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Precaution in the Governance of Technology

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PRECAUTION IN THE GOVERNANCE OF TECHNOLOGY

Chapter for Forthcoming Oxford Handbook on the Law and Regulation of Technology

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Biographical note

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Abstract

Equally at national and the highest international levels, few issues in technology governance are more vexed than those around the precautionary principle. Often using colourful rhetoric – and frequently paying scant attention to the substantive form taken by precaution in any given setting, even ostensibly academic analyses accuse precautionary approaches of being ‘dangerous’, ‘arbitrary’, ‘capricious’ and ‘irrational’ – somehow serving indiscriminately to ‘stifle discovery’, ‘suppress innovation’ and foster an ‘anti-technology’ climate. The widely advocated alternative is ‘science based’ risk assessment – under which single aggregated probabilities are assigned to supposedly definitively-characterised possibilities and asserted to offer sufficient representations of the many intractable dimensions of uncertainty, ambiguity and ignorance. The high economic and political stakes combine with their expediency to entrenched institutional and technological interests, to intensify these arguments. Amidst all the noise, it is easy to miss the more balanced, reasonable realities of precaution.

By reference to a large literature on all sides of these debates, this paper shows how these pressures are not only misleading, but themselves seriously unscientific – leading to potentially grave vulnerabilities. Experience over more than a century in technology governance, shows that the dominant issues are not about calculation of probabilities, but about the effects of power in innovation and regulatory systems, the need for balanced consideration of alternative options, scrutinising claimed benefits as much as alleged risks and always being vigilant for the ever-present possibility of surprise. In this light, it is not rational to assert that incertitudes of many difficult kinds must always take the convenient forms susceptible to risk assessment. To invoke the name of science as a whole, in seeking to force such practices, is gravely undermining of science itself. And these pressures also seriously misrepresent the nature of innovation processes, in which the

branching evolutionary dynamic means that concerns over particular trajectories simply help to favour alternative innovation pathways.

Precaution is about steering innovation, not blocking it. It is not necessarily about ‘banning’ anything, but simply taking the time and effort to gather deeper and more relevant information and consider wider options. Under conditions of uncertainty to which risk assessment is – even under its own definition – quite simply inapplicable, precaution offers a means to build more robust understandings of the implications of divergent views of the world and more diverse possibilities for action. Of course, like risk assessment, precaution is sometimes implemented in mistaken or exaggerated ways. But the reason such a sensible, measured approach is the object of such intense general criticism, has more to do with the pervasive imprints of power in and around conventional regulatory processes, than it does with any intrinsic features of precaution itself. Whilst partisan lobbying is legitimate in a democracy as a way to advance narrow sectoral interests, it is unfortunate when such rhetorics seek spuriously to don the clothing of disinterested science and reason in the public interest.

Taking the best of all approaches, this paper ends by outlining a general framework under which more rigorous and comprehensive precautionary forms of appraisal, can be reconciled with risk-based approaches under conditions where these remain applicable. A number of practical implications arise for innovation and regulatory policy alike, spanning many different sectors of emerging technologies. In the end, precaution is identified to be about escaping from technocratic capture under which sectoral interests use narrow risk assessment to force particular views of the world. What precaution offers to enable instead is more democratic choice under ever-present uncertainties, over the best directions to be taken by innovation in any given field.

Keywords: risk assessment, uncertainty, precaution, technology governance, direction of innovation

Introduction

Worldwide and at every level, institutions concerned with technology governance are not short of pressing social, environmental and health challenges. Ever more potent new convergences are occurring between revolutionary developments in individual areas of science and technology, that together present prospects that are even less predictable than the many radical surprises of the past. Areas of accelerating technological change include synthetic biology [1] and gene editing [2]; nanotechnology and new materials [3]; neuroscience [4] and cognitive enhancement [5]; artificial intelligence and autonomous robotics [6]; climate geoengineering [7] and planetary management [8].

These technological trends take place amidst intensifying pre-existing inequalities and vulnerabilities [9], affected by longstanding accumulations of toxic and nuclear pollution [10] and compounded by climate change and other forms of ecological destruction [11]. Interacting with

new geopolitical tensions [12] and many other dynamic changes in encompassing economies and social contexts [13], formidable challenges are presented for conventional regulatory practices [14]. In particular, what results from these trends and interactions is an array of radical uncertainties [15]. Equally surrounding future, current (and even historic) developments [16] and recognised in diverse forms and degrees [17], these uncertainties arise in a multitude of sources [18], involving divergent perspectives as well as unknown outcomes [19] and implicating potential benefits as much as risks [20].

Acknowledging that conventional methods of regulatory risk assessment address only restricted aspects of these challenges [21], a variety of understandings of ‘precaution’ have come to the fore as a response [22]. Among the many disciplines in which active discussions have focused in some depth on different aspects, are: environmental [23] and social science [24]; market [25] and ecological economics [26][27]; science and technology studies [28] and political theory [29]; and communications research [30] and management studies [31]. As a result, diverse versions of the concept of precaution feature prominently in risk regulation [32], and innovation policy [33] as well as mainstream political discourse [34].

When combined with the multiplicity of traditions and contexts in international jurisprudence [35], it is hardly surprising that – just as a variety of practises have evolved in regulatory risk assessment [36] – so too there has grown up a diversity of forms for associated formalisations of ‘the’ precautionary principle [32]. Various embodied in ‘soft’ as well as ‘hard’ law [37], many differences of detail have emerged in proliferating international instruments [38] and across contrasting national jurisdictions [39]. This diversity of detail is enhanced by the range of regulatory sectors in which different versions of the precautionary principle have developed, including food safety [40] [41], chemicals regulation [42], genetic modification [43], telecommunications [44], nanotechnology [45], climate change [46], conservation [47] and general health protection [48].

Despite this complexity and diversity, however, a coherent summary story can nonetheless be told concerning the broad development of ‘the’ precautionary principle [38]. Originating in the earliest international initiatives for environmental protection in the 1970s, it first came to legal maturity in the ‘*vorsorgeprinzip*’ of German environmental policy in the 1980’s [49]. In the rising tide of environmentalism in that period [50], the precautionary principle was championed by environmentalists and public health advocates – and so established at an early stage in a series of the most actively contested global environmental conventions [51], culminating in the Rio Convention on Sustainable Development of 1992 [52]. This burgeoning growth led to strong resistance by some of the industries most under pressure in these fora [23], with the precautionary principle becoming particularly controversial in the USA [53]. Despite a more complex picture at a detailed level between different jurisdictions and between ‘political’ and ‘legal’ arenas [54], precaution grew especially firmly established in Europe in the 1990s [55]. Here, the precautionary principle moved

from a guiding theme in European Commission (EC) environmental policy [56], to become a general principle of EC law [57]. With the transatlantic contrasts in this story at the centre of wider global contentions on various high stakes economic and industrial issues, precaution then became a repeated focus of attention in a series of noisy international trade disputes [58][59]. Across all these settings, contention focused especially intensively on the role of science in the precautionary principle [60][61].

With more recent worldwide growth in practices of ‘evidence based policy’ [62][63], the challenges posed by scientific uncertainties have become increasingly salient – and uncomfortable. Although one reaction is to diminish or deny the inconvenient intractabilities of uncertainty to which precaution is a response, another is to seek to address them more fully and openly. It is under these latter imperatives, that influence of the precautionary principle has extended, expanding from environmental regulation [64], to wider policy making on issues of health [23], risk [65], science [60], innovation [66], emerging technologies [67] and world trade [68].

But at the same time, the significance of the worldwide establishment of precaution has also been widely discussed in relation to diverse wider social issues ranging from inequalities and collective action [69] and the nature of irreversibility in politics [70], to ‘degrowth’ visions in economics [71], practices of health and psychiatric care [72] and co-operative transdisciplinary research [73]. As associated issues have mushroomed in scope, so the theme of precaution has grown in profile and authority and in its general implications for the governance not only of science and technology, but of wider social issues [74].

This chapter will review global policy debates over the relevance of precaution for risk regulation and wider technology governance and assess some practical policy implications. The next section summarises some of the key background issues bearing on discussions of the precautionary principle. This is followed by an evaluation of some of the principal concerns that have been raised in different quarters. Although (like risk regulation more generally) raising many queries, the precautionary principle does emerge in general terms as a robust response to the kind and degrees of uncertainty discussed in this introduction – that have been recognised in so many different areas and perspectives as going beyond the limits of conventional forms of regulatory risk assessment.

The paper closes by considering some of the practical repercussions for regulatory appraisal – identifying a variety of readily-implemented appraisal methods that are often neglected where governance institutions remain unduly wedded to simplified notions of risk. In order to substantiate some specific possible implications for regulating issues like those with which this chapter began, the discussion ends by briefly describing a general framework for implementing precautionary forms of regulatory appraisal, which are at the same time operational and avoid the pitfalls of conventional over-reliance on risk assessment.

General Underlying Issues Around the Precautionary Principle

As mentioned above, a widely influential early formulation of the precautionary principle was provided in the United Nations 1992 Rio Declaration. This formulation is especially relevant, because it has been accepted by more states than any other – including some of the more sceptical jurisdictions like the USA [75]. Here, Principle 15 states that: “*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*” [52]. This is sometimes glossed as an injunction, to “*look before you leap*” [65] or remember “*it is better to be safe than sorry*” [76]. Other versions of the principle are variously rated to be weaker or stricter [77], with ‘*strong precaution*’ sometimes characterised (by supporters as well as detractors) as a blanket reversal of ‘the burden of proof’ away from critics and towards proponents of a regulated activity [78]. Some of these issues will be discussed shortly. For now, the simple wording and canonical status of Rio Principle 15 nicely exemplifies four key (and quite essential) features of a majority of versions of the precautionary principle, which can be seen to be central to the bulk of the debate.

First, precaution is not indiscriminate, but hinges on the presence of particular properties in decision making, notably (in Rio Principle 15): a potential for particularly serious or irreversible harm under conditions of scientific uncertainty [79].

Second, precaution is not open-ended, but rests on a clear normative presumption in favour of particular values or qualities like the environment or human health (rather than, for instance: economic, sectoral, or partisan institutional interests) [80].

Third, precaution is not simply about acting to stop something, but introduces instead a responsibility for more careful and explicit reasoning over what kinds of action might be appropriate. So, it is about reinforcing qualities of understanding deliberation and accountability, rather than just the stringency of the resulting actions [81].

Fourth, precaution is not in itself biased, but applies symmetrically to all decision alternatives in any given context (including ‘doing nothing’). Like risk assessment (but in ways that the focus on uncertainty does more to encourage), it is most rigorous when implemented in a balanced comparative way with respect to a full range of policy options [82][53].

In these terms, the precautionary principle can be seen as a succinct distillation of more than a century of experience with the unexpected consequences of new knowledges, technologies and associated social innovations [83]. In particular (and unlike idealised notions of ‘sound scientific’ risk assessment), it embodies an awareness of the asymmetries and inequalities of the power relationships that bear on processes of regulatory appraisal and help to shape the fabrics of the knowledges produced within them [84].

As such, precaution bears a close relationship with other parallel principles (with which it is sometimes compared), like those concerning ‘*prevention*’ [85], ‘*polluter pays*’ [86], ‘*no regrets*’ [87], ‘*participation*’ [88], ‘*substitution*’ [89] and ‘*clean production*’ [90]. Like these, precaution serves to enrich and reinforce appreciations for duties of care on the part of commercial firms and the protective responsibilities of sovereign governments and regulatory administrations [45] [91]. In short, the precautionary principle requires more explicit, scientifically rigorous and socially-sophisticated attention to the implications of incomplete knowledge, than is routinely provided in the conventional regulatory assessment of ‘risk’ [16][92].

Some Key Criticisms and Responses

Given the nature of the issues and the powerful interests at stake, the precautionary principle has been subject to some quite vehement rhetorical criticism [93][94][95]. One frequent concern is that it is ill-defined. In the Rio formulation, for instance, how serious is ‘serious’? What exactly does ‘irreversible’ mean? Does ‘full scientific certainty’ ever exist? Such concerns seem well-founded if the precautionary principle is presented as a sufficient, comprehensive or definitive procedural rule. Yet legal scholars point out that (as with any general legal principle like ‘*proportionality*’ or ‘*cost effectiveness*’), no given wording of precaution can in itself be entirely self-sufficient as a decision rule [59]. Nor is precaution typically presented as such [32]. Just as these other principles rely on specific methods and procedures (e.g. risk assessment, cost-benefit analysis) in order to make them operational, so too is any application of the precautionary principle simply a framework for the development and application of more detailed complementary practices [96]. This point is returned to at the end of this chapter.

A further criticism is that the explicitly normative character of the precautionary principle somehow renders it ‘irrational’ [97] or ‘unscientific’ [98]. In one form, this concern rests on the (usually implicit) assumption that conventional ‘science based’ regulatory procedures manage somehow to transcend normative content [84]. However, this neglects the ways in which practical applications of methods like risk assessment and cost-benefit analysis also require inherent exercise of evaluative judgements [99]. For instance, values are intrinsic to the setting of levels of protection in risk assessment, the weighing of different forms of harm and their balancing with countervailing benefits [100].

Beyond this, an extensive literature documents how the claimed ‘sound scientific’ methods so often contrasted with precaution, are typically subject to serious uncertainties concerning divergent possible ‘framings’ [99]. As a consequence, ‘evidence based’ results obtained in areas such as energy [101], chemicals [102], genetic modification [103] and industrial regulation [104] often display strong sensitivity to assumptions, that can vary radically across different equally-authoritative

studies [33]. When all analysis is acknowledged necessarily to be subject to such framing by value judgements, then it emerges that the more explicit normativity of the precautionary principle is actually more, rather than less, reasonable and accountable [100]. As illuminated by other critiques of the fact-value dichotomy [105], what is irrational, is denial by many critics of the precautionary principle – even if only implied – that there are inherent normativities in all risk assessment.

It is on the basis of this normative orientation, however, that there remains (for those so inclined) scope for criticism of the precautionary principle simply on the overtly political grounds that it addresses general concerns like environment and human health, rather than more private interests like commercial profit or the fate of a particular kind of technology [97][106]. Such partisanship is understandable given the high stakes involved in many regulatory arenas where precaution comes to be discussed. But it is not defensible on the part of those who wish to be regarded as neutral regulators or dispassionate scholars, to seek to stigmatise precaution as being somehow self-evidently ‘unreasonable’.

It is a grave feature of precaution debates worldwide, then, that such partisan polemics against precaution are so often and loudly voiced in the ostensible name of academic independence or ‘sound science’ [107]. Whatever position might legitimately be taken on the prioritising of values or importance of uncertainty, to reject out of hand the reasoned basis for precaution is (for reasons that will be further explored below) not only ironically irrational, but profoundly anti-democratic [66].

These kinds of debates between contending political values are entirely legitimate in technology regulation. What is problematic, is where the political content is suppressed and dressed up in the ostensible “neutrality” of science [108]. Yet here, there is a key general rationale for the precautionary principle that can be appreciated even by those who might otherwise be sceptical. This lies simply in understanding the ever-present politics around technologies, health and environment, in which contending interests across different sectors seek to assert their own most expedient framings as if these were the singular definitive representations of science [109].

This is not a partisan point, it occurs on all sides of regulatory debates. What is crucial to realise, however, is that it is by definition incumbent interests (of whatever kind) that are most likely in the position of ‘capturing’ regulation with their own particular framings [110]. Highly instrumental interpretations of uncertainty have featured prominently, for instance, in regulatory histories in areas like asbestos, benzene, thalidomide, dioxins, lead in petrol, tobacco, many pesticides, mercury, chlorine and endocrine-disrupting compounds, as well as chlorofluorocarbons, high sulphur fuels and fossil fuels in general [83][92]. The point here is not that incumbency is somehow of itself a bad thing, but that it has consequences for regulatory understandings as well as actions, that it would not be rational to dismiss.

In this bigger and more pluralistic picture, then, the precautionary principle can be recognised simply as a means to resist over-privileged incumbency where it occurs and restore a more

reasonable balance of interests in regulatory appraisal [96]. In any event, adoption of the precautionary principle does not necessarily negate the possibility that other normative values might be applied elsewhere in a regulatory process – such as prioritisation of profit, employment or GDP. All it does, is help ensure that – where scientific knowledge is insufficient under conditions of uncertainty to settle a regulatory issue on its own – then decisions will be subject to more explicitly open deliberation and argument about which values to prioritise [16][100].

A related set of concerns focus on other political implications of precaution. Cases are sometimes cited in which precaution itself appears to have been applied in an inconsistent or expedient fashion, to achieve outcomes that are actually pursued for rather different reasons [111]. An example might be the rejection of technologies that are disfavoured by particular influential interests or the protection of national industries from international trade competition [112]. At one level, this simply highlights a general tendency found on all sides in the real-world politics of technology. Reasonable advocacy should acknowledge that the precautionary principle is no more intrinsically immune to manipulation than any other principle. For example, a principle of rational utility maximisation in risk assessment can also often end up asserting particular partisan framings as if these were synonymous with ‘rationality’ [96]. Such dynamics played a prominent part in many regulatory histories like those mentioned above [83], [92][8]. It is irrational to single out precaution for particular criticism on these grounds.

However, there do nonetheless remain reasonable grounds for concern in cases where the precautionary principle is invoked in an opaque or discriminatory way [100]. For instance, imposing precaution selectively on particular policy options, whilst not doing so to alternative options (including ‘business as usual’) is illegitimate. Where this occurs, perverse environmental or health outcomes may arise [97][100]. However, the fact that different versions of the precautionary principle apply symmetrically across all decision options in any given context, means that this is clearly not an inherent fault of precaution per se, but a matter of inadequate application [96]. Here, both critics and proponents of the precautionary principle hold common ground, in aiming for a situation in which the particular methods adopted in the implementation of regulatory appraisal are more rigorous, systematic and transparent about challenges of incomplete knowledge and potentially irreversible harm, than is typically currently the case in established practice of regulatory assessment [96][99][100]

There are also many loudly-voiced, but typically under-substantiated, assertions that precaution can be motivated by, or might lead to, a blanket rejection of all new technologies [97]. This is the point underlying increasing rhetorics around ‘permissionless innovation’ [114], or various kinds of ‘proactionary’ [115][116][117] or ‘innovation’ principle [118]. Although legitimate rhetorical interventions by particular industrial interests or their lobbyists [119], it is difficult to justify how such relatively casual concepts can be propounded on a par with the outcomes of decades of

cumulative rigorous adversarial negotiation and authoritative judicial practice that are embodied in the various forms of the precautionary principle.

A more serious problem here, though, is that these kinds of political move involve fundamental misrepresentations not only of precaution, but also of the nature of innovation itself [99][33]. It is easy to explain why. First, precaution focuses on the reasons for intervening, and carries no necessary implications for the substance or stringency of the interventions themselves [39]. Rather than bans or phase-outs, precautionary actions may as readily take the form of strengthened standards, containment strategies, licensing arrangements, monitoring measures, labelling requirements, liability provisions or compensation schemes [96].

Second, general ‘anti-innovation’ accusations fail to address the fundamental point that technological and social change are branching evolutionary processes [120]. As repeatedly shown in the application of precaution, the inhibition of one particular trajectory (e.g., nuclear power or genetically modified organisms) becomes an advantage for another (e.g., renewables or marker assisted breeding) [83][121]. Precaution is about steering, not stopping, innovation [66]. In this sense, precaution can actually offer to help reconcile tensions between political pressures for promotion and control [122]. The selective branding of specific concerns over particular technologies as if they represent an undifferentiated general ‘anti’ technology position can on these dispassionate grounds be recognised simply as polemics – legitimate expressions of partisan political views, but not credible as a full or fair characterisation of these important issues.

Precaution and the Nature of Uncertainty

Perhaps the most important practical feature of all these critical debates, is a recognition that the substantive significance of the precautionary principle rests largely in the specific institutional frameworks, deliberative procedures and analytical methods through which it is implemented. In other words, precaution is more important as an epistemic and deliberative process, than as a supposedly self-sufficient ‘decision rule’ [96][123][37].

With the precautionary principle as a cue to such a process, a key ensuing purpose is to help address the recognised lack of scientific certainty by expending more effort in hedging against unknown possibilities and investing in ‘social learning’—exploring a wider and deeper array of salient types of knowledge than would normally be engaged with [16][24][96]. Much of the ostensible support currently afforded to the precautionary principle by governmental bodies—like that sporadically offered by the European Commission in the past—is explicitly predicated on the qualification that precaution is purely a risk ‘management’ (rather than an ‘assessment’) measure [56]. When the implications of precaution are understood for processes of regulatory appraisal, however, it can be seen that such a position threatens to undermine the real logic and value of precautionary responses to strong uncertainty [124]. Precaution is as much about appraising threats as managing them.

This point is also relevant to arguments that precaution is somehow ‘un-’ or ‘anti-scientific’ [97]. In short, these involve assumptions that ‘sound scientific’ regulation is synonymous with application of a narrow set of techniques based around probabilistic analysis, which treat all uncertainties in conveniently reduced and aggregated quantitative terms, as if they were ‘risk’ [109]. This is perhaps the most serious of all misrepresentations around the precautionary principle. Precaution is not a cause of uncertainty, but a response to it. Where they are given a chance, different versions of the precautionary principle simply remind that it is often necessary to move beyond the usual exclusive reliance on conventional risk assessment. What is irrational and unscientific, is to react to this predicament by rejecting precaution itself and denying that the real nature of uncertainty is that it cannot be reduced merely to probabilities [96].

The reasons for this can be appreciated by considering Figure 1. This is structured according to the two parameters that shape conventional risk assessment. First (on the horizontal axis), there are the magnitudes of the things that may happen (‘hazards’, ‘possibilities’ or ‘outcomes’). Second (on the vertical axis), there are the likelihoods (or probabilities) associated with each. In mainstream risk assessment, these are each aggregated across a diversity of relevant dimensions, contexts, aetiologies and perspectives and then multiplied together. Attention thereby moves to the top left of the diagram. This confident ‘reductive aggregative’ style [109], expressed in an apparently authoritative quantitative idiom, lends itself to assertive disciplinary or political agendas [99]. But the resulting political body language side-lines and implicitly denies deeper conditions of incertitude lying in the lower and right-hand fields [24], under which probabilities (in the words of the probability theorist de Finetti simply “do not exist” [127]. Through this process of “organised irresponsibility” [125], those actors driving particular kinds of development can hope effectively to externalise possible adverse consequences onto others.

The bottom line here is that the focus of precaution on ‘lack of scientific certainty’, points to the necessity for different kinds of regulatory appraisal methods, processes and practices under forms of incertitude that are not addressed by risk assessment. Where these are held to be applicable, they are not necessarily exclusive alternatives to risk assessment, but can be supplemental to it in ways that take responsibility for these wider issues [126]. Here, an especially significant contribution has been made by an extensive literature in the social and policy analysis of science [24][74]. Offering pioneering explorations of the contrasting aspects of incertitude illustrated schematically in Figure 1, this literature points to a range of rigorous responses that avoid the kind of ‘pretence at certainty’ that can come with conventional risk assessment [127].

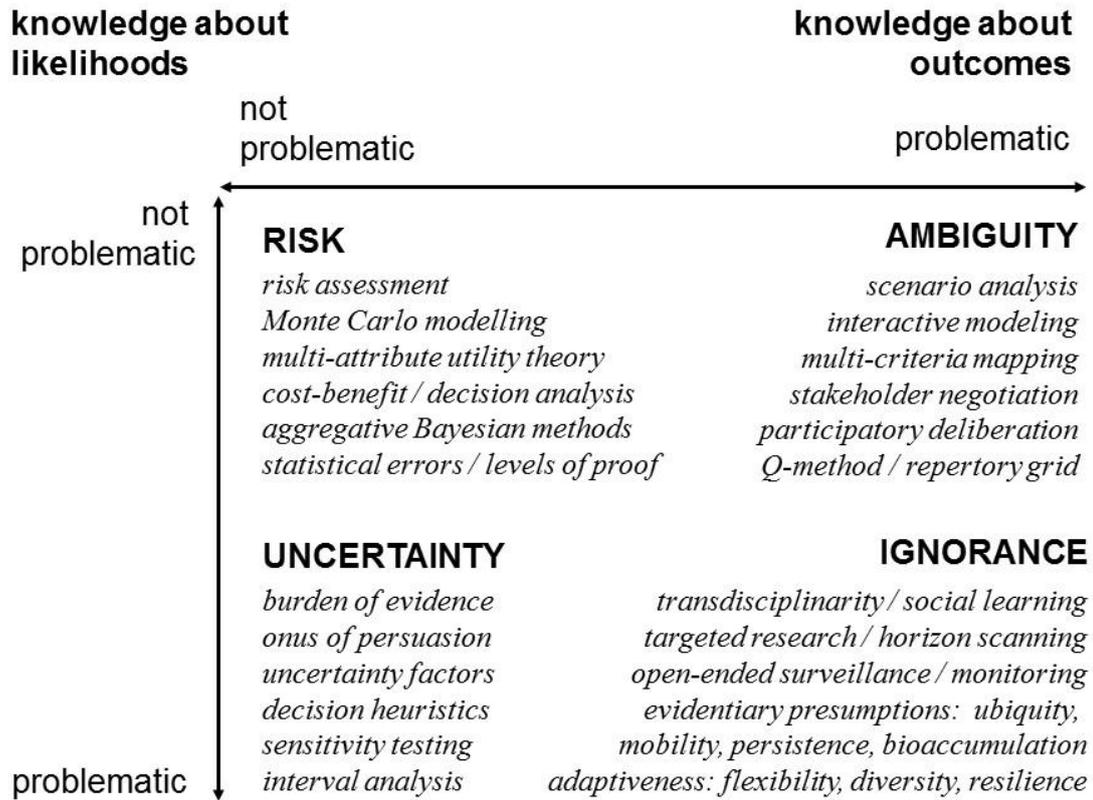


Figure 1

Starting with the strict state of ‘uncertainty’ in the lower left hand quadrant of Figure 1, the term itself was introduced in this sense nearly a century ago by the economists Knight and Keynes [128][129]. Much elaborated since, this definition makes very clear the difference between ‘uncertainty’ and the relatively tractable state of ‘risk’ – under which it is held to be possible confidently to determine both the probabilities and the magnitudes of contending forms of benefit and harm [99]. Under Knight’s more intractable state of uncertainty, there may be confidence in characterising a range of possible outcomes, but the available empirical information or analytical models simply do not present a definitive basis for deriving a single aggregated representation of probabilities [109].

This prompts consideration of the further contrasting condition addressed in the top right of Figure 1, which might most straightforwardly be called ambiguity [96]. This is where it is the characterisation of outcomes that is problematic, rather than the probabilities. Ambiguity arises where there are ‘contradictory certainties’ [130], applying even to outcomes that have occurred already. Disagreements may persist, for instance, over the selection, partitioning, bounding, measurement, prioritisation, interpretation and aggregation of different forms or understandings of benefit or harm [109]. Where there are multiple divergent values, foundational work in rational

choice theory has shown that the assertion of a single aggregated preference function – implicitly central to conventional regulatory risk assessment and cost-benefit analysis – is itself a deeply irrational aim to strive for, let alone claim [131]. In a plural society, then, the idea of a single definitive ‘sound scientific’ resolution to regulatory challenges is an oxymoronic contradiction in terms [132].

What Figure 1 also shows, is that there lies beyond (below and to the right) of both uncertainty and ambiguity, the even less tractable predicament of ignorance. Here (where it is recognised that neither probabilities nor outcomes can be fully characterised [133]), ignorance involves recognition that “we don’t know what we don’t know” [24]. It is an acknowledgement of the ever-present prospect of ‘surprise’ [134]. Crucially, of course, surprises can be positive as well as ‘nasty’ [135]. But it is central to the predicaments of regulation, that some of the most iconic environmental and health issues of recent years (like stratospheric ozone depletion [83], BSE [136] and endocrine disrupting chemicals [137]), were not simply matters of mistakenly optimistic calculations of probability or magnitude. It was the formative mechanisms and outcomes themselves that were unexpected – thus denying knowledge of the parameters necessary even to structure risk assessment, let alone perform the calculations [109].

The point in distinguishing these contrasting aspects of incertitude is not to assert particular terminologies. In a vast and complex literature, each of the terms in Figure 1 can be used in radically divergent ways. The point here – for the purpose of illustrating practical precautionary responses – is simply to emphasise the diversity of contexts. In practice, of course, these four ‘ideal-typical’ states of knowledge typically occur together. The scheme is thus not a taxonomy, but a heuristic distinction between different aspects of incertitude [109], each spanning a variety of specific causes, settings and implications. What each aspect is called, is secondary. But what is crucial, is to avoid the present situation in much everyday regulatory practice reliant on risk assessment, in which all forms of incertitude beyond probabilistic risk are effectively excluded and denied even a name. With even the most basic recognition for the real nature of uncertainty thereby so often and deeply undermined, it is hardly surprising that precaution as a response should so frequently be so badly misunderstood.

To sum up, what is typically neglected in conventional risk assessment, then, is that both magnitudes and probabilities may each be subject to variously incomplete or problematic knowledge, of kinds that are (by definition) not susceptible to probabilistic analysis [16]. This is why it is mistaken to seek to address precaution in probabilistic or statistical terms [138]. This is why it is illogical to imply – as does much of the European legal apparatus on precaution – that precaution can be secondary and subordinate to risk assessment [56][139]. Under conditions where it is by definition not rigorously possible to neatly quantify singular scalar values for risks and benefits and balance them against each other, to insist that this nonetheless be performed, represents a triumph of ideology over realism.

It implies no slur on intelligence or integrity, to note the prevalence of such flawed processes in regulatory appraisal. It is in exactly the above spirit of rigour and realism, that it must be acknowledged that powerful pressures nonetheless serve to force otherwise reasonable actors to put on this kind performance. The ‘real world’ of political demand for conveniently simple justifications, is in deep tension with the ‘real real world’ of the fundamentally under-determined natural and physical processes themselves. Such are the vulnerabilities, that it is entirely rational in apolitical sense to seek various kinds of reduction and closure that are not actually warranted in scientific terms [99], This is the way in which it might be hoped that justification be secured for decisions [140], trust fostered [141], acceptance procured [142] and blame managed [143].

Regulatory reliance on forms of risk assessment that generate unrealistically singular aggregated pictures of probabilities and magnitudes, has the effect not only of misleading decision-making, but also of concealing these underlying pressures. Where these politically-driven practices of reduction and aggregation are justified in rhetorics of ‘sound science’, the pathology is compounded [99]. What is threatened is not just the efficacy of the regulatory process, but the integrity and cultural standing of science itself. In response to this, different versions of the precautionary principle hold in common that they: resist strong political pressures to deprecate possibilities of serious or irreversible harm; promote more careful and deliberate forms of reasoning in the face of uncertainty; are more explicit and accountable in their normativity in the face of ambiguity; and prioritise the benefits of attending to diverse alternative actions in the face of ignorance. Despite the many undoubted flaws and shortcomings of real-world instantiations of precautionary practice, it is these qualities that offer to join with other principles of rigour in regulation, to mitigate some of the otherwise corrosive political pressures.

Fortunately, there is no shortage of operational practices by means of which to implement these more precautionary responses to the less tractable aspects of incertitude outlined in Figure 1. A key feature of these precautionary methods highlighted lower down and to the right of the picture, is that they are less reductive or aggregative than those that are appropriate under the strict condition of ‘risk’ in the upper left. However, these more precautionary alternatives are no less systematic or ‘scientific’ in nature than is risk assessment. By drawing attention to this diversity of practical responses in appraisal, the direct relevance of precaution can more readily be appreciated, not just to the management but also to the appraisal of ‘risk’.

Precaution can thereby be seen to hold important implications not just for risk management (where it is so often confined in regulation [56]), but also for policy appraisal. Indeed, the methods shown under uncertainty, ambiguity and ignorance in Figure 1 are not only consistent with ‘sound scientific’ practice, but are actually more rigorous than is risk assessment under these particular conditions, in their resistance to pretence at knowledge [16][24][96]. Crucially, however, risk assessment techniques remain applicable under specific conditions where they apply – for familiar deterministic systems where there this confidence that probabilistic calculus is sufficient.

This said, none of this negates that precaution can also be relevant in particular ways under narrow conditions of risk. Different versions of the precautionary principle can still hold important implications for evaluative aspects of regulatory dilemmas, such as the setting of levels of protection, the striking of a balance in avoiding different kinds of statistical errors. Precaution can also be relevant here in setting requirements for what are often wrongly asserted in simplistic singular terms as ‘the burden of proof’ [144] – promoting distinct consideration for contrasting aspects relating to necessary strengths of evidence, levels of proof, onūs of persuasion and responsibilities for resourcing analysis in respect of the diverse contexts encompassed in Figure 1.

An Indicative Practical Framework

The bulk of this chapter has been taken up in explaining why so many conventional criticisms – and, indeed, implementations – of the precautionary principle are quite seriously mistaken and misleading. Of necessity, despite the attention to practical methods in Figure 1, much of the discussion has been quite general in scope. This leaves a danger, that the picture presented here of the role of precaution in regulatory appraisal might be perceived to be rather abstract. So (albeit in limited space), there is a need to end this account on a more specific, concrete and constructive note.

Central to this, is the key challenge of how in practice to implement the diversity of precautionary approaches to uncertainty, ambiguity and ignorance (like those illustrated in Figure 1), and articulate them together in a more broad-based process of appraisal? Drawing on a body of recent theoretical empirical and methodological work (e.g.: [96][83][92]), Table 1 summarises a series of key considerations, which together help in responding to this challenge. Each represents a general quality, of a kind that should be displayed in any process of technology appraisal that may legitimately be considered to be precautionary in a general sense. Each is briefly illustrated by reference to an example drawn from regulatory experience. In many ways, the qualities listed in Table 1 are simply common sense. As befits their general nature, they apply equally to the implementation of any approach to technology appraisal, including risk assessment. This underscores that precaution represents an enhancement, rather than a contradiction, of accepted principles of scientific rigour under uncertainty.

Table 1: Key features of a precautionary appraisal process

(After D. Gee, P. Harremoes, J. Keys, M. MacGarvin, A. Stirling, S. Vaz, B. Wynne (eds), *Late Lesson from Early Warnings: the precautionary principle 1898-2000*, European Environment Agency, Copenhagen, 2001)

1. independence from vested institutional, disciplinary, economic and political interests; *as long constrained attention to problems caused to industrial workers by asbestos.*
2. examination of a greater range of uncertainties, sensitivities and possible scenarios; *as*

<p><i>addressed in early attention to risks of antimicrobials in animal feed, but later neglected.</i></p> <ol style="list-style-type: none"> 3. deliberate search for ‘blind spots’, gaps in knowledge and divergent scientific views; <i>as with assumptions over the dynamics of environmental dispersal of acid gas emissions.</i> 4. attention to proxies for possible harm (eg: mobility, bioaccumulation, persistence); <i>as encountered in managing chemicals like the ostensibly benign fuel additive MTBE.</i> 5. contemplation of full life cycles and resource chains as they occur in the real world; <i>like failures in PCB containment during decommissioning of electrical equipment.</i> 6. consideration of indirect effects, like additivity, synergy and accumulation; <i>of a kind long neglected in the regulation of occupational exposures to ionizing radiation.</i> 7. inclusion of industrial trends, institutional behaviour and issues of non-compliance; <i>the latter featuring prominently in the large scale misuse of antimicrobials in animal feed.</i> 8. explicit discussion over appropriate burdens of proof, persuasion, evidence, analysis; <i>for instance around the systematic neglect of ‘Type II errors’ in risk assessment.</i> 9. comparison of a series of technology and policy options and potential substitutes; <i>a topic neglected in the over-use of diagnostic X-rays in health care.</i> 10. deliberation over justifications and possible wider benefits as well as risks and costs; <i>as insufficiently considered in licensing of the drug DES for pregnant mothers.</i> 11. drawing on relevant knowledge and experience arising beyond specialist disciplines; <i>like the knowledge gained by birdwatchers concerning the dynamics of fish stocks.</i> 12. engagement with the values and interests of all stakeholders who stand to be affected; <i>as with experience of local communities on pollution episodes in the Great Lakes.</i> 13. general citizen participation in order to provide independent validation of framing; <i>as was significantly neglected in checking assumptions adopted in the management of BSE.</i> 14. a shift from theoretical modeling towards systematic monitoring and surveillance; <i>which would help address conceptual limitations, such as those affecting regulation of PCBs.</i> 15. a greater priority on targeted scientific research, to address unresolved questions; <i>as omitted for long periods over the course of the development of the BSE crisis.</i> 16. initiation at the earliest stages ‘upstream’ in an innovation, strategy or policy process; <i>helping to foster cleaner innovation pathways before lock-in occurs to less benign options.</i> 17. emphasis on strategic qualities like reversibility, flexibility, diversity, resilience; <i>these can offer ways partly to hedge against even the most intractable aspects of ignorance.</i>

Table 1

Of course, important questions remain over the extent to which fully implementing the diversity of methods shown indicatively in Figure 1 is possible in existing institutional contexts in a fashion that displays all the qualities summarised in Table 1. There may be greater confidence over forestalling costs of environmental or health risks that might have been missed in risk assessment. But this may incur more immediate and visible demands on money, attention, time and evidence in regulatory appraisal. So precaution does present real dilemmas for the design of regulatory practice. Such questions require more constructive discussions than is evident in much current polarised debate over precaution.

This final section of this chapter, will therefore sketch as an illustrative basis for discussion, one concrete procedural framework by means of which a variety of specific methods might readily be implemented in the regulatory appraisal of emerging technologies, such as to more fully respect the intractabilities of incertitude and the imperatives of precaution. Building on recent analysis and adapted from a series of stakeholder deliberations [145], Figure 2 offers a stylised outline of an illustrative general framework for the articulation of conventional risk in a procedural design that offers some prospect of doing justice to the challenges of precaution [100].

By providing for an initial screening process, this deals with concerns over proportionality in appraisal. Always under review, only the most appropriate issues are allocated to treatment by more broad-based (and onerous) processes of precautionary appraisal. Subject to a set of detailed screening criteria applied in stakeholder deliberation, contrasting cases and aspects are variously allocated to more inclusive and participatory forms of appraisal (in the case of ambiguity) or more straightforward and familiar forms of risk assessment (where these are held to be sufficient). In this way, established notions of proportionality are reconciled with precaution, through the employment of more targeted approaches to appraisal. Since the screening applies to all cases, the resulting analytic-deliberative framework as a whole remains precautionary [146].

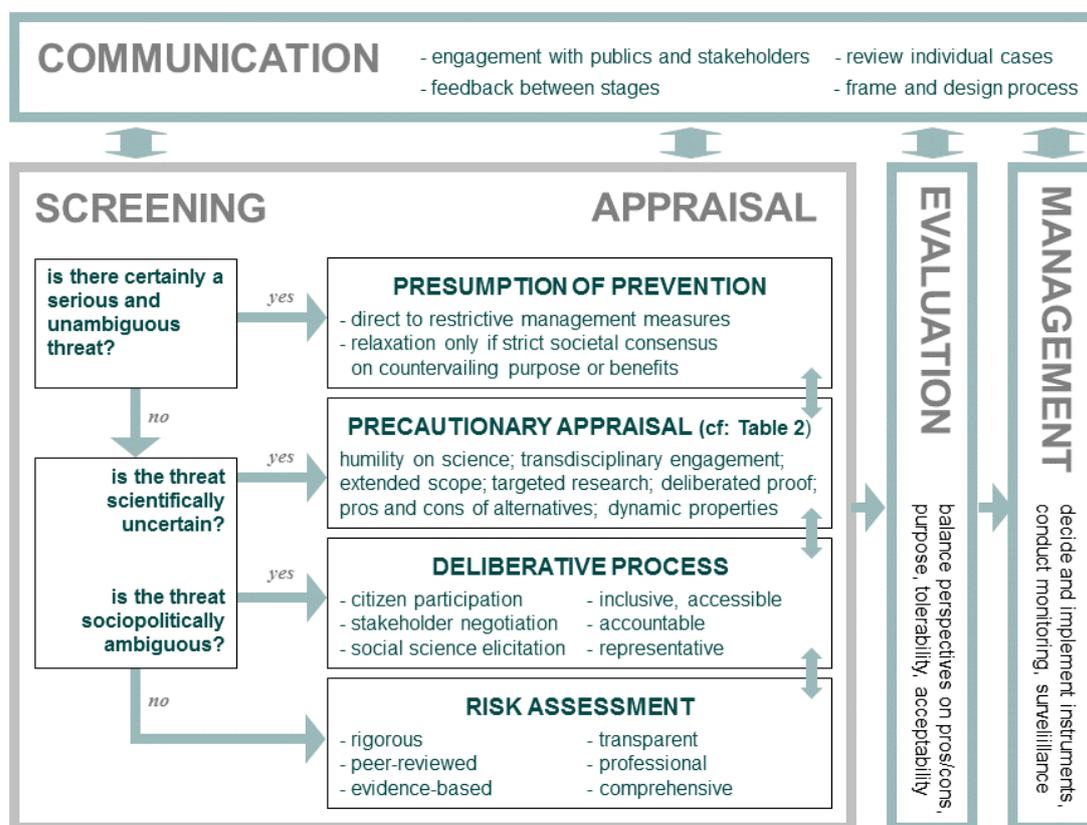


Figure 2

Of course, these kinds of operational framework can look highly schematic and instrumental. If too simplistic an impression is given of the underlying challenges, then they can even be counterproductive. A fear is, that their compatibility with existing practices may simply serve to reinforce current institutional inadequacies. However, by respecting some of the key underlying imperatives, such frameworks at least refute the blanket assertions over the non-operational status of precaution [97]. They offer a way to provoke greater policy attention to crucial wider political issues concerning the governance of science and technology [147].

In summary there are two important general promises for the regulation of emerging technologies, that are offered in these kinds of emerging frameworks for more precautionary appraisal. These are, first, to help 'broaden out' attention to greater diversities of options, practices and perspectives in policy debates over technology [148]. Secondly, there is the promise of 'opening up' more vibrant, mature and robust policy debates over the implications of different interpretations of uncertainty [99]. Neither of these implies any necessary conflict between precaution and innovation [122]. Nor is there any tension between precaution and science [149]. Understood in terms less coloured by partisan interests, the precautionary principle can thereby be recognised simply to point to a range of practical regulatory tools, through which to better address the unavoidable (if often neglected) challenges of incomplete knowledge. By helping to reduce intensities of regulatory capture [150], the main contributions of such approaches are to encourage more robust methods in appraisal, make value judgements more explicit, and enhance qualities of deliberation.

It is in these senses, that a further quality of precaution comes to the fore, in keeping with its canonical formulation as part of the formative wider injunctions of the 1992 Rio Declaration [52]. Reflecting decades of struggle by social movements against incumbent patterns of privilege and power in the orienting of science and technology, various forms of the precautionary principle serve in many specific ways, to help foster more transparent and deliberate democratic decision making concerning the steering of alternative directions for innovation [120][151]. It is the momentous political pressures generated by this dynamic, that (intentionally or inadvertently) make criticism so intense. And this is why the precautionary principle is so important. By contrast with the technocratic procedures of risk assessment, precaution is about greater democracy under uncertainty.

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