and efficient knowledge representation).

4 *Uncertainty about the correct model, out of several alternatives, can be treated in the same framework.* To include uncertainty, model-based predictions or inferences are calculated for each of a set of *alternative models* that are considered to be mutually exclusive and collectively exhaustive. *Bayesian Model Averaging* (*BMA*) uses the predictions from these multiple plausible models, weighted by ‘Bayes factors’ (ratios of posterior odds to prior odds for different models), reflecting their relative plausibility condition on the data.

A way to represent causation consistent with probability measures is through causal diagrams such as Bayesian Networks (BNs). Briefly, a causal network (M) is a set V of variables, each represented by a distinct node. This representation includes multiple intermediate variables explained by their predecessors, unlike done in regression models. Directed arcs connect nodes such that the conditional probability distribution of the value for each node is a function only of the variables pointing to it. The probabilistic form of M allows Bayesian updating, as new evidence becomes available. The structure of a BN is a clear and replicable mathematical representation of known or postulated probabilistic relations among variables. It implies testable relations of conditional independence among variables and composition among functions and conditional probability maps. (For example, in the graph $X \rightarrow Y \rightarrow Z$, variable Z is conditionally independent of X given Y, $Pr(Z \mid X, Y) = Pr(Z \mid Y)$, and $Pr(Z = z \mid X = x) = \Sigma_y Pr(Z = z \mid Y = y)Pr(Y = y \mid X = x)$.) However, learning such networks directly from data is in general a computationally intractable (it is *NP*-hard) problem. Thus, in practice, these problems can be solved with knowledge-based constraints (e.g. a birth year may be a causal predecessor of lifetime exposure, but not vice versa). A BN can be used to test the plausibility of alternative hypotheses about causation and 'whether a proposed set of causal relationships is consistent with the available temporal-probabilistic information' (Pearl, 2000). For example, suppose that one investigator hypothesises that exposure to environmental agent A causes increased risk of lung cancer, while another proposes that 'unhealthy lifestyle' (a hidden or latent variable having high beer consumption as an observable indicator) is the true cause of the observed statistical association between them. Yet a third investigator suggests that beer consumption itself may be a risk factor for lung cancer. BN versions of these rival hypotheses are as follows:

1 A → Lung cancer risk ← Unhealthy lifestyle → High beer consumption

2 Lung cancer risk ← Unhealthy lifestyle → High beer consumption, A

3 Lung cancer risk ← High beer consumption ← Unhealthy lifestyle → A.

In version 1, but not in 2 or 3, reducing exposure to A without changing *unhealthy lifestyle* can reduce lung cancer risk. In versions 2 and 3, *lung cancer risk* is conditionally independent of exposure to A, *given* the value of *unhealthy lifestyle*. Testing such implied conditional independence relation statistically discriminates among alternative causal hypotheses, clarifies and resolves controversies about the causes of empirical epidemiological associations. These methods can deal with counterfactual reasoning, an important aspect of dealing with incomplete knowledge.

2 Conclusion

The variants of the precautionary principles discussed in this essay would benefit by including specific directions on dealing with uncertainty. The first conclusion is that uncertainty is measured and manipulated probabilistically. Precautionary decision-making must also recognise the distinction between statistical and causal associations and must depend on the latter to provide useful and defensible guidance to policy-makers. The specific directions should quantify uncertainty about causal relations, by quantifying model uncertainties, to provide credible guidance without assuming either more or less than the factual evidence allows.

While probabilities may be required to capture genuinely stochastic relations, as well as to express ignorance, merely statistical relations do not in general provide an adequate guide for either rational or precautionary decision-making. Rather, the appropriate combination of statistical tools of causal analysis and uncertainty analysis must be deployed to identify, test and correctly quantify the uncertain probabilistic *causal* relation among acts and their consequences. In this sense, these bridge the gap between incomplete knowledge and the level of causal explanation that must be available to determine if a choice is legally sound and demonstrably societally optimal. If there is no knowledge, and an action is taken, it will most surely be publicly flogged and be open to legal action.

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