Is there a role for risk assessment within precautionary legislation?

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ABSTRACT

Posing the question of whether the precautionary principle has a role in risk assessment effectively constrains any debate of the issue within a framework predicated on the assumption that application of risk assessment is inevitable in the formulation of regulatory decisions. The question can equally validly be expressed in terms of whether there is a role for risk assessment in the formulation of precautionary legislation. This allows the debate then to turn on consideration of two questions: Firstly, does the precautionary principle have a role in policy development? and secondly, is this role consistent and compatible with a risk based approach to regulation? When recast in these terms, a more holistic comparison of the aims and objectives of both approaches and of their relative power in the formulation of regulation becomes possible. This leads to the conclusion that the precautionary principle is, when defined and applied correctly, scientifically more robust than risk assessment. Precautionary approaches utilise scientific information and conform robustly to a scientific process but also explicitly incorporate indeterminacies into the decision making framework. Moreover, the precautionary principle when applied to environmental regulation, is more likely to lead to regulation consistent with global sustainability. On this premise, this paper argues that risk based approaches are essentially incompatible with approaches based on the precautionary paradigm, and that of the two, risk assessment is more likely to lead to unsustainable underprotection of the environment.

KEYWORDS

precautionary principle, sustainability, risk assessment, regulation, chemicals

ASKING THE RIGHT QUESTIONS

One of many aspects of the application of environmental (ecological) risk assessments to decision-making which has increasingly been questioned is their ability to ensure adequate framing of the problems under study, i.e. the inclusion of all relevant considerations (Stirling 1999). Where the boundaries of an assessment are set (in terms of the activities, pathways, end-points, etc. to be considered) will, of course, depend on the specific questions it is intended to address. In turn, the scope of the

questions, or defined "scenario", will inevitably exert a strong influence on all subsequent stages of the assessment, including the outcome and its practical application. The potential for important aspects to have been wrongly excluded or overlooked introduces what Murphy (1998) terms "scenario uncertainty", i.e. limitations to interpretation built into an assessment during its initial formulation. There is, moreover, a tendency to define the scope of assessments in terms of those components that are more readily subject to analytical determination (Lackey, 1997). This common failure to take a step back and evaluate the underlying framing of the assessment scenario can result in the analytical neglect of key dimensions of potential impact. In turn, this results in management decisions which are confined within the same narrow framing. Consequently, an equitable consideration of what may be fundamentally different approaches to the same problem becomes impossible.

In a similar context, it can reasonably be argued that the framing of the question comprising the title of this debate will inevitably limit the scope of the ensuing discussion. The question as formulated ("Is there a role for the precautionary principle within risk assessment?") threatens to restrict the debate primarily through its implication that risk assessment is an inevitability and that, as a result, the task is to judge the applicability of other paradigms within its bounds. Indeed, this reflects a wider assumption that risk assessment is entirely synonymous with science-based evaluation and regulation (Stirling, 1999). This misconception is reinforced by the common use of "risk assessment" and "sound science" as interchangeable terms.

The view that it is only through the application of risk assessment that proper consideration can be given to science in guiding decision-making has, quite rightly, been challenged (Johnston and Simmonds, 1990; Wynne, 1992; Santillo et al., 1998; Stirling, 1999). Similarly the related contention that the precautionary principle is unscientific (Gray, 1990; Bewers, 1995) has also been scrutinised. In order to avoid this polarity in the debate and to address the application of the precautionary principle in broader and more practically meaningful terms, it is more appropriate to recast the current debate around two alternative questions:-

1. Is there a role for the precautionary principle in policy development and decision-making?
2. If so, can this role be met within a risk-based approach to regulation?

The second question is clearly contingent upon the answer to the first and, accordingly, the two are discussed in turn below.

IS THERE A ROLE FOR THE PRECAUTIONARY PRINCIPLE IN LEGISLATION FOR ENVIRONMENTAL PROTECTION?

The precautionary principle is, in very simple terms, an expression of the ethic that "prevention is better than cure". As a paradigm in international environmental law, it has developed from a recognition of the need to take decisions in the face of considerable and, frequently, irreducible uncertainties surrounding the properties of the system under study and the nature of the threats to that system (including their magnitude and likelihood). Few, if any, decisions relating to resource management and environmental protection can be made with the luxury of a comprehensive understanding of ecosystem structure and dynamics (Berg and Scheringer, 1994;

Power and McCarty, 1997). Furthermore, forecasting of impacts is and will remain an inexact science, despite the predictive power which advanced quantitative modelling techniques appear to offer at first sight. Hence, a mechanism to account for uncertainties and indeterminacies (factors which are not amenable to analytical reduction), and the potential for existence of threats of which we are ignorant (i.e. which lie outside the framing of the scenario), is an essential part of any responsible decision-making framework. If the decisions taken are to ensure a high degree of environmental and human health protection, such a mechanism must be precautionary. Input from scientific research is clearly a necessary condition, though such data are of themselves not sufficient for decision-making. (McCarty and Power , 1997; Stirling, 1999).

In its most widely cited formulation (e.g. UNCED, 1992) the precautionary principle encourages action to prevent, or avoid the threat of, serious or irreversible damage, even in the absence of "full scientific certainty" regarding the cause and likely extent of the damage. This is, however, only one element of the precautionary principle as originally formulated (FRG, 1986). In more comprehensive terms, the principle stresses that preventative action in the absence of certainty is not just a possibility, but a necessity.

Although it is intended to provide for inclusive consideration of a wide range of information and concerns, the principle is based fundamentally on the evaluation and use of scientific information. Existing and ongoing scientific research provides a vital input to precautionary regimes, with the intention of identifying the potential for harm, particularly that which might be great in magnitude, spatial or temporal scale (or, indeed, effectively irreversible), such that action can be taken to avoid such harm in advance. Furthermore, the precautionary principle also engenders the aspiration to achieve a progressive reduction in environmental burden, without a reliance on the need to identify and quantify specific risks. As such, implementation of the principle may be viewed as a necessary condition in the pursuit of sustainability. Although this approach may be viewed by some to be idealistic, it is worth noting that a general requirement to avoid or minimize hazards wherever possible, irrespective of the risk they may pose, has long been central to the UK Health and Safety Executive's approach to protection of public health (HSE, 1999).

Substantial aversion to the implementation of the precautionary principle still remains (Gray, 1990; Gray and Bewers, 1996; Holm and Harris, 1999). To a large extent, such aversion appears to stem from misconceptions surrounding its formulation and purpose, and its relationship to scientific research in particular. If precautionary regimes did not utilise evidence from science and other disciplines as guidance they would, indeed, be as arbitrary and potentially misguided as any other regime which opted similarly for ignorance. But this is simply not the case. The difference between risk-based and precautionary approaches is not that one uses science while the other does not; the difference lies simply in the manner in which scientific evidence is considered and utilised in coming to a decision.

On the one hand, risk-based approaches use evidence in an attempt to arrive, at least theoretically, at descriptions of systems, exposures and effects which are an accurate reflection of the probability of harm, assuming that much of the uncertainty may ultimately be eliminated through further analytical research. Precautionary

approaches incorporate what Stirling (1999) refers to as a greater "humility" about our level of knowledge and ultimate ability to achieve ever greater understanding of chains of causality. Stirling (1999) further argues that such humility, combined with recognition of the importance of broader scenario framing and plurality of perspectives, are fundamental characteristics of scientific process and that precautionary regimes, in better incorporating these aspects, may be judged to be actually more scientific than narrow risk-based approaches.

Opposition to the precautionary principle is, however, further fuelled by continued misrepresentation of it by some as a barrier to innovation and development (see e.g. Holm and Harris, 1999). Such views attempt to cast precautionary decisions as inevitably restrictive such that, as an alternative to "business as usual", precaution advocates "no business at all", leading ultimately to paralysis. These misconceptions are based on a fundamental misunderstanding of the purpose and application of the precautionary principle. Rather than preventing change, precaution actually necessitates the development of technologies and practices which exert progressively lower impacts on ecosystems and human health and as a result contribute to the goal of global sustainability.

More specifically, in relation to hazardous chemicals, progressive reduction of potential impact might be achieved through the principle of substitution, i.e. the replacement, over a limited timeframe, of hazardous chemicals with less hazardous, or preferably non-hazardous, alternatives. In fact the latter approach is central to the implementation of the precautionary principle within the OSPAR Convention (1992). This aims to protect the marine environment of the North East Atlantic region. The Strategy with Regard to Hazardous Substances (OSPAR, 1998) commits contracting parties to the goal of cessation of all releases of hazardous substances to the marine environment within one generation (i.e. by 2020). Hazardous substances are defined on the basis of intrinsic properties (toxicity, persistence, liability to bioaccumulate or properties giving rise to an equivalent level of concern) which are considered to render the introduction of those substances to the marine environment fundamentally undesirable.

This approach has developed from a recognition that the fate and effects in the marine environment of substances with these hazardous properties, particularly persistence, have the potential to be severe or irreversible while, at the same time, remaining very difficult to evaluate and in practical terms, impossible to control. In other words, OSPAR has recognised the essentiality of precaution for protection of the marine environment from hazardous chemicals and has implemented the precautionary principle in the form of practical measures. Clearly, further measures to address losses to the marine environment of, for example, PCBs (although necessary) would hardly be precautionary. The adverse consequences of these chemicals are already well documented. Extending the goal of elimination to those substances with equivalent properties, even where scientific evidence of adverse effects is limited or lacking, however, is a clear application of precaution. Similarly, this is true for the provisions under the Strategy which aim to prevent the release of any "new" hazardous substances which may be developed in the future. There are important generalised advantages to such a precautionary stance. Chief amongst these is the fact that the problems encountered in attempting to identify and quantify specific risks, when organisms are commonly exposed to low levels of hazardous chemicals for long

periods and as complex mixtures of variable composition (Johnston, Santillo, and Stringer, 1996; Johnston, Stringer, and Santillo 1996), are simply avoided. Risk assessment of chemicals (which is generally conducted on a ponderous substance by substance basis) then becomes redundant as a tool for determining which specific substances require action. The fundamental role of science, nonetheless, is retained. An approach to the regulation of manufacture, marketing and use of chemicals in the European Union as a whole, predicated upon the application of the precautionary principle, has been outlined by Santillo, Johnston, and Singhofen (1999).

It should be self evident that the implementation of the OSPAR Strategy and the consequent progression towards "zero discharge" for all hazardous substances will necessitate fundamental changes within industry and society. Far from stifling innovation, therefore, precautionary regimes may actively encourage the development of new technologies and approaches, providing they are consistent with the trajectory of sustainability.

CAN PRECAUTION BE BUILT INTO RISK-BASED APPROACHES?

An important conclusion from the preceding discussion, is that precaution has an essential (and fundamental) role to play in environmental and human health protection. If this is accepted, the question may then be posed as to whether risk-based approaches can fully address this need for precaution. To proponents of risk assessment, the key debate appears to be at which point precautionary decision making is invoked within a risk-based assessment and management procedure (e.g. Brown 1998). As discussed below, such an approach fails to recognise that the precautionary principle is a higher order paradigm which guides the decision making process from problem identification through to action, and not simply a management tool to be invoked when a risk assessment identifies substantial residual uncertainties. In fact, this latter approach would render precautionary action subject to the same limitations as the risk assessment itself.

The portrayal of risk assessment as "sound science", to the exclusion of other approaches to evaluation and use of scientific information, confers an apparent acceptability and a reputation for analytical determinism which belies its underlying limitations and subjectivity. The rather Laplacian notion of a reliable and absolute metric of risk may be an attractive one given that, if it could be realised, it would enable decisions to be made on the expectation of highly predictable and verifiable outcomes. In reality, of course, risk assessments are far from absolute. They are limited, for instance by statistical variation, data quality, inherent (and often poorly defined) assumptions and uncertainties. As outlined above, they also depend upon the validity of the initial framing of the risk scenario that bounds the resultant assessment in all its subsequent stages. In common practice, they also tend, by design, to be highly reductionist in approach, frequently leading to remarkable over-simplification of complex systems in the pursuit of a single ratiometric expression of risk. As a corollary they tend also to act as a prescription for avoiding resolute action while attempting to reduce such indeterminacies through further research.

The PEC/PNEC approach, for example, which forms the basis of ecological risk assessments within the European Union, is popular with risk managers. It presents them with a definitive fulcrum around which decisions may turn (i.e. whether the

predicted environmental concentration for the compartment under study is greater or less than the concentration at which it is predicted that no effects will occur in the target system). Risk managers can later justify their decisions with reference to this seemingly empirical value (Moore and Elliot, 1996). Appreciation of the degree of uncertainty in the assessment and of statistical variation in the point estimate is commonly lost between assessment and management phases (Felter and Dourson, 1998). Furthermore, despite attempts to harmonise assessment protocols, EU risk assessments frequently suffer from lack of key input data (EEA, 1998).

The merits and failings of risk assessment have been extensively debated elsewhere (Johnston, Santillo, and Stringer 1996; Lackey, 1997; Santillo et al., 1998) and will not be addressed again in detail here. There is, however, an emerging consensus that risk assessment is not a panacea and that it is essential that its limitations be recognised and addressed (see e.g. review by Adams and Power, 1997 and associated papers). Indeed, presumptions towards its universal applicability and utility could be viewed as far more idealistic than pursuit of a precautionary approach. In short, precaution is by far a more pragmatic approach.

Uncertainty, indeterminacy and ignorance are recognised as major issues which must be addressed within risk assessment (Stirling, 1999). Quantitative uncertainty analysis and Bayesian statistical approaches are advocated by some as possible, or even essential, developments which would enable more appropriate expressions of risk estimates (i.e. as probability density functions rather than point values). In addition to the substantial further (and possibly intolerable) complexity that this would introduce to risk assessments (Moore and Elliot 1996; Hoffman, Chambers, and Stager, 1999), and the ambiguity thereby introduced into risk management decisions, such proposals do not address the need for precaution at a fundamental level. In short, these developments may arguably improve the statistical rigour of the final outcome, but the problems of subjectivity and scenario uncertainty remain unaddressed and frequently unrecognised. For example, the assessment will not tell us when the confidence intervals of uncertainty are artificially low as a result of incomplete problem definition.

Numerous attempts, nonetheless, have been made to subsume the precautionary principle within risk-based approaches (Gray and Bewers, 1996; Brown, 1998). Such exercises have, in some cases, extended simply from a perceived threat posed by the principle to science-based regulation. For example, Gray and Bewers (1996) suggested that the inclusion of pessimistic (or worst case) assumptions within standard risk assessments could act as a surrogate for precautionary legislation. In practice, pessimistic assumptions are likely to be as subjectively derived as optimistic ones, and may even be indistinguishable from one another. Moreover, the wider problem of the framing of the assessment, and the selection of those parameters for which assumed values are required, could not be addressed by such an approach. Ultimately, if the principle were to be redefined in these terms, it would simply necessitate the formulation of a new principle of precautionary action to serve its initially intended function.

Other approaches attempt to restrict the precautionary principle to a tool of risk management, to be invoked only when a risk assessment remains subject to irresolvable uncertainties and a decision is urgent (e.g. DOE, 1995; Brown, 1998).

Such an approach assumes that risk assessments in themselves generally provide a reliable basis for decision making and for the identification of those instances in which precautionary action may be required. In this manner, they are open to the same criticisms as already raised above. In order to ensure that regulations may be truly protective, the precautionary paradigm must be central to all phases of the definition, evaluation and decision-making process.

In short, it is difficult to envisage how the precautionary principle could ever be implemented through risk-based approaches, arising as they do from fundamentally different standpoints. Risk assessments start from the premise that the likelihood of adverse effects in the field can be quantitatively and reliably forecast and that, subsequently, potential stressors may be effectively managed at levels of risk deemed acceptable. Acceptable impact is also a highly subjective domain of debate and definition. Precautionary approaches accept that a reliable, robust and rigorous estimation of risks in complex natural systems is, in many cases, likely to remain an unachievable goal. An inherent potential for harm is sufficient basis on which to take action to reduce, prevent or avoid hazards and a manifest impact. In either approach there exists, of course, the possibility that a decision will later prove to have been incorrect. In this regard, risk-based approaches are, however, the more likely to err on the side of under-protection.

CONCLUSIONS

1. The question "is there a role for the precautionary principle within risk assessment" is inappropriately framed, introducing the assumption that risk assessment is an indispensable regulatory tool. It may be more appropriate to ask firstly whether precaution is a necessary part of environmental regulation and, subsequently, whether risk assessment is compatible with a precautionary approach.
2. The precautionary principle, though frequently misrepresented or misunderstood, is scientific in its formulation and application, recognising and accounting for limitations to knowledge and the need for a broad framing of the issues to be addressed. As a component of science-based legislation designed to protect the environment or human health it is not an idealistic paradigm but a necessity.
3. The principle cannot be effectively incorporated as a tool within risk-based approaches. In their underlying assumptions and processes, risk-based approaches differ fundamentally from, and in many aspects conflict with, precautionary approaches.
4. The commonly held misconception that science-based regulation and risk assessment are synonymous, to the exclusion of other approaches, must be dispelled.

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