

# A PRECAUTIONARY-PRINCIPLED APPROACH TOWARDS UNCERTAIN RISKS: REVIEW AND DECISION-THEORETIC ELABORATION

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## **Abstract**

Precautionary judgment, decision, and action are needed in situations involving serious uncertain risk. Examples are mountain climbing, nanotechnology, global warming, and international terrorism. The history of the Precautionary Principle (PP) shows that its proponents and opponents have different appraisals of probabilistic risk analysis. However, modern 'risk governance' and precautionary safety management seem to be converging into a balance of useful substance and feasible procedure. In this paper, the PP is unfolded as a three-way principle for risk assessment, decision-making, and risk control. For an integrative circumscription of the PP, ten key issues are identified. These are discussed one by one, whereby 'rational' precautionary decision-making is particularly illustrated via the concrete example of a railway bomb alarm. It is argued that a substantive-analytical framework is indispensable, that a decision-

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theoretic perspective may offer useful guidance, that the PP is a rational (survival) rather than a normative (ideological) principle, that the need to avoid false negatives versus false positives may well differ among distinct policy domains, and that precautionary ‘pessimism’ should stimulate towards improved, multi-sided control of uncertain risks. Concluding questions are answered and research suggestions are formulated.

## 1 Introduction and overview

The ongoing international debate about the Precautionary Principle (PP) continues to plague policy-makers, entrepreneurs, and scientists around the world. The crucial question is not ‘What does the PP practically involve?’, but rather ‘How could uncertain risks be adequately assessed and managed?’ This paper is meant to provide a review and decision-theoretic clarification of the PP, as a basis for a practical approach towards uncertain-risk situations. An attempt is made to balance a sociological and legal inclination – it seems – towards careful procedures, against an economic and psychological quest for meaningful substance.

### 1.1 Emergence of the Precautionary Principle

In the 1970s and 1980s, the PP emerged as a management perspective for dealing with serious uncertain risks for the natural environment and for public health. Original domains of precautionary action were the marine environment and the use of hazardous chemicals.<sup>1</sup> A precautionary approach had already been adopted in the US Federal Water Pollution Control Act of 1972, and during the 1970s for an international moratorium on commercial whaling.<sup>2</sup> Other areas of application were atmospheric pollution, global warming, and climate change.<sup>3</sup> Biosafety and the safety of food and

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<sup>1</sup> *London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter 1972, and 1996 Protocol Thereto* (London: International Maritime Organisation 1972/2003), <<http://www.imo.org>>; M. Karlsson, ‘The pre-cautionary principle, Swedish chemicals policy and sustainable development’ (2006) 9 *Journal of Risk Research* 337.

<sup>2</sup> D. Bodansky, ‘Scientific uncertainty and the precautionary principle’ (1991) 33 *Environment* 4 at 4 and 43.

<sup>3</sup> UNEP, United Nations Environment Program, *The Montreal Protocol on Substances that Deplete the Ozone Layer* (1987) available at <<http://www.unep.org/ozone>>; UNFCCC, United Nations Framework Convention on Climate Change, *Kyoto Protocol* (1997) available at <<http://unfccc.int>> or <<http://unep.org/climatechange/>>.

foodstuffs were explicitly brought under the PP somewhat later,<sup>4</sup> while nanotechnology is currently gaining precautionary attention.<sup>5</sup>

More recently, the PP has also been appreciated in connection with threats from international terrorism; the USA's 'pre-emptive strike' against Iraq in March 2003 was presented officially as a precautionary strategy under the uncertain risk of 'weapons of mass destruction'.<sup>6</sup> Since the terrorist attacks of 11 September 2001, on the New York WTC towers and the Pentagon building in Washington D.C., precautionary anti-terrorism policies have also been developed in several European countries, notably Spain, Great Britain, Denmark, and The Netherlands.<sup>7</sup>

Since its official adoption as Principle 15 of the Rio Declaration,<sup>8</sup> the PP has been spreading as part of national and international policy-making, especially in EU countries.<sup>9</sup> However, the UK House of Commons,<sup>10</sup> apparently discontented with the European Commission's circumscription of the PP, has expressed scepticism about the 'ill-defined and practically unsatisfactory' PP and has recommended that the government not use the term.<sup>11</sup> The UN/WHO Codex Alimentarius Commission also decided not to

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<sup>4</sup> United Nations, *Carthage Protocol on Biosafety to the Convention on Biological Diversity* (Montreal, 29 January 2000) available at <[www.cbd.int/biosafety/protocol/shtml](http://www.cbd.int/biosafety/protocol/shtml)>; WTO, *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) (Geneva: World Trade Organization 1994) available at <<http://www.wto.org>>.

<sup>5</sup> R. Haum and others, *Nanotechnology and regulation within the framework of the precautionary principle* (Berlin: Institut für Ökologische Wirtschaftsforschung 2004) available at <<http://www.ioew.de>> (accessed December 2004)

<sup>6</sup> R. Jervis, 'Reports, politics, and intelligence failures: The case of Iraq' (2006) 29 *The Journal of Strategic Studies* 3; J. Stern and J.B. Wiener, 'Precaution against terrorism' (2006) 9 *Journal of Risk Research* 393.

<sup>7</sup> M. J. Borgers, *De vlucht naar voren* [The flight forward] - Inaugural address, Free University of Amsterdam (The Hague: Boom Juridische Uitgevers 2007), discusses relevant changes in Dutch criminal law.

<sup>8</sup> UNCED, United Nations Conference on Environment and Development 1992 (see Table 2 below).

<sup>9</sup> EC, European Commission, *Communication from the Commission on the precautionary principle*. COM (2000) 1 [Summary-2007 at <[http://europa.eu/scadplus/glossary/precautionary\\_principle\\_nl.htm](http://europa.eu/scadplus/glossary/precautionary_principle_nl.htm)>]; EC, European Commission, *The White Paper on Strategy for a Future Chemicals Policy* COM (2001) 88 Final; République Française, *Charte de l'Environnement* (2005) Loi constitutionnelle n° 2005-205 du 1er mars 2005 Paris.

<sup>10</sup> UK House of Commons Select Committee on Science and Technology, *Science and Technology: Fourth Report* (London, Her Majesty's Stationary Office 2006), ch. 4: 'The Precautionary Principle' available at <[www.publications.parliament.uk/pa/cm/200506/cmselect/cmsctech/1030/103007](http://www.publications.parliament.uk/pa/cm/200506/cmselect/cmsctech/1030/103007)>.

<sup>11</sup> EC (2000), above n. 9.

adopt the PP explicitly in its *Working Principles for Risk Analysis*.<sup>12</sup>

## 1.2 Scientific debate and controversy

Nevertheless, almost in concert with the international reception of the PP as a policy principle, a lively and sometimes fierce scientific debate has arisen concerning its actual meaning and practical application. As an early skeptic, Bodansky raised several questions that are still haunting proponents today.<sup>13</sup> Active promoters of the PP are Grandjean,<sup>14</sup> Hansen,<sup>15</sup> Latour,<sup>16</sup> Martuzzi,<sup>17</sup> O’Riordan,<sup>18</sup> Sandin,<sup>19</sup> and Weiss.<sup>20</sup> Vigorous critics are Bergkamp,<sup>21</sup> Entine,<sup>22</sup> Hanekamp,<sup>23</sup> IEM,<sup>24</sup> Majone,<sup>25</sup> Marchant,<sup>26</sup> Peterson,<sup>27</sup> and

<sup>12</sup> Codex Alimentarius Commission, *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (2007) available at <<http://www.fao.org/docrep/006/y4800e/y4800e0o/htm>> (Accessed 29 October 2007).

<sup>13</sup> Bodansky, above n. 2.

<sup>14</sup> P. Grandjean and others, ‘Implications of the precautionary principle in research and policy making’ (2004) 45 *American Journal of Industrial Medicine* 382.

<sup>15</sup> S.F. Hansen, L. Carlsen and J.A. Tickner, ‘Chemicals regulation and precaution: does REACH really incorporate the precautionary principle?’ (2007) 10 *Environmental Science and Policy* 395.

<sup>16</sup> B. Latour, ‘Du principe de précaution au principe du bon gouvernement: vers de nouvelles règles de la méthode expérimentale’ (2000) available at <<http://www.bruno-latour.fr/poparticles/poparticle/p088.html>>.

<sup>17</sup> M. Martuzzi, ‘The precautionary principle: in action for public health’ (2007) 64 *Occupational and Environmental Medicine* 569.

<sup>18</sup> T. O’Riordan, ‘The precautionary principle in environmental management’ in R.U. Ayres and U.E. Simonis (eds.), *Industrial Metabolism: Restructuring for Sustainable Development* (Tokyo: The United Nations University 1994).

<sup>19</sup> P. Sandin and others, ‘Five charges against the precautionary principle’ (2002) 5 *Journal of Risk Research* 287.

<sup>20</sup> Ch. Weiss, ‘Scientific uncertainty and science-based precaution’ (2003) 3 *International Environmental Agreements: Politics, Law and Economics* 137.

<sup>21</sup> L. Bergkamp, ‘Understanding the precautionary principle’ in *Environmental Liability* (Brussels: Hunton & Williams 2002) 10, 1: Part 1, 18-30; 10, 2: Part II, 67-82.

<sup>22</sup> J. Entine, *Let them eat precaution* (Washington D.C.: American Enterprise Institute, AEI Press 2006).

<sup>23</sup> J.C. Hanekamp, ‘Precaution and cholera: a response to Tickner and Gouvea-Vigeant’ (2006) 26 *Risk Analysis* 1013.

<sup>24</sup> IEM, *Economic note: Precaution with the precautionary principle* (Bruxelles: Institut Économique Molinari 2005) available at: <[www.institutmolinari.org](http://www.institutmolinari.org)>.

<sup>25</sup> G. Majone, ‘What price safety? The precautionary principle and its policy implications’ (2002) 40 *Journal of Common Market Studies* 89.

<sup>26</sup> G.E. Marchant, ‘The precautionary principle: an unprincipled approach to biotechnology regulation’ (2001) 45 *Journal of Risk Research* 143.

Sunstein.<sup>28</sup>

The controversiality of the PP is focused on its ‘vague’ definition (‘What should we apply?’), its inherent pessimism aimed at avoiding false negatives (i.e. neglect of real danger), its dependence on plausibility reasoning, the lack of comparative risk evaluation, its openness as regards legal obligations, and its implied shift in the burden of proof. Other key issues (see Table 3 below) have been criticised to a lesser extent, although in practice they may prove problematic as well.

### 1.3 Being cautious from principle to practice

The PP involves a principal attitude of provisional caution or circumspection towards serious uncertain risks, under pessimistic assumptions about possible negative outcomes.<sup>29</sup> For practical application, the PP may be unfolded as:

- a. an *assessment* principle focused on evidentiary rules and plausibility judgment;
- b. a *decision* principle focused on the evaluation of alternative courses of action;
- c. a *control* principle focused on the practical realisation of precautionary safety.

Thus, clear answers are given to the ‘why, what, and how?’ question: Why be cautious? What must be done? How should this be done? Then follows the ‘Who?’ question, about the role of authorities and other parties responsible for uncertain-risk assessment and management.

### 1.4 Organisation of the paper

We first consider the types of uncertain risk for which the PP seems most properly invoked, and we look briefly into the basic criticisms and developments of probabilistic risk analysis. Several PP definitions are presented in Section 3, where ten key issues are identified and an integrative

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<sup>27</sup> M. Peterson, ‘The precautionary principle should not be used as a basis for decision-making’ (2007) 8 *EMBO Reports*, *European Molecular Biology Organization* 305.

<sup>28</sup> C.S. Sunstein, ‘Beyond the precautionary principle’ (2003) 151 *University of Pennsylvania Law Review* 1003.

<sup>29</sup> G. Immordino, ‘Looking for a guide to protect the environment: the development of the precautionary principle’ (2003) 17 *Journal of Economic Surveys* 629; Ph. Kourilsky and G. Viney, *Le Principe de Précaution. Rapport au Premier Ministre* (15 Octobre 1999) (Paris: La Documentation Française/Éditions Odile Jacob 2000). Also available at <<http://lesrapports.ladocumentationfrancaise.fr/BRP/004000402/0000.pdf>>; Ch. Weiss, ‘Can there be science-based precaution? Institute of Physics Publishing’ (2006) 1 *Environmental Research Letters* 1.

circumscription is proposed. In Section 4, five substantive issues are discussed from a largely decision-theoretic perspective. Critical points of understanding are illustrated via the concrete example of a railway bomb alarm. Section 5 deals with five largely procedural PP issues. In Section 6, concluding answers are given to various general questions about precautionary risk management, and research suggestions are formulated.

## 2 Uncertain risks and the development of risk analysis

The enormous technological development and economic expansion in the industrial countries since World War II have gradually caused new risks to arise with respect to public health and safety, and to environmental security. Well-known risk sources are synthetic chemicals, nuclear power, large-scale fossil-fuel combustion, genetically modified organisms (GMOs), avian influenza, and nanotechnology. The risks involved may be called 'environmental', but in most cases public health seems equally at stake. At the heart of the 'new risk' issues are uncertainties about problem boundaries, the sources of risk, dose-effect relationships, risk-reduction options and their costs, and the seriousness of possible consequences. The simple fact that different stakeholders are involved underlies the socio-political controversy of such problems.

In view of various dimensions of risk,<sup>30</sup> we may summarily conclude that problematic 'new risks' are characterised by complexity, spatial and temporal extent, potential catastrophality, improbability, diverse uncertainties, plurality of perspectives, and learning-with-time.<sup>31</sup> Such

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<sup>30</sup> See U. Beck, 'The terrorist threat: world risk society revisited' (2002) 19 *Theory, Culture and Society* 39; see also D. Matten, 'The impact of the risk society thesis on environmental politics and management in a globalizing economy – principles, proficiency, perspectives' (2004) 7 *Journal of Risk Research* 377; A. Klinke and O. Renn, 'A new approach to risk evaluation and management: risk-based, precaution-based, and discourse-based strategies' (2002) 22 *Risk Analysis* 1071; T. Page, 'A generic view of toxic chemicals and similar risks' (1978) 7 *Ecological Law Quarterly* 207; RIVM (National Institute for Public Health and Environmental Protection), *Zorgen voor Morgen; Nationale Milieuverkenning 1990-2005* (Concern for Tomorrow; National Environmental Outlook 1990-2005) (Bilthoven, Alphen a/d Rijn: Samson Tjeenk Willink 1988); P. Slovic, B. Fischhoff and S. Lichtenstein, 'Facts and fears: understanding perceived risk' in R.C. Schwing and E. Albers Jr. (eds.), *Societal risk assessment: how safe is safe enough?* (New York: Plenum 1980); Ch. Vlek and G.B. Keren, 'Behavioral decision theory and environmental risk management: assessment and resolution of four 'survival' dilemmas' (1992) 80 *Acta Psychologica* 249.

<sup>31</sup> Klinke and Renn's distinction among simple, complex, uncertain and (sociopolitically) ambiguous risk problems indicates some important aspects of the

general characteristics may be supplemented with more specific features like the more or less gradual development of risk (as in atmospheric pollution), the relative modesty of expected benefits (as in food supplements?), either social ('diffuse') or individual ('point') sources of risk, and the costs of reversing or compensating for eventual harm or damage.

Table 1 gives a condensed categorisation of different types of uncertain-risk situations, showing one specific example per cell. The 'short-term, local criminal' problem of a railway bomb alarm is decision-analysed in Section 4.4.4.

Table 1 Condensed categorisation of uncertain-risk situations.

Focus of risk ↓		Natural	Human-caused		
			Criminal action <sup>1)</sup>	Point source	Diffuse sources
Short-term	Local	Avalanche	Railway bomb-alarm	LPG/LNG BLEVE <sup>2)</sup>	Electr. power blackout
	Extensive	Heavy storm	Football hooliganism	Oil tanker crash	BSE crisis (1996-)
Long-term	Local	Volcanic eruption	WTC attack '9/11'	Nuclear waste	Urban air pollution
	Extensive	Sequake tsunami	Genocide (WW-II, Ruanda, Darfur)	Bhopal MIC <sup>3)</sup> Gas release (1984)	GMO-technology

<sup>1)</sup> Here, the point versus diffuse sources distinction is not made explicit.

<sup>2)</sup> BLEVE = Boiling Liquid Expanding Vapour Explosion.

<sup>3)</sup> MIC= methylisocyanate.

## 2.1 Criticisms of probabilistic risk assessment and management

Already in the early days of probabilistic risk analysis (PRA), uncertainty about probabilities and about possible consequences was a major source of doubt with regard to PRA's potential as a basis for responsible risk

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'new risks'. Klinke and Renn, above n. 30. However, it would seem that ambiguity often flows from uncertainty, which itself flows from complexity, and there are other important aspects as well.

assessment and management; see, for instance, Lewis'<sup>32</sup> critique of the reactor-safety study Wash-1400.<sup>33</sup> In view of the many time-honoured criticisms (see references below), we may generally conclude that: (a) a formal concept of risk and the notion of model rationality properly apply only to reasonably well-defined risk problems; (b) probabilistic risk analysis has always had to grapple with assessment uncertainties; (c) the social dynamics of safety management (in design, decision, and control) are hard to model predictively a priori; and (d) often different scientific and social perspectives on risk assessment and management may be equally valid.

On the one hand, in response to these criticisms since the 'formal-quantitative' 1970s, practical risk assessment and management have come a long way to gaining a grip on, and certainly acquiring more understanding of, the kind of uncertain-risk problems for which the PP is being advanced.<sup>34</sup> On the other hand, the PP debate has gradually become more sensitive to issues like credibility of evidence, cost-benefit balancing, and risk-risk trade-offs.<sup>35</sup> Such a rapprochement between risk-analytic and precautionary-principled thinking meets with Majone's (2002) critique that uncertainty about possible harm or damage is a continuous and not a dichotomous variable.<sup>36</sup>

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<sup>32</sup> See H.W. Lewis and others, *Risk assessment review group report to the the U.S. Nuclear Regulatory Commission*, Report no. NUREG/CR-0400 (Washington D.C., September 1978).

<sup>33</sup> Wash-1400, *Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants* (Washington D.C.: U.S. Nuclear Regulatory Commission 1975).

<sup>34</sup> IRGC, *White Paper on Risk Governance. Towards an Integrative Approach* (Geneva: International Risk Governance Council 2005) available at <[www.irgc.org](http://www.irgc.org)>; H. Otway and M. Peltu (eds.), *Regulating industrial risks. Science, hazards and public protection* (London: Butterworths 1985); Presidential-Congressional Commission, 1997; Royal Society, *Risk: Analysis, Perception and Management. Report of a Royal Society Study Group* (London: The Royal Society 1992); P.C. Stern and H.V. Fineberg (eds.), *Understanding risk; informing decisions in a democratic society* (Washington D.C.: National Academy Press 1996); G.M. Gray, 'The precautionary principle in practice: comparing US-EPA and WHO pesticide risk assessments' *Risk in Perspective* (2004) 12 *Newsletter of the Harvard Center for Risk Analysis*, available at <[www.hcra.edu](http://www.hcra.edu)>.

<sup>35</sup> Cf. J.D. Graham, 'Decision-analytic refinements of the precautionary principle' (2001) 4 *Journal of Risk Research* 127; J. Scott and E. Vos, 'The juridification of uncertainty: observations on the ambivalence of the Precautionary Principle within the EU and the WTO' in C. Joerges and R. Dehousse (eds.), *Good Governance in Europe's Integrated Market* (Oxford: Oxford University Press 2002) at 253; Stern and Wiener, above n. 6; E. Stokes, 'The EC courts' contribution to refining the parameters of precaution' (2008) 11 *Journal of Risk Research* 491.

<sup>36</sup> Majone, above n. 25, at 104.

### 3 Definitions of the Precautionary Principle

As a principle – ‘a comprehensive and fundamental law or doctrine, or a rule or code of conduct’ – the PP has been formulated in various ways.<sup>37</sup> From the many definitions proposed, Table 2 gives four illustrative examples.

Table 2 Specimen definitions of the Precautionary Principle.

	<b>Strong</b>	<b>Weak</b>
<b>Narrow</b>	Wingspread (1998): ‘When an activity raises threats of harm to human health or the en-vironment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. ... the proponent of an activity ... should bear the burden of proof’. <sup>38</sup>	UNCED (1992), Rio-Declaration, Principle 15: ‘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’. <sup>39</sup>
<b>Broad</b>	Unesco-COMEST (2005): ‘When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm. ... Morally unacceptable harm is .... The judgment of plausibility should be grounded in scientific analysis. ... Actions should be ... proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences. ... The choice of action should be the result of a participatory process’. <sup>40</sup>	Graham’s (2001) extension of UNCED (1992): ‘Prior to enacting precautionary measures, decision makers should consider any potential benefits of unintended exposures, any potential risks of precautionary actions, and the promise of targeted investments in scientific research as a precautionary strategy. ... other refinements ... include formal measurement of citizen preferences about societal risk aversion and temporal preferences, concerns raised by Page <sup>41</sup> more than 20 years ago’. <sup>42</sup>

<sup>37</sup> Following <www.merriam-webster.com/dictionary>. See also A. Trouwborst, ‘The precautionary principle in general international law: combating the Babylonian confusion’ (2007) 16 *Review of European Community and International Environmental Law* 185.

<sup>38</sup> ‘Wingspread Statement on the Precautionary Principle’ (1998) 586 *Rachel’s Environment and Health Weekly*.

<sup>39</sup> UNCED, above n. 8. Rio-Declaration, Principle 15.

<sup>40</sup> Unesco-COMEST, World Commission on the Ethics of Scientific Knowledge and Technology, *The Precautionary Principle* (Paris: United Nations Educational, Scientific and Cultural Organization 2005).

<sup>41</sup> T. Page, ‘A generic view of toxic chemicals and similar risks’ (1978) 7 *Ecological Law Quarterly* 207.

<sup>42</sup> Graham’s extension of UNCED, above n. 8; Graham, above n. 35.

Strong, ‘obligatory’ versions of the PP such as UN General Assembly,<sup>43</sup> Wingspread<sup>44</sup> and Unesco-COMEST,<sup>45</sup> may be distinguished from weak, ‘optional’ versions such as UNCED,<sup>46</sup> EC,<sup>47</sup> and Graham.<sup>48</sup> There is also a significant variation in the scope of precaution. Somewhat compact but open statements are those made by UNCED<sup>49</sup> and Resnik.<sup>50</sup> In contrast, comprehensive formulations have been proposed by Graham,<sup>51</sup> Unesco-COMEST,<sup>52</sup> Kourilsky and Viney,<sup>53</sup> and Martuzzi.<sup>54</sup> Wide-scope versions of the PP are explicit about such things as risk comparisons, cost-benefit analysis, and participatory decision-making. All versions of the PP provoke questions about substantive and procedural methodology: How could this ‘principle’ be clearly elaborated and practically applied?

After reviewing the many different proposals, one may conclude that, for a comprehensive circumscription of the PP, ten key issues are important, as listed in Table 3.

Table 3 Ten key issues for a precautionary-principled approach to uncertain risks.

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1. General inclination and motivation (‘Why precaution?’)
  2. Nature and seriousness of potential harm (e.g. ‘Worst case?’)
  3. Plausibility of possible harm or damage
  4. Precautionary decision-making: balancing over- vs under-protection
  5. Precautionary safety actions (‘What could we do, provisionally?’)
  6. Optional versus obligatory precaution
  7. Who carries the burden of proof of risk or safety?
  8. Further research and policy development
  9. Multiparty communication and deliberation
  10. Distribution of responsibilities (‘Who should do what, and when?’)
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<sup>43</sup> United Nations General Assembly, *World Charter for Nature* UN GA/RES/37/7 (New York, 28 October, 1982).

<sup>44</sup> Wingspread, above n. 39.

<sup>45</sup> Unesco-COMEST, above n. 40.

<sup>46</sup> UNCED, above n. 8.

<sup>47</sup> EC (2000), (2001), above n. 9.

<sup>48</sup> Graham, above n. 35.

<sup>49</sup> UNCED, above n. 8.

<sup>50</sup> D.B. Resnik, ‘Is the precautionary principle unscientific?’ (2003) 34 *Studies in the History and Philosophy of Biological and Biomedical Sciences* 329.

<sup>51</sup> Graham, above n. 35.

<sup>52</sup> Unesco-COMEST, above n. 41.

<sup>53</sup> Ph. Kourilsky and G. Viney, above n. 29.

<sup>54</sup> Martuzzi, above n. 17.

The ten issues form the basis of a precautionary approach comprising both substantive and procedural elements. Key issues 1-5 are explained in Section 4; issues 6-10 are discussed in Section 5.

### 3.1 An integrative circumscription of the Precautionary Principle

In view of the definitions represented in Table 2 and the key issues listed in Table 3, a general circumscription of the PP may be given as in Box 1.<sup>55</sup>

#### Box 1 Integrative circumscription of the Precautionary Principle

*The Precautionary Principle applies when people (one or more persons, a group, organisation, society) are confronted with a situation of serious uncertain risk or threat.*

It involves:

- an analysis and evaluation of credible worst-case scenarios;
- the making of epistemic judgments on the basis of incomplete evidence;
- the inclination to take a cautious or ‘pessimistic’ decision about a provisional course of action;
- a careful evaluation of expected costs, risks, and benefits of the target activity and its feasible alternatives;
- and the timely selection and implementation of ‘reasonable’ precautionary (i.e. early-safety) measures.

Whereby:

- the proponent of the relevant activity has a special responsibility in demonstrating the likelihood of safety;
- further research is undertaken to reduce uncertainties;
- risk management decisions can be revised when new information becomes available, and
- the entire process of assessment, decision, and control is the subject of open communication and an information exchange among relevant stakeholders;
- supervision and coordination is undertaken by an appropriate independent authority.

The upper five items in Box 1 cover ‘assessment, decision, and control’, and they largely indicate what the PP substantively involves. These

<sup>55</sup> The items in Box 1 do, of course, reflect but are not fully parallel to the issues in Table 2.

five apply to small-scale individual situations, such as undertaking a mountain cycling trip on a rainy day, as well as to large-scale collective situations, such as the international spread of avian influenza.<sup>56</sup> The lower five items in Box 1 are largely procedural; in principle, they may also apply to small-scale activities, but typically they apply to societal risk situations in which responsible risk managers must eventually make decisions that can be well understood by all parties concerned.

The precautionary heart of the principle is its ‘pessimistic’ or unusually protective inclination towards foregoing an activity or imposing strict(er) safety measures upon it, both of which are induced by the great uncertainty about possible disastrous consequences. The difference between weak and strong precaution (cf. Table 2) lies mainly in the greater emphasis on risk avoidance, ‘proving’ safety and the obligation to take safety measures, that characterises strong precaution.<sup>57</sup>

In comparison to probabilistic risk analysis, Box 1 contains three distinctive elements: (i) the uncertain inclination of ‘pessimism’, (ii) the proponent’s larger burden of demonstrating the likelihood of safety, and (iii) a tendency to delay risk-taking until sufficient new information becomes available. A fourth distinctive element – multiparty deliberation – might be added, but this has already been recommended for quite some time, since the development of risk analysis (cf. Section 2).

#### **4 A precautionary-principled approach to uncertain-risk problems**

In this section, the practical meaning and application of the PP is elaborated in terms of substantive key issues 1-5 in Table 3, whose labels will reappear as subheadings below. This labelling also offers the opportunity of a systematic response to major criticisms of the PP, as summarised in Section 1.

##### **4.1 General inclination and motivation**

A basic proposition inherent to the PP is that more caution is justified when there is greater uncertainty about possible negative consequences and/or

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<sup>56</sup> In principle, the substantive meaning of precaution (upper five items in Box 1) also applies to animal behaviour: for example, in the case of a hungry fox warily foregoing the tempting bait in a trap.

<sup>57</sup> M. Basili and M. Franzini, ‘Understanding the risk of an avian flu epidemic: rational waiting or precautionary failure?’ (2006) 26 *Risk Analysis* 617; P. Gardiner, ‘A core precautionary principle’ (2006) 14 *The Journal of Political Philosophy* 33; J. Hughes, ‘How not to criticize the precautionary principle’ (2006) 31 *Journal of Medicine and Philosophy* 447.

about the seriousness of those consequences. Another proposition is that any risk problem always implies at least two choice alternatives: go/do not go, accept/reject, or permit/restrict. Also, there are at least two ‘states of nature’: there is a serious threat or there is not. This elicits two possible basic decision errors: (1) a false positive, when you take costly precautions while there actually is no threat, and (2) a false negative, when you neglect real danger. The gravity of these two errors is relative to the corresponding benefits of deciding ‘correctly’: being costly cautious when there is a threat, and being profitably careless when there is none.

A further point is that a precautionary decision often is provisional; a revised choice can be made when new information becomes available. When one knows more about the possible consequences of a target course of action, about their manageability by further safety measures, and/or about feasible alternatives, then the initial cautious decision may be revised, and the original goal(s) may be achieved in a safer way. Thus there are in fact not two but three basic decision options: do, do not do, or defer (see Section 4.4.4).

The fundamental problem, not of the PP but of uncertain-risk situations, is the great uncertainty about the possibility of serious harm. This may lead one to call it a normative principle, but only if one does not accept the rationality of temporarily shrinking back from a course of action that *might* lead into disaster.<sup>58</sup>

## 4.2 Nature and seriousness of potential harm

What is a ‘serious threat’ that could initially trigger and later justify precaution? It must be something that could thoroughly disrupt a person’s, life, harming its positive development, bringing about long-term trauma, and causing very high costs of recovery, reversal, or compensation. Or, at the societal level, a serious threat might cause severe social disruption, environmental damage, and political shock, which would take many years, numerous debates, and considerable funds to overcome. In view of these considerations, the notion of serious harm may be assessed in terms of the criteria assembled in Box 2; these link up with basic results from risk-risk-perception research.

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<sup>58</sup> See Bergkamp, above n. 21; Peterson, above n. 27; WRR, Wetenschappelijke Raad voor het Regeringsbeleid (Scientific Council for Government Policy), *Naar nieuwe wegen in het milieubeleid* [Towards new ways in environmental policy-making] WRR-rapport no. 67 (Den Haag: SDU Uitgevers 2003).

## Box 2 Criteria for assessing the seriousness of possible harm

- Degree of harm or fatality for human, animal, and/or plant life;
- Degree of material, economic damage;
- Extent of social damage (number of people involved);
- Extent of environmental damage (animals/plants, ecosystems involved);
- Timing, duration, and/or persistence of harm;
- Costs of restoring, reversing, or recovering from the damage;
- Causation of significant social inequities in quality of life;
- Causation of significant intergenerational inequities.

Psychologically, a focus on possible worst cases or potential catastrophality is more obvious the greater the uncertainty about its actual, often very unlikely, occurrence.<sup>59</sup> This ‘probability neglect’ may be enhanced by the emotions surrounding images of disaster.<sup>60</sup> Godard’s<sup>61</sup> warning about radical ‘catastrophism’ lines up with Starr’s,<sup>62</sup> who ascribes present-day ‘hypothetical fears’ (e.g. of global warming, irradiated foods, and GMOs) as arising from a primitive instinct to suspect the unknown, which leads to the PP – seen by Starr – as a barrier to an adaptive future.<sup>63</sup> Thus, under great uncertainty, worst-case analysis may be inevitable, but ‘worst-case thinking’ may be a tricky affair, which should be guarded from improper influences and considerations, such as special interests, exaggerated fears, and unreasonable assumptions. In cases of catastrophic potential, however, there is a high burden of proving their impossibility.<sup>64</sup>

<sup>59</sup> Slovic, Fischhoff and Lichtenstein, above n. 30; Ch. Vlek and P.J. Stallen, ‘Judging risks and benefits in the small and in the large’ (1981) 28 *Organizational Behavior and Human Performance* 235.

<sup>60</sup> C.S. Sunstein, ‘Terrorism and probability neglect’ (2003a) 26 *Journal of Risk and Uncertainty* 121.

<sup>61</sup> O. Godard, ‘The precautionary principle and catastrophism on tenterhooks: lessons from constitutional reform in France’ in E. Fisher, J. Jones and R. von Schomberg (eds.), *The Precautionary Principle and Public Policy Decision Making* (London: Edward Elgar 2006) at 63.

<sup>62</sup> Ch. Starr, ‘Hypothetical fears and quantitative risk analysis (2001) 21 *Risk Analysis* 803.

<sup>63</sup> Starr, above n. 63, and others, e.g., R. Pieterman, ‘Culture in the risk society. An essay on the rise of a precautionary culture’ (2001) 22 *Zeitschrift für Rechtssoziologie* 145.

<sup>64</sup> ‘Serious harm’ may not only pertain to false-negative consequences (neglecting real danger), since false-positive decisions (taking needless precautions) may also

### 4.3 Plausibility of possible harm or damage

Uncertainty is the taproot of precaution. If one worries about a serious uncertain threat, a key judgment about the plausibility of possible grave harm or damage is needed for a take-risk versus enhance-safety decision. Here, the PP may function as an *assessment principle*.

Uncertainty is a multifactorial concept. In a reasonably complex decision problem there may be uncertainty about one's assessment of the status quo, one's options and their feasibility, the likelihood of conditioning events, relevant cause-effect relationships, the nature of possible consequences and their valuation, and – after a choice to defer the decision – the utility of new information to be collected before reconsidering the decision. A great deal of the uncertainty-justifying precaution is due to the time lag between cause and effect; when the latter manifests it may be too late to reduce or eliminate its cause.<sup>65</sup>

#### 4.3.1 Different kinds of uncertainty

Focused uncertainty about serious risks may have various sources. Following EC:

Scientific uncertainty results usually from five characteristics of the scientific method: the variable chosen, the measurements made, the samples drawn, the models used and the causal relationship employed. Scientific uncertainty may also arise from a controversy on existing data or lack of some relevant data. Uncertainty may relate to qualitative or quantitative elements of the analysis.<sup>66</sup>

Internationally, several other taxonomies have been proposed.<sup>67</sup> From these

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have rather bad consequences to which several of the above-listed criteria may apply.

<sup>65</sup> F. Ewald, 'The return of Descartes's malicious demon: An outline of a philosophy of precaution' in T. Baker and J. Simon (eds.), *Embracing Risk: The Changing Culture of Insurance and Responsibility* (Chicago: University of Chicago Press 2002) at 273; E.D. Richter and R. Laster, 'The precautionary principle, epidemiology and the ethics of delay' (2005) 11 *Human and Ecological Risk Assessment* 17.

<sup>66</sup> EC (2000), above n. 9, at 14.

<sup>67</sup> J. Lemons, K. Shrader-Frechette and C. Cranor, 'The precautionary principle: scientific uncertainty and Type I and Type II errors' (1997) 2 *Foundations of Science* 207; M.E. Paté-Cornell, 'Uncertainties in risk analysis: six levels of treatment' (1996) 54 *Reliability Engineering and Systems Safety* 95; M. Regan, M. Colyvan and M.A. Burgman, 'A taxonomy and treatment of uncertainty for ecology and conservation biology' (2002) 12 *Ecological Applications* 618; C. Tannert, H.-D. Elvers and B. Jandrig, 'The ethics of uncertainty' (2007) 8 *EMBO Reports*,

we may identify four basic questions about uncertainties and their possible reduction:

1. How adequate are the concepts, model, method, variables, and sample and data analysis used?
2. How complex and/or variable (and thus: how unpredictable) is the process, object, or system we wish to understand?
3. What and how much could in principle be known about the subject matter of interest?
4. What values and/or weights should be attached to possible decision consequences and/or options?

Question 1 may get higher-quality answers via *better* research. Question 2 is about inherent limited predictability which, in principle, no further research could improve. Question 3 in fact demands *more* innovative and pioneering research. Question 4 may reveal personal or organisational value diversity. The latter may be approached via social-deliberative procedures for judgment and decision-making, under the presumption that this may yield sufficient understanding and/or consensus for relevant decisions (see further Section 5).

#### 4.3.2 Judging the plausibility of serious harm

To prevent unfounded presuppositions, assumptions, and imaginings from playing a significant role in precautionary policies, epistemic criteria are needed to judge the plausibility of possible serious effects, in the shorter and the longer term, of target activities or developments.

More than 40 years ago, Hill considered a set of criteria for inferring a causal relationship from an observed association between phenomena A (e.g. an environmental condition) and B (e.g. a health condition),<sup>68</sup> as summarised in the left column of Table 4.<sup>69</sup> The right column lists six criteria for judging the plausibility of a hypothesis (e.g. about a serious threat) as proposed by Resnik.<sup>70</sup>

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*European Molecular Biology Organization* 892; M.B.A. van Asselt, *Perspectives on Uncertainty and Risk* (Dordrecht: Kluwer 2000).

<sup>68</sup> A.B. Hill, 'The environment and disease: association or causation?' *Proceedings of the Royal Society of Medicine, Section of Occupational Medicine*, Meeting of January 14, 1965 (London: Royal Society of Medicine 1965) at 295.

<sup>69</sup> Hill nicely quotes the famous detective Sherlock Holmes as having said: 'When you have eliminated the impossible, whatever remains, *however improbable*, must be the truth.' (Hill's italics); Hill, above n. 69, at 298.

<sup>70</sup> Resnik, above n. 51.

Table 4 Hill's and Resnik's criteria for judging plausibility of causality

<b>Hill's criteria for causality judgment</b>	<b>Resnik's epistemic criteria for plausibility</b>
<ol style="list-style-type: none"> <li>1. *Strength of association</li> <li>2. *Consistency of association</li> <li>3. Specificity of association</li> <li>4. Temporality of association</li> <li>5. *Biological gradient of association (dose-response curve)</li> <li>6. *Plausibility of association (after elimination of the impossible)</li> <li>7. Coherence of causal interpretation with known facts</li> <li>8. Experimental test of causality</li> <li>9. Analogy of association with other, known cause-effect relationships</li> </ol>	<ol style="list-style-type: none"> <li>1. Coherence (consistency of background knowledge and theories)</li> <li>2. Explanatory power</li> <li>3. Analogy (to similar, well-understood mechanisms and processes)</li> <li>4. Precedence (similar to previously observed events)</li> <li>5. Precision (the hypothesis should be reasonably precise)</li> <li>6. Simplicity (the hypothesis should be parsimonious)</li> </ol>

Note: \*Asterisked Hill-criteria are most often used by practitioners, following Weed.<sup>71</sup>

These and similar sets of criteria hold the message that, under major uncertainty, the plausibility of a hypothesis about a causal relationship – or of finding an alternative course of action, or of discovering hitherto unknown possible consequences, for that matter – always is a tentative, fumble-and-grope affair. It is a scientist's 'best bet', whereby one may eventually turn out to be right or wrong, since nature ultimately determines the actual outcome.<sup>72</sup>

#### 4.3.3 Evidence scales and standards of proof

The extent to which a given phenomenon (often a cause-effect relationship) occurs may be expressed as a greater or lesser probability or plausibility. We should remember that probability is a mathematical concept ranging from 0: impossibility, to 1: necessity of occurrence. Probability measures should

<sup>71</sup> D.L. Weed, 'Precaution, prevention, and public health ethics' (2004) 29 *Journal of Medicine and Philosophy* 313.

<sup>72</sup> Extreme uncertainty, of course, comes close to total ignorance, whereby the English proverb may apply: 'Where nought's to be got, kings lose their scot.'

fulfil a limited set of measurement axioms: for example, that the probabilities of an exhaustive set of mutually exclusive events should amount to 1.

In contrast, or rather, in supplement to, the notion of plausibility reflects a combination of possibility ('cannot be excluded') and a vague but a priori low likelihood ('worth looking into'). Traditionally, scientists don't like 'plausibility reasoning'<sup>73</sup> and it has been argued that the controversial PP derives from the limitations of scientific knowledge.<sup>74</sup>

Scales covering various degrees of evidence and their implication for decision-making have been assembled by IARC,<sup>75</sup> Weiss<sup>76</sup> and Wiedemann, Mertens, and others.<sup>77</sup> After a careful comparison of legal, scientific, and Bayesian-statistical levels of uncertainty, Weiss proposes the ten-point 'subjective scale of scientific certainty' as summarised in Table 5;<sup>78</sup> the final column indicates the corresponding evidentiary qualifications of the Intergovernmental Panel on Climate Change (IPCC) in its Fourth Assessment Report.<sup>79</sup>

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<sup>73</sup> J.S. Gray, 'Statistics and the precautionary principle' (1990) 21 *Marine Pollution Bulletin* 174; M. Iaccarino, 'A cost/benefit analysis. About the Precautionary Principle' (2000) 1 *EMBO Reports, European Molecular Biology Organization* 454; Peterson, above n. 27; E. Soule, 'The precautionary principle and the regulation of U.S. food and drug safety' (2004) 29 *Journal of Medicine and Philosophy* 333.

<sup>74</sup> J. Van der Sluijs, 'Uncertainty and precaution in environmental management: Insights from the UPEM conference' (2007) 22 *Environmental Modelling and Software* 590.

<sup>75</sup> IARC, International Agency for Research on Cancer. *IARC monographs on the evaluation of carcinogenic risks to humans, Preamble* (Lyon: World Health Organization-IARC 2006) available at: <<http://monographs.iarc.fr/eng/preamble/currentpreamble.pdf>>.

<sup>76</sup> Ch. Weiss, 'Expressing scientific uncertainty' (2003) 2 *Law, Probability and Risk* 25; Ch. Weiss, above n. 29.

<sup>77</sup> P.M. Wiedemann and others, *Risikopotenziale elektromagnetischer Felder: Bewertungsansätze und Vorsorgeoptionen*, Endbericht für das Bayerische Staatsministerium für Landesentwicklung und Umweltfragen. (Jülich: Forschungszentrum Jülich, Programmgruppe Mensch, Umwelt, Technik 2001).

<sup>78</sup> Weiss (2003), above n. 77, Tables 2 and 3.

<sup>79</sup> IPCC, '*IPCC Fourth Assessment Report: Climate Change 2007*' (Synthesis Report and Working Group I-III Summaries and Reports). Geneva (CH): Intergovernmental Panel on Climate Change, <[www.ipcc.ch](http://www.ipcc.ch)>.

Table 5 Adapted (un)certainty scale as proposed by Weiss,<sup>80</sup> with IPCC-2007 column<sup>81</sup> added

Level	Legal standard of proof	Scientific qualification	Bayesian Probability	IPCC-scale of likelihood 2007
10.	Beyond any doubt	Experimentally broadly validated theory	100%	(None)
9.	Beyond a reasonable doubt	Rigorously proven	> 99%	Virtually certain
8.	Clear and convincing evidence	Substantially proven, reasonably certain	> 95%	Extremely likely
			> 90%	Very likely
7.	Clear showing	Very probable	80-90%	Likely
6.	Substantial and credible evidence	Probable, not fully Proven	67-80%	
5.	Preponderance of the evidence	More likely than not to be true	50-67%	> 50%: more likely than not; 33-67%: about as likely as not
4.	Clear indication	Attractive but unproven	33-50%	
3.	Probable cause, reasonable grounds for belief	Plausible hypothesis	10-33%	Unlikely
2.	Reasonable, articulable grounds for suspicion	Possible, worth investigating	5-10%	Very unlikely
			1-5%	Extremely unlikely
1.	No reasonable grounds for suspicion	Unlikely, but not excludable	< 1%	Exceptionally unlikely
0.	Impossible	Against known laws of science	0%	(None)

<sup>80</sup> Weiss, above n. 77.<sup>81</sup> IPCC (2007), above n. 80.

From a Bayesian decision-theoretic point of view, a given level of certainty/uncertainty or probability in Table 5 could be used in a formal policy ‘gamble’. One might, for example, invest more or less public money in developing a mitigation and/or adaptation strategy for climate change, the more or less certain one is about the human causes of and solutions to problems of climate change.

#### 4.3.4 ‘Sufficient evidence’ for diagnostic judgments

How much evidence is needed, or how much uncertainty may remain before one embarks upon a precautionary strategy? Here, it should be realised that empirical scientific conclusions (e.g. about a chemical being carcinogenic, or an animal population being at risk) may, perhaps improbably, be wrong in two ways: they may be falsely positive or falsely negative. Thus, the implicit value question for the scientist is: What is worse? Stating that a risk is present when it actually is not (a false positive or Type I error), or declaring that there is no risk when there actually is one (false negative or Type II error)? The basic proposition here is that in a diagnostic choice (or ‘epistemic decision’) between alternative hypotheses – ‘risk’ versus ‘no risk’ – the relative seriousness of a false positive versus a false negative plays a crucial role.<sup>82</sup> Or, to quote Rudner: ‘How sure we need to be before we accept a hypothesis will depend on how serious a mistake would be’.<sup>83</sup>

A formal analysis of diagnostic judgment may well follow signal detection theory (SDT), a well-established methodology for separating an observer’s discriminative capacity from his/her ‘response bias’.<sup>84</sup> According to SDT, the useful thing for scientists to do is to show how the probability of a true positive (i.e. 1 minus the probability of a false negative) is related to the probability of a false positive (i.e. 1 minus the probability of a true negative) when the evidentiary requirement is gradually relaxed (cf. Table 5). Note that the probability of a true positive reflects the *sensitivity* of the diagnostic test (which may just be an expert’s decisive judgment), while the probability of a true negative reflects the test’s *specificity*.

Obviously, when the evidentiary criterion is weakened, the probability of a true positive (and thus the test sensitivity) increases, but so

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<sup>82</sup> Resnik, above n. 51.

<sup>83</sup> R. Rudner, ‘The scientist *qua* scientist makes value judgments’ (1953) 20 *Philosophy of Science* 1 at 2.

<sup>84</sup> J.A. Swets, W.P. Tanner and T.G. Birdsall, ‘Decision processes in perception’ (1961) 68 *Psychological Review* 301; J.A. Swets, R.M. Dawes and J. Monahan, ‘Psychological science can improve diagnostic decisions’ (2000) 1 *Psychological Science in the Public Interest* 1; see also S.E. Hradey and W. Leiss, ‘Risk management and precaution: Insights on the cautious use of evidence’ (2003) 111 *Environmental Health Perspectives* 1577.

does the probability of a false positive. However, for a powerful diagnostic test (or expert judgment), the probability of a true positive,  $p(\text{TP})$ , increases much faster than does the probability of a false positive,  $p(\text{FP})$ ; for a weak test or judgment,  $p(\text{TP})$  increases only moderately with a weakening criterion. In the limiting case, where the ‘risk’ and ‘no risk’ hypotheses cannot be empirically discriminated at all, there is an equal rate of change for both probabilities when the evidentiary criterion varies.

The primary message from SDT is that there is no single absolute threshold level (‘sufficient evidence’ or ‘standard of proof’) for making sensory and/or cognitive judgments about physical signals (e.g. a warning sound) or more complex states of the world (e.g. serious risk), because some kind of response bias grounded in the relative seriousness of judgmental mistakes always plays a role, the more so the greater the uncertainty (the ‘noise’) about the available evidence.

Thus, the scientist attempting to offer useful information about an uncertain risk might deliver three things: (i) his/her best estimate of the probability that the risk hypothesis is true relative to some null hypothesis, (ii) a specification of the relationship between the true-positive probability and the false-positive probability as the evidentiary requirement varies from strong to weak, and (iii) a demonstration of his/her willingness to virtually bet on the true outcome, given certain negative utilities attached to a false-positive (Type I error) and a false-negative (Type II error) diagnosis. These utilities in fact are or should be decision-maker values that do not seem to belong to the realm of science.<sup>85</sup>

#### **4.4 Precautionary decision-making: balancing over- versus under-protection**

Deciding whether to undertake precautionary action is the centre piece of any approach towards uncertain-risk situations. Given that we know reasonably well how to avoid or diminish the relevant uncertain risk (see Section 4.5 about safety actions), key questions here are: How could decisions about uncertain-risk management best be taken? How rational could they be? Who should prepare and/or take such decisions? These issues have attracted considerable attention from theoretical economists, decision theorists, and risk analysts, who all seem to acknowledge that uncertainty itself holds limitations for rational problem solving. A concrete example is elaborated in Section 4.4.3.

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<sup>85</sup> Grandjean emphasises that scientists and policy-makers naturally differ in their desire to avoid false positives and false negatives, respectively, Grandjean and others, above n. 14.

#### 4.4.1 Limitations of rational decision-making

Decision theory is meant to be a rational framework for individual (or single-agent) decision-making in reasonably well-defined situations.<sup>86</sup>

‘Rational’ here means that:

- the decision-maker obeys certain axioms such as the dominance principle, transitivity of preferences, and consistency of probability estimation;
- relevant choice alternatives, critical uncertain events, and possible consequences are eventually known so that the problem structure is ‘closed’;
- the decision-maker can assign probabilities (however vague) to uncertain event-outcomes;
- he/she can attach goal-consistent (possibly vague) utility values to possible consequences;
- his/her goal is to maximise the expected utility of an action’s possible consequences.

In ill-defined decision situations, one or more of the above conditions often can be fulfilled only with difficulty or not at all. This natural limitation has led to the formulation of different decision rules. Moreover, in multiple-stakeholder problems, the rationality of multiparty decision-making is limited by the interpersonal incomparability of individual utilities. As a result, individual preference orders of alternative courses of action cannot easily be aggregated into a single social preference order free of circularities and/or intransitivities.<sup>87</sup>

Hence, rational decision analysis of uncertain-risk situations may be a useful but inherently limited tool for disciplining one’s thoughts and feelings about problem structuring, option evaluation, and the preferential ordering of choice alternatives. The surrounding context of the analysis proper may comprise persistent uncertainties, sheer ignorance about long-term developments, stakeholder differences in judgments and preferences, and difficulties in communication between experts, policy-makers and judicial authorities. The contextual complexities of intentionally rational decision-making are clearly illustrated in the precautionary case studies

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<sup>86</sup> D.V. Lindley, *Making decisions* (London, New York: Wiley 1985 2<sup>nd</sup> ed.); R.D. Luce and H. Raiffa, *Games and decisions* (New York: Wiley 1957).

<sup>87</sup> K.J. Arrow, *Social choice and individual values* (New York: Wiley 1963/1951); D.H. Blair and R.A. Pollak, ‘Rational collective choice’ (1983) 249 *Scientific American* 76; T. Bezembinder, ‘Social choice theory and practice’ in C. Vlek and G. Cvetkovich (eds.), *Social decision methodology for technological projects* (Dordrecht: Kluwer Academic Publishers 1989) at 15.

reported by Forrester and Hanekamp,<sup>88</sup> Stern and Wiener,<sup>89</sup> and Van Asselt and Vos.<sup>90</sup>

#### 4.4.2 Decision rules for uncertain-risk taking

As a *decision principle*, the PP is often related to the maximin utility (or payoff) criterion for decision-making under total uncertainty about which state of the world would obtain after a choice has been made. Under the ‘bad-luck’ assumption that each alternative action would yield the least favourable consequence, one may best choose the alternative having the least-bad consequence (*maximum minimorum*). Maximin, however, is only one of various rules for decision-making under uncertainty. Other rules are maximax, minimax regret, and the principle of insufficient reason.<sup>91</sup>

Next to these, weighted combinations of maximax and maximin, or of maximax/maximin and expected utility, have been proposed for uncertain-risk situations characterised by extreme possible consequences.<sup>92</sup> Various practical examples with numerical exercises might be given that would clearly reveal that different decision rules may lead to different optimal choices. This, however, would far exceed the scope of this paper.<sup>93</sup> Instead, the following conclusions are presented about precaution via formal decision rules.

1. For reasonably well-defined decision problems – with known options, states, and payoffs or utilities – under full uncertainty about which state of the world would obtain, there exist different formal decision rules that may lead to different optimal choices depending on what exactly one wishes to maximise or to minimise. Among these, ‘Maximin’ would reflect an indiscriminate belief in bad luck whatever one chooses.

<sup>88</sup> I. Forrester and J.C. Hanekamp, ‘Precaution, science and jurisprudence: a test case’ (2006) 9 *Journal of Risk Research* 297,

<sup>89</sup> Stern and Wiener, above n. 6.

<sup>90</sup> M.B.A. van Asselt and E. Vos, ‘The precautionary principle in times of intermingled uncertainty and risk: some regulatory complexities’ (2005) 52 *Water Science and Technology* 35.

<sup>91</sup> See Luce and Raiffa, above n. 87.

<sup>92</sup> M. Basili, ‘A rational decision rule with extreme events’ (2006) 26 *Risk Analysis* 1721; Basili and Franzini, above n. 58; C. Henry, ‘Decision-making under scientific, political and economic uncertainty’ (2006) *Working Paper Laboratoire d’Économetrie, École Polytechnique*, available at <economix.u-paris10.fr/pdf.sem\_economix/2006-10-12.Henry.pdf>; D. Kelsey and J. Quiggin, ‘Theories of choice under uncertainty’ (1992) 6 *Journal of Economic Surveys* 133.

<sup>93</sup> Meanwhile, a more extensive review paper has been completed about different formal models and rules for decision-making under substantial uncertain risk (Ch. Vlek, ‘Judicious management of uncertain risks: II. Simple rules and more intricate models for precautionary decision-making’; 2009, submitted for publication).

Similarly, ‘Maximax’ would reflect an indiscriminate belief in good luck. Formally, such consequence-pessimism/optimism follows a weighted combination of the minimum and maximum possible consequence-utilities (or payoffs) per option,  $\alpha\text{Min} + (1-\alpha)\text{Max}$ , whereby  $0 \leq \alpha \leq 1$  reflects the degree of *consequence-pessimism*.

2. Alternatively, partial uncertainty about future states of the world may be quantitatively expressed in a more or less *event-pessimistic probability distribution*. The latter may serve to compute the Expected Utility (EU) for each choice alternative, which EU may then be used as a maximisation criterion.<sup>94</sup> Obviously, a more event-pessimistic probability distribution would yield a lower EU value for options implying a lower utility when the relevant ‘negative’ event would occur.
3. To the extent that there is a lack of confidence in the probability distribution under consideration, decision-makers may attenuate the significance of the resulting EU (using a less-than-full-confidence parameter  $0 \leq \beta \leq 1$ ) and assign relative greater (additional) weight  $1-\beta$  to some combination of the plausible minimum and maximum consequences of each option.<sup>95</sup> The latter themselves may also be differentially weighted following a consequence-pessimism parameter  $0 \leq \alpha \leq 1$ , as above. This may be called the W(eighted)EU- $U_{\text{Min}}/U_{\text{Max}}$  decision rule. The parameter  $\beta$  would reflect the degree of *probability confidence*.
4. When more than one probability distribution over the possible uncertain-event outcomes is considered (e.g. as a result of different experts’ advice), the decision-maker may:
  - a. follow the ‘Maximin EU’ rule and choose the option for which the minimal EU over distributions is maximal across the set of choice alternatives (quite analogous to the pure maximin rule);
  - b. follow a  $\gamma$ -weighted combination of the minimum and maximum EU values per choice alternative and choose the option for which the Weighted-EU $_{\text{Min}}/EU_{\text{Max}}$  value is largest (quite analogous to the pure  $\alpha$ -weighted Maximin/Maximax rule). The parameter  $\gamma$  would reflect the decision-maker’s degree of *ambiguity aversion*.
5. ‘Pessimism’ (or rather, fear or aversion) may also be expressed in an especially negative evaluation of the most undesirable plausible consequences, which optimists in turn may not interpret as

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<sup>94</sup> Expected Utility simply is the sum of probability-weighted utilities of possible consequences. This is demonstrated in Section 4.4.3.

<sup>95</sup> Some (probability) weight of the utilities of extreme consequences is already implied in the EU formula.

catastrophically severe.<sup>96</sup> Such differences in evaluation may be attributable to variations in risk exposure, system knowledge, perceived controllability, and personal efficacy in risk management.

6. In general, the PP implies giving a high weight to the minimum possible or highest-negative utility, or expected utility, per choice alternative. As indicated above, the pessimism implied may have various reasons.
7. Finally, we should note that there is no logical reason to be either pessimistic or optimistic in situations where probability information about future states of the world is lacking. If one feels strongly attracted by the plausible highest-utility consequence for each option (i.e. one consistently believes in, or hopes for good luck), then maximax utility, or some maximax-EU criterion, would be the decision rule to apply. In contrast, when one is pessimistic and fears bad luck, maximin-utility or maximin-EU should be followed.

#### 4.4.3 Minimal probability for an Avoid-Risk decision

A signal-detection analysis of diagnostic judgment (Section 4.3.4) is only one step away from a full expected-utility analysis of an important precautionary decision problem, as presented below. Let us adapt Rudner's statement slightly: 'How sure we need to be before we accept *an uncertain-risk course of action* [instead of 'a hypothesis'] will depend on how serious a mistake would be'.<sup>97</sup> This clearly means that the minimal probability of serious harm, however uncertain, should depend on the seriousness of a possible mistake when deciding in favour of a risk-avoiding versus a risk-taking action. To appreciate this, let us elaborate the example of a suspected suitcase left behind ('perhaps by a terrorist?') on a crowded Dutch passenger train, say, between Amsterdam and the Hague.<sup>98</sup> Table 6 shows fictitious utility values on a 0-100 ('worst-best') scale for the four possible consequences of the authorities deciding to temporarily stop or not to stop all rail transport on the Amsterdam-The Hague line, under the mutually exclusive hypotheses that the unguarded suitcase is either harmless ( $H_0$ ) or dangerous ( $H_1$ ).

Briefly, a utility scale covers personal or agency values assigned to possible decision consequences. These may be described initially in terms of 'objective' financial, material, and/or social benefits and/or costs. Utility may be directly judged on a one-dimensional interval scale with an arbitrary

<sup>96</sup> For example, the release of radioactive materials from a nuclear installation may be evaluated by an optimist as 'a serious but preventable accident', while a pessimist may characterise the same event as 'an alarming signal of potential catastrophe'.

<sup>97</sup> Rudner, above n. 84, at 2.

<sup>98</sup> Other examples from Table 1 could be analysed as well, but some cases would require a more complex decision model and extensive elaboration.

zero point and measurement unit (e.g. 0-10, 0-100, or from -10 to + 10). Alternatively, a multi-attribute utility model may be used, to determine for instance a weighted combination of utilities assessed on different independent attributes.<sup>99</sup>

The four cells in Table 6 actually indicate complex consequence-situations having both short- and long-term effects of various kinds. Thus their comprehensive utility assessment may require a separate exercise. Here, final-aggregate utility values are used that should reasonably well indicate the relative attractiveness/unattractiveness of the four consequence situations. Note that, given the utility values, none of the two options is dominating (i.e. always at least as good as) the other.

Table 6 Fictitious utility values ( $U_{..}$ ) on a 0-100 scale for possible consequences of a decision to to stop or not to stop all rail transport between Amsterdam and The Hague after the discovery of an unguarded suitcase on a train.

	<b>H<sub>0</sub>: suitcase is harmless</b>	<b>H<sub>1</sub>: suitcase is dangerous</b>
<b>Take Risk: let rail transport continue</b>	$U_{T0} = 100$ (TN)	$U_{T1} = 0$ (FN)
<b>Avoid Risk: stop all rail transport</b>	$U_{A0} = 60$ (FP)	$U_{A1} = 80$ (TP)

TN = true negative, FN = false negative; FP = false positive; TP = true positive.

Under a straightforward application of the maximin-utility rule (see above) the optimal choice here would be ‘Avoid Risk’, since its minimal utility value  $U_{A0} = 60$  is much higher than the minimal value  $U_{T1} = 0$  for ‘Take Risk’. Given that  $U_{T0} = 100$  and  $U_{T1} = 0$  are fixed as the measurement range and zero point of the interval utility scale, respectively, the mutual relations among the four utility values could only change via variations in  $U_{A0}$  en  $U_{A1}$ ; the relative focus of the evaluation thus lies in the possible consequences of ‘Avoid Risk’, whereby the problem-characteristic rank order  $U_{T0} > U_{A1} > U_{A0} > U_{T1}$  (see Table 6) should be preserved. Thus, should somebody come up and say: ‘Okay, but an actual bomb explosion after a Take-Risk decision would be really disastrous and should therefore be valued even more negatively’, this might be expressed through decreasing the differences among  $U_{T0}$ ,  $U_{A1}$  en  $U_{A0}$ . This could be done by setting  $U_{A0} =$

<sup>99</sup> H. Raiffa, *Decision analysis. Introductory lectures on choices under uncertainty* (Reading: Addison-Wesley 1968); K.P. Yoon and C.-L. Hwang, *Multiple attribute decision making. An Introduction*. Series: Quantitative Applications in the Social Sciences, no. 07-104 (Thousand Oaks: Sage Publications 1995).

90 and  $U_{A1} = 95$  (instead of 60 en 80).<sup>100</sup>

Now, given the utility values in Table 6, suppose that one would start from the prior probabilities  $p(H_0) = 0.80$  en  $p(H_1) = 0.20$ . Thus, the threat would be considerable, but the probability that the suitcase is harmless is four times larger. The ensuing expected utility (EU) values for the two choice alternatives would be:

$$\text{EU (Take Risk)} = 0.80 (100) + 0.20 (0) = 80 \text{ and}$$

$$\text{EU (Avoid Risk)} = 0.80 (60) + 0.20 (80) = 64.$$

By implication, 'Take Risk' appears more attractive than 'Avoid Risk', and rail transport between Amsterdam and The Hague may best be continued.

However, when the utility values of 'false-positive',  $U_{A0}$ , and 'true-positive',  $U_{A1}$ , come to lie much closer to the value of 'true-negative' ( $U_{T0} = 100$ ), with  $U_{A0} = 90$  en  $U_{A1} = 95$  as proposed above (and whereby the threat would be evaluated as much worse), we would obtain:

$$\text{EU (Take Risk)} = 0.80 (100) + 0.20 (0) = 80 \text{ and}$$

$$\text{EU (Avoid Risk)} = 0.80 (90) + 0.20 (95) = 91,$$

whereby 'Avoid Risk' would be more attractive than 'Take Risk'. More generally and formally, the expected utility of the two options can be represented as:

$$\text{EU(Take Risk)} = p(H_0) \cdot U_{T0} + p(H_1) \cdot U_{T1} \text{ and}$$

$$\text{EU(Avoid Risk)} = p(H_0) \cdot U_{A0} + p(H_1) \cdot U_{A1}.$$

How large should the danger probability  $p(H_1)$  minimally be in order to lead to a preference for 'Avoid Risk'? Consider that  $p(H_1) = 1 - p(H_0)$  and let  $p(H_1)$  be conveniently written simply as  $p$ . Thus,

$$\text{EU(Take Risk)} = (1-p) \cdot U_{T0} + p \cdot U_{T1} = U_{T0} + p \cdot (U_{T1} - U_{T0}) \text{ and}$$

$$\text{EU(Avoid Risk)} = (1-p) \cdot U_{A0} + p \cdot U_{A1} = U_{A0} + p \cdot (U_{A1} - U_{A0}).$$

<sup>100</sup> With this modified set of utility values, one pure-maximin condition would be even better fulfilled. J. Rawls, *A theory of justice* (Cambridge (Mass.): The Belknap Press of Harvard University Press 1971) (Revised ed. 1999: Cambridge (Mass.): Harvard University Press) at 152; see also Gardiner, above n. 58: the additional

The critical (as yet a priori) probability  $p_{AT}$ , whereby a preference for ‘Take Risk’ changes into ‘Avoid Risk’, can be inferred from the condition in which  $EU(TR) = EU(AR)$ , i.e. when

$$U_{T0} + p.(U_{T1} - U_{T0}) = U_{A0} + p.(U_{A1} - U_{A0}).$$

It follows that  $p_{AT} = (U_{T0} - U_{A0}) / \{(U_{T0} - U_{A0}) + (U_{A1} - U_{T1})\}$ , or the minimum p-value is:

$$p_{AT} = 1 / [1 + (U_{A1} - U_{T1}) / (U_{T0} - U_{A0})].$$

In other words, under an Avoid-Risk decision the critical probability of danger is a simple function of the expected ‘satisfaction’ about a true-positive consequence in comparison to the expected satisfaction about a true-negative consequence under a Take-Risk decision. Inversely expressed,  $p_{AT}$  is a function of the ‘regret’ (i.e. the inverse of satisfaction) one expects to experience from a false-positive consequence relative to the expected regret under a false-negative consequence.<sup>101</sup>

In conclusion, one’s preference for the precautionary option ‘Avoid Risk’, and more generally the preferred degree of precaution, is a function of the estimated probability of serious harm *and* the relative seriousness of a false-negative consequence compared to a false-positive consequence. Thus, PP proponents need not consider the initiator of an uncertain-risk activity as ‘guilty until proven innocent’ (fearing a false negative), nor should they consider him or her ‘innocent until proven guilty’ (fearing a false positive); see Van den Belt.<sup>102</sup> It is all a matter of weighing possible false positives versus false negatives, and this may have to be done differently for different domains such as, for instance, criminal justice, transport safety, and environmental protection. These conclusions and the above analysis are fully compatible with the signal detection-theoretic argument explained in Section 4.3.4.<sup>103</sup>

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benefits of what could be obtained above the maximin-utility value (now  $U_{A0} = 90$  instead of 60) are of limited significance only.

<sup>101</sup> For lack of space, enlightening decision models about the minimisation of anticipated regret (e.g. M. Braun and A. Muermann, ‘The impact of regret on the demand for insurance’ (2004) 71 *Journal of Risk and Insurance* 737) cannot be discussed here; see Vlek, above n. 94.

<sup>102</sup> H. Van den Belt, ‘Debating the precautionary principle: “guilty until proven innocent” or “innocent until proven guilty”?’ (2003) 132 *Plant Physiology* 1122.

<sup>103</sup> Inspired by M.L. DeKay and others, ‘Risk-based decision analysis in support of precautionary policies’ (2002) 5 *Journal of Risk Research* 391.

#### 4.4.4 Decision deferral and the value of new information

For an Avoid-Risk versus Take-Risk decision, the prior probability or plausibility,  $p(H_1)$ , of serious harm plays a crucial role.<sup>104</sup> However, prior beliefs may be a weak basis for justifiable decisions, except when already considerable, perhaps intuitive, statistical evidence is available. For example, one may hold a clear, low prior probability about the delayed arrival of a train, plane, or ferry boat. However, in fairly unique situations of uncertain risk the latter is rarely the case. There, often under time pressure and despite a lack of sufficient evidence, important choices may have to be made. Hence, what could or would a rational actor do to avoid simply taking chances?

If at all possible, the uncertain decision-maker would prefer to gather new information,  $t_x$ , which may lead him/her to revise the prior probability of harm,  $p(H_1)$ , into a posterior probability  $p(H_1 | t_x)$ , whereby  $t_x$  represents a particular test result  $x$ , e.g., 'positive' or 'negative'. The test may actually consist of systematic research, closer inspection and/or further observation of the situation.<sup>105</sup> Formally, such probability revision may follow Bayes' Theorem:<sup>106</sup>

$$p(H_1 | t_x) = \frac{p(H_1) \cdot p(t_x | H_1)}{p(t_x)} = \frac{p(H_1) \cdot p(t_x | H_1)}{p(H_0) \cdot p(t_x | H_0) + p(H_1) \cdot p(t_x | H_1)} .$$

Expressed in words, the posterior probability  $p(H_1 | t_x)$  of danger given the test result  $t_x$  equals the product of the prior probability  $p(H_1)$  and the likelihood of  $t_x$  under  $H_1$ , divided by the unconditional probability of  $t_x$  (across all available hypotheses). Thus, to revise the danger-probability  $p(H_1)$  into a more empirically supported  $p(H_1 | t_x)$ , it is important to know how likely a certain test result, say  $t_{\text{pos}}$ , is if  $H_1$  were actually true, but also how likely the same  $t_{\text{pos}}$  is when  $H_0$  is true ( $t_{\text{pos}}$  would be indicative of serious danger).

In a two-hypotheses situation, Bayes' Theorem can be written conveniently in terms of the odds of  $H_1$  relative to  $H_0$ :

<sup>104</sup> Decision-theoretically, a certain degree of plausibility is inevitably treated as an uncertain probability (having a certain confidence interval) about a particular event-outcome.

<sup>105</sup> Note that in Section 4.3.4 it is indicated that a diagnostic result  $t_x$  itself may depend on evidence strength *and* seriousness of possible mistakes.

<sup>106</sup> W. Edwards, H. Lindman and L.J. Savage, 'Bayesian statistical inference for psychological research' (1963) 70 *Psychological Review* 192; Lindley, above n. 87.

$$\frac{p(H_1 | t_x)}{p(H_0 | t_x)} = \frac{p(H_1)}{p(H_0)} \cdot \frac{p(t_x | H_1)}{p(t_x | H_0)}.$$

This formula shows that the *posterior odds* of  $H_1$  versus  $H_0$  equal the product of the *prior odds* and the *likelihood ratio* of the test result in light of  $H_1$  versus  $H_0$ . One implication of this is that when  $p(H_1)$  equals  $p(H_0)$ , which would reflect perfect uncertainty, the likelihood ratio would be decisive. Hereby, one may hope that the latter is appreciably different from 1, indicating that the test itself has a significant diagnostic value; an undiagnostic ('worthless') test result would be about equally likely under both hypotheses –  $p(t_x | H_1) \approx p(t_x | H_0)$  – and would not lead to an appreciable change in prior probability.

The above formula also demonstrates that the prior odds,  $p(H_1) / p(H_0)$ , always have a moderating (either strengthening or weakening) effect on the posterior odds  $p(H_1 | t_x) / p(H_0 | t_x)$ , apart from the test result  $t_x$  itself via the likelihood ratio. Thus 'evidence' may or may not go against prior beliefs, and when the evidence is weak prior probabilities may remain most important.

#### 4.4.5 Analysing the value of new information

In the example discussed above, the expected utility (EU) of the actual decision for the optimal course of action equals:

$$\begin{aligned} & \text{Max}\{\text{EU}(\text{Take Risk}), \text{EU}(\text{Avoid Risk})\}, \\ & \text{or: Max}\{p(H_0) \cdot U_{T0} + p(H_1) \cdot U_{T1}, p(H_0) \cdot U_{A0} + p(H_1) \cdot U_{A1}\}; \end{aligned}$$

see Section 4.4.3. After the acquiring of new information concerning  $H_1$  versus  $H_0$ , by way of a test possibly yielding result  $t_{\text{pos}}$  or  $t_{\text{neg}}$ , the prior probability  $p(H_1)$  can be revised into a posterior probability  $p(H_1 | t_x)$  carrying index  $x = \text{'pos'}$  or  $\text{'neg'}$  (for the test result cannot be known in advance).

The obvious question then is: In light of the newly obtained information, is the expected utility of the best option higher than the EU of the best option (possibly an other one) determined without that information? In other words, is it worth the inevitable costs and efforts to conduct the test and to obtain the new information? This question can be answered as follows.<sup>107</sup>

Taking into account the new information  $t_x$ , the expected utility of

<sup>107</sup> Lindley, above n. 87; Raiffa, above n. 100; see also Graham, above n. 35.

‘Take Risk’ and ‘Avoid Risk’ can be written formally as:

$$EU(\text{Take Risk} \mid t_x) = p(H_0 \mid t_x) \cdot (\dot{U}_{T0} - k_t) + p(H_1 \mid t_x) \cdot (\dot{U}_{T1} - k_t), \text{ and}$$

$$EU(\text{Avoid Risk} \mid t_x) = p(H_0 \mid t_x) \cdot (\dot{U}_{A0} - k_t) + p(H_1 \mid t_x) \cdot (\dot{U}_{A1} - k_t),$$

whereby  $t_x$  could be either  $t_{\text{pos}}$  or  $t_{\text{neg}}$ ,  $\dot{U}_{\dots}$  (instead of  $U_{\dots}$ ) represents the revised utility of the four original decision consequences (Table 6), and  $k_t$  indicates the costs (all-in) of conducting the test. The expected utility of the postponement option ‘get new information’ can be written as:

$$EU(\text{New Information}) = p(t_{\text{pos}}) \cdot \text{Max}\{EU(\text{Take Risk} \mid t_{\text{pos}}), EU(\text{Avoid Risk} \mid t_{\text{pos}})\} + p(t_{\text{neg}}) \cdot \text{Max}\{EU(\text{Take Risk} \mid t_{\text{neg}}), EU(\text{Avoid Risk} \mid t_{\text{neg}})\}.$$

If this ‘postpone and decide after test’ strategy appears to have a higher expected utility than the best option (Take Risk or Avoid Risk) without the test result, it is better to defer the original decision and to first collect new information.

Thus, the value of new information about an uncertain-risk situation depends on the revision of the prior probability of serious harm into a posterior probability, the unconditional probability  $p(t_x)$  of a particular test result, the all-in costs of acquiring the new information, and the possibly revised utilities:  $\dot{U}_{T0}$ ,  $\dot{U}_{T1}$ ,  $\dot{U}_{A0}$ ,  $\dot{U}_{A1}$ , of the four original consequences (Table 6). In other words, acquiring new or further information seems especially meaningful when:

- one is a priori uncertain about which hypothesis is correct;
- the test has a high diagnostic value (i.e. it may discriminate well between  $H_1$  and  $H_0$ );
- the test itself is not costly in terms of money, time, and effort; and/or
- the test may lead to a more valid evaluation of the relevant decision consequences.

#### 4.4.6 Risk-risk tradeoffs

Many authors have criticised the PP for being focused on the uncertain risks of particular, often controversial activities, such as using hazardous chemicals, GMOs, and nanotechnology.<sup>108</sup> In an early critique, Bodansky

<sup>108</sup> J. Adler. ‘More sorry than safe: assessing the precautionary principle and the proposed international Biosafety Protocol’ (2000) 35 *Texas International Law Journal* 173; G. Calzada, C. Philippe and X. Méra, *The precautionary principle: a high-risk principle - Institute of Economic Affairs: Economic Viewpoints* (Oxford: Blackwell Publishers 2005); H.T. Engelhardt and F. Jotterand, ‘The precautionary principle: a dialectical reconsideration’ (2004) 29 *Journal of Medicine and*

wrote: ‘The precautionary principle seems to suggest that the choice is between risk and caution, but often the choice is between one risk and another’.<sup>109</sup>

The gist of this persistent critique is well in line with the decision-theoretic treatment presented above, requiring a weighing of possible false-positive versus false-negative consequences. Basically, precaution – if called for – should result (and inevitably does result) from a decision between at least two alternatives: do/do not do, go/do not go, or permit/restrict. The fact that only one of these may involve a serious uncertain risk does not absolve the decision-maker from the task of weighing pros and cons, comparing risks, however difficult, and ordering his/her preferences about the available courses of action. Stern and Wiener conclude that: ‘Full portfolio-driven risk analysis can be a powerful counterweight to mission-driven agencies, passion for precaution, neglect of unintended consequences, and “groupthink”’.<sup>110</sup>

An illustration of the need to trade off one type of risk against another is the case of GMOs in food production. Here the proposed tradeoff is between genetic contamination of natural ecosystems (around GMO fields) and the occurrence of large-scale food shortages, especially in poorer countries, due to insufficient crop harvests.<sup>111</sup> Other examples are nuclear-powered versus fossil-fuelled electricity generation – in view of radioactive waste versus global warming, and of course the USA’s pre-emptive war in Iraq.<sup>112</sup>

#### 4.5 Precautionary safety actions

Immediate responses to uncertain-risk situations are meant to eliminate or reduce the threat, evade it, or effectively cope with its potential implications (e.g. a serious accident). Here, the search is for a type and degree of ‘uncertain safety’ (as WRR, 2008, has titled its report) that would

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*Philosophy* 301; Graham, above n. 35; IEM, above n. 24; Marchant, above n. 26; W.J. McKinney and H.H. Hill, ‘Of sustainability and precaution: the logical, epistemological, and moral problems of the precautionary principle and their implications for sustainable development’ (2000) 5 *Ethics and the Environment* 77; Weiss, above n. 20.

<sup>109</sup> Bodansky, above n. 2, at 43.

<sup>110</sup> Stern and Wiener, above n. 6, at 442.

<sup>111</sup> Adler, above n. 109; Engelhardt and Jotterand, above n. 109; R. Hill, S. Johnston and C. Sendashonga, ‘Risk assessment and precaution in the Biosafety Protocol’ (2004) 13 *Review of European Community and International Environmental Law* 263.

<sup>112</sup> Stern and Wiener, above n. 6.

compensate properly for the uncertain risk under consideration.<sup>113</sup> Separately, one may start further explorations aimed at reducing major uncertainties: for example, about choice alternatives, possible consequences, groups of people at risk, and optimal methods of eventual victim assistance. Through precautionary actions, the PP is applied as a *control principle* having the double character of both immediate protection and deeper investigation.

Meeting the challenges of an uncertain risk head-on generally means that, at least for the time being, one adopts a restrictive strategy of early prevention or reduction of the possibilities and conditions of serious harm or damage, while trying to get risks As Low As Reasonably Achievable.<sup>114</sup> Given the uncertainties involved, this may best be done such that the activity, system, or situation under consideration becomes – or remains – robust, resilient, and flexible.<sup>115</sup> Being practically precautionary may be aimed either at reducing the threat or at enhancing victim protection, accompanied by further research. Orthogonal to this, precautionary actions may be organisational, technical, or behavioural in nature. Combining these two dimensions of practical action, we obtain the set of nine categories of specific possibilities given in Table 7.

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<sup>113</sup> WRR, Wetenschappelijke Raad voor het Regeringsbeleid (Scientific Council for Government Policy), *‘Onzekere Veiligheid. Verantwoordelijkheden rond fysieke veiligheid’*, (2008) [Uncertain safety, responsibilities around physical safety.] (The Hague: WRR and Amsterdam: Amsterdam University Press).

<sup>114</sup> See for example ALARA; S. Lierman and L. Veuchelen, ‘The optimisation approach of ALARA in nuclear practice: An early application of the precautionary principle? Scientific uncertainty versus legal uncertainty and its role in tort law’ (2006) 15 *European Environmental Law Review* 98; O. Godard, ‘Justification, limitation, and ALARA as precursors of the precautionary principle’ in G. Eggermont and B. Feltz (eds.), *Ethics and Radiological Protection* (Louvain-la-Neuve: Bruylant-Academia s.a. 2008) at 133; M.D. Rogers, ‘Risk analysis under uncertainty, the precautionary principle, and the new EU chemicals strategy’ (2003) 37 *Regulatory Toxicology and Pharmacology* 370.

<sup>115</sup> L. Clarke, ‘Worst-case thinking. An idea whose time has come. Invited comment’ (2005) XXIX *Natural Hazards Observer* 1; Klinke and Renn, above n. 30; T. O’Riordan, J. Cameron and A. Jordan, ‘The evolution of the precautionary principle’ in T. O’Riordan, J. Cameron and A. Jordan (eds.), *Reinterpreting the Precautionary Principle* (London: Cameron & May 2001) at 9; Unesco-COMEST, above n. 41.

Table 7 Nine kinds of practical measures (illustrations) for realising precautionary safety

	<b>Reducing the threat</b>	<b>Enhancing victim protection</b>	<b>Further research: topics</b>
<b>Organisational</b>	Strengthening/enforcement of rules, standards, quota; introducing strict damage liability; changing, forgoing, prohibiting activity.	Organising emergency aid; evacuation, area closure; communicating on self-help; supplying immediate practicalities; regular feedback.	Supervisory management; revision of rules, standards, quota; effects and side-effects of precautions; public health screening.
<b>Technical</b>	Best available control technology (BACT); spatial and temporal restrictions; reducing size or volume; adopting safer alternatives.	Warning signs/labels, safety devices, survival packages, communication equipment, transport opportunities, evacuee accommodation.	Safer technical design; feasible alternatives; self-help products and facilities; technical/physical infrastructure for emergency.
<b>Behavioural</b>	Organising group action for safety; reducing individual contributions to collective risk; urging authorities; assisting other potential victims.	Avoiding risk exposure; shielding from immediate danger; assisting others and being prepared to offer medical first aid.	Immediate self-protection; motivation and capabilities of safety operators; risk/safety communication; social response to emergency.

The lower left quadrant of Table 7, reducing the threat via behavioural measures, gains a special meaning when the uncertain risk under consideration is the collective outcome of numerous individual behaviours

such as, for example, fish consumption, car driving, or household energy use. To resolve such commons dilemmas, well-coordinated large-scale changes in individual behaviours are required.<sup>116</sup> To promote social cooperation for the common good, one may not only wish to apply instrumental strategies for behaviour change (e.g. regulation, pricing and/or persuasion) but may also need to strengthen important effectiveness conditions, such as subjects' problem awareness, the availability of behaviour alternatives, and a future perspective on a safer living environment.

For all precautionary actions, careful monitoring and evaluation of their actual impact and effects is necessary for enhanced learning about the practical meaning and usefulness of precaution. As Borgers remarks, government protection of public safety against terrorist acts may well infringe ('false-positively') on democratic values and civil liberties.<sup>117</sup> This poses political choice dilemmas whereby it is vital to know how effective (and side-effective) precautionary measures actually are or could be. Proper monitoring and evaluation is also needed to decide at some point when, where, and for whom current measures could be mitigated, withdrawn, or otherwise changed because new risk information has become available and important uncertainties have been reduced.<sup>118</sup>

## 5 Largely procedural key issues of the PP

Compared to the substantive issues 1-5 in Table 3, issues 6-10 are of secondary importance. However, they cover vital elements of an orderly procedure to apply the PP as an assessment, decision, and control principle for uncertain-risk situations. Each of these remaining issues is discussed briefly below, following their numbering in Table 3.

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<sup>116</sup> G. Hardin, 'The tragedy of the commons' (1968) 162 *Science* 1243; E. Ostrom and others (eds.), *The drama of the commons* (Washington D.C.: National Academy Press 2002); Ch. Vlek and L. Steg, 'The commons dilemma as a practical model for research and policy making about environmental risks' in G. Bartels and W. Nelissen (eds.), *Marketing for sustainability. Towards transactional policy-making* (Amsterdam, Berlin, Oxford: IOS Press 2002) at 205.

<sup>117</sup> Borgers, above n. 7.

<sup>118</sup> C. Gollier and N. Treich, 'Decision-making under scientific uncertainty: the economics of the precautionary principle' (2003) 27 *The Journal of Risk and Uncertainty* 77; ILGRA, Interdepartmental Liaison Group on Risk Assessment, *The precautionary principle, policy and application* (London: UK Health and Safety Executive 2002) available at: <<http://www.hse.gov.uk/aboutus/meetings/ilgra/pppa.pdf>>; Kourilsky and Viney, above n. 29.

### 5.1 Issue 6: Optional versus obligatory precaution

The necessity and the strength of precaution cannot but depend on the seriousness of the threat, judged by its possible consequences and their probability or plausibility. ‘Wait!’, ‘Don’t!’, ‘Defer!’, or ‘Do something else!’ are natural responses to avoid taking chances in potential-catastrophe situations. Thus the difference between ‘optional’ and ‘obligatory’ precaution can only be relative. Obligation, of course, also depends on the distribution of responsibilities, and power, among relevant authorities, entrepreneurs, and other expert safety managers.

### 5.2 Issue 7: Who carries the burden of proof of risk or safety?

Clearly, while safety cannot be proven, risk can.<sup>119</sup> However, if the proponent of an uncertain-risk activity does not already believe him-/herself that precautions are needed and further safety research is required, the other parties involved may demand that the initiator of the activity demonstrate the likelihood of safety. Again, this shifting of the burden of proof should depend on the seriousness of the threat and, of course, on the ease with which the proponent of the activity might obtain and/or deliver the relevant data. Strong precaution, if called for, implies a stronger shift in the burden of proof than does weak precaution. Gollier and Treich, however, warn that producers in a competitive market may feel pressed to market new and uncertain-risk products before convincing safety research has been conducted.<sup>120</sup> In such situations, precautionary government policies may be at variance with venturesome free-market conditions.

### 5.3 Issue 8: Further research and policy development

This topic has already been formally discussed under the headings of Bayesian probability revision and value-of-information analysis; see Section 4.4.4. The conclusions there should speak for themselves. However, uncertainties may spoil the direction and progress of an optimal information-processing and policy-development strategy. Admittedly, safety tests may be costly and time-consuming, and opponents’ enduring concerns may be pressing proponents into ‘paralysis by analysis’.<sup>121</sup> Nevertheless, a systematic consideration of the uncertain-risk problem at hand may

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<sup>119</sup> A thousand black crows do not prove that all crows are black; one white crow proves that a crow can be white.

<sup>120</sup> Gollier and Treich, above n. 119.

<sup>121</sup> Presidential-Congressional Commission on Risk Assessment and Risk Management, *Risk Assessment and Risk Management in Regulatory Decision-Making* (1997) Final Report, available at <[www.riskworld.com](http://www.riskworld.com)> at 29.

significantly facilitate a quick search for the most relevant data, possibly safer alternatives, and/or a revision of the original problem definition.<sup>122</sup>

#### 5.4 Issue 9: Multiparty communication and deliberation

A comprehensive precautionary approach could well comprise elements that may be appreciated differently by different stakeholder groups. A natural strategy in such situations is to organise stakeholder meetings where diverse participants can exchange information, deliberate options, and try to formulate common preferences.

However, as already mentioned in Section 4.4.1, the rationality of multiparty judgment and decision-making is limited. First, participant views should be ‘informed’ and well considered so that they can be taken seriously, particularly vis-à-vis expert scientific opinions.<sup>123</sup> Second, conditions should enable participants to express common interests instead of strictly personal values. Even so, inconsistent social preferences may occur because of the impossibility of designing a practical method that simultaneously meets the three fundamental principles of collective-choice theory: rationality, equal participation, and decisiveness.<sup>124</sup>

Since public-interest decisions must be made frequently anyway, there exist various pragmatic ways to resolve interindividual preference aggregation problems. Majority voting on at most two alternatives (‘yes/no’), consensus seeking through orderly deliberation, and some kind of benevolent leadership (formally ‘dictatorship’) are obvious solutions, each having its own strengths and weaknesses. However, theoretically as well as methodologically there is no guarantee that participative procedures lead to convergent results that might impress responsible authorities. Bekkers, Dijkstra, and others document the ‘democratic deficit’ of various new ways to compensate for the shortcomings of representative democracy.<sup>125</sup> About ‘environmental democracy’, Edwards concludes that pluralistic participation may enrich representative government, whereby elected officials may well function as process managers.<sup>126</sup>

<sup>122</sup> Hansen, Carlsen, and Tickner, above n. 15; Martuzzi, above n. 17; Unesco-COMEST, above n. 41.

<sup>123</sup> See Scott and Vos’ 2002, thoughtful conclusions on this point; Scott and Vos, above n. 35.

<sup>124</sup> Blair and Pollak, Bezembinder, above n. 88.

<sup>125</sup> V. Bekkers and others (eds.), *Governance and the Democratic Deficit. Assessing the Democratic Legitimacy of Governance Practices* (Aldershot: Ashgate 2007).

<sup>126</sup> A. Edwards, ‘Embedding deliberative democracy: local environmental forums in The Netherlands and the United States’ in V. Bekkers and others (eds.), above n. 126, at 165.

### 5.5 Issue 10: Distribution of responsibilities

Determining the need for, the nature of, and the proper execution of a precautionary strategy is a labour-intensive and time-consuming process. Key issues 1-5 in Table 3 specify the substantive focus of such a process, while issues 6-10 indicate procedural essentials. An obvious question here is: Who may best do what, and when? An organised answer follows the three phases of precautionary assessment, decision-making, and risk control, followed by coordination.

*Assessment* comprises an initial problem definition, signalling the preliminary need for precaution, and estimating the probability or plausibility as well as the seriousness of possible harm. In addition, feasible choice alternatives with their likely benefits, costs, and risks may be identified. Through further investigation and deliberation, the problem definition may be revised such that hitherto unrecognised options and/or consequences are also incorporated. Assessment tasks are diverse enough to involve experts of various kinds, proponents and opponents of an activity, and responsible policy-makers. Available opinions and data may be collected and evaluated from different viewpoints, and different results may be aggregated and jointly discussed. Expert committees, proponent-opponent debates, and discussions about preliminary policy conclusions are feasible ways to achieve reasonable clarity and consensus about an overall assessment.

*Decision-making* involves an evaluation and rank-ordering of some reasonably well-defined action versus inaction and perhaps further alternatives, such as more or less stringent packages of safety measures. One may also, quite rationally, postpone the decision proper and first obtain new information, especially about the nature and the likelihood of possible serious harm (see Section 4.4.4). Decision tasks are sensitive to participants' goals and values and to their prior positions *vis-à-vis* the uncertain-risk problem. Some kind of systematic decision analysis may reveal specific uncertainties and/or differences in valuation, which might be resolved by further investigation, debate, and/or aggregation of judgments. Inevitably, any remaining controversy about the decision(s) to be made should be resolved by the competent authority.

*Control* amounts to the careful execution of the chosen course of action under pre-specified safety conditions. Here, a general tendency of precaution following the ALARA principle would be obvious. Precautionary action may be organisational, technical, and/or behavioural in nature and it should be aimed at reducing the threat and/or enhancing victim protection. To improve future risk control, various further research and observation may also be undertaken (see Section 4.5). Control of uncertain risks could best be divided among the parties most responsible for particular risk factors (cf. Table 7). Depending on the nature of the uncertain risk and the location, the

sectors, and the persons potentially affected, relevant parties may each be assigned a significant role in reducing the threat and/or enhancing victim protection.

*Coordination* properly carried out is necessary in the entire process of uncertain-risk assessment, decision, and control. Should this be somehow institutionalised? Should a formal protocol be developed and distributed among various relevant parties? Or should the competent authorities nominate an independent project group or steering committee? These questions need further consideration and experimentation in the field.

## 6 Concluding questions and answers

To clarify focal points for a precautionary-principled approach towards uncertain risk, this paper so far has emphasised the substantive meaning of the PP as an assessment, decision, and control principle. Let us put the paper's conclusion in terms of several Questions and Answers.

*Q1. Are there not often so many uncertainties that your only recourse is to a careful procedure?*

A1. No. Procedure can never make up for lack of substance, if only because participants in any procedure must know *what* to assess, decide about, and control, and *how* this could be usefully done. Good decision-making always depends on structure, content, and process regarding the problem at hand. Thus, a substantive-analytical framework for precautionary risk management seems indispensable for the careful management of uncertainties and a proper weighing of false positives versus false negatives.<sup>127</sup>

*Q2. Is a decision-theoretic perspective not too limited for handling uncertain-risk problems: for example, in consideration of the more extensive and long-term risk categories in Table 1?*

A2. Of course, but this goes for just about every theory or model of a complex phenomenon. However, decision theory – thoroughly and broadly developed since the 1950s – is a rich framework for systematising one's thoughts, data, and judgments about more or less uncertain decision problems. In the quest for 'rational' applications of the PP, decision-theoretic thinking may offer useful support, although it will never be sufficient.<sup>128</sup> For more-encompassing and far-reaching uncertain-risk

<sup>127</sup> Cf. Gardiner, above n. 58; Graham, above n. 35; M. Feintuck, 'Precautionary maybe, but what's the principle? The precautionary principle, the regulation of risk and the public domain' (2005) 32 *Journal of Law and Society* 371.

<sup>128</sup> Cf. R.L. Keeney and D. Von Winterfeldt, 'Appraising the precautionary principle – a decision analysis perspective' (2001) 4 *Journal of Risk Research* 191; Resnik, above n. 50; E. Soule, 'The precautionary principle and the regulation of U.S. food and drug safety' (2004) 29 *Journal of Medicine and Philosophy* 333.

problems (as in Table 1), decision-theoretic discipline – including issues of spatial-temporal discounting – may enhance the quality of procedures while reducing the risk of participants losing the forest among the trees.

*Q3. Should the PP be considered a normative principle?*

A3. No, at least not distinctly. Precautionary behaviour and the preceding decision(s) may be rational survival strategies based on human goals and values. Ideological disputes about the PP are often rooted in differing views about the long-term sustainability of particular technologies and/or behaviour patterns. Understandably, serious uncertain-risk situations may appeal to more fundamental ('ethical') values than do more familiar risk problems.

*Q4. Could the PP not be formulated as a rule of law, clearly identifying the conditions, actors, and obligations involved?<sup>129</sup>*

A4. No. As a general principle the PP reflects the wisdom of prudence in risk assessment, decision-making, and risk control. Its very generality allows for, and invites, well-tuned elaboration for various domains. Decision-theoretic instrumentation may serve to clarify the judgments, choices, and actions required.

*Q5. Why should we apply the PP if we have such sophisticated approaches towards risk assessment and management?*

A5. The sophistication of safety can be significantly enhanced by conceiving 'risk' as a multistage process, accounting for plural roles and responsibilities, and incorporating precaution as a logical response to increasing uncertainty. As indicated in Section 2, modern 'risk governance' and precautionary safety management seem to be gradually converging. From a decision-theoretic perspective this is inevitable if one accepts that uncertainty about risk is a continuous, not a dichotomous variable.<sup>130</sup>

*Q6. What are vital research questions about the practical meaning and application of the PP?*

A6. First, what are different people's (or groups' and organisations') gut responses to uncertain-risk situations that are systematically varied in benefits-at-stake, worst-case consequence, uncertainty of 'disaster', and immediacy versus delay of possible disaster?

Second, what would people deliberately expect, and what would they favour, by way of common-authoritative measures to assess, decide about, and control collective uncertain risks?

Third, which policy domains are most burdened with uncertain risks, which safety measures (if any) are in place, and how effective are or were these? Which domains and types of uncertain risk elicit most public concern,

<sup>129</sup> See J. Ellis, 'Overexploitation of a valuable resource? New literature on the precautionary principle' (2006) 17 *The European Journal of International Law* 445; Lierman and Veuchelen, above n. 115; and Trouwborst, above n. 38.

<sup>130</sup> Cf. Majone, above n. 25.

and why?

Fourth, what are the merits and drawbacks – in different domains – of various specific precautionary strategies (cf. Table 7) such as technical facilities, behavioural education, lawful regulation, and financial incentives?

*Q7. Should the PP not be rejected for its basic ‘pessimism’ whereby innovation may be stifled and society might become largely scrupulous and conservative?*

A7. No. Being precautionary is a time-honoured social and behavioural strategy vis-à-vis serious threats. The pressures from uncertain risk should lead to preventive anticipation, deeper reflection, better-balanced decisions, and stronger, more flexible control. Pessimism, like optimism, can very well be a rational strategy, depending on what is at stake. But, agreed, ‘fear is a bad counsellor’, and optimism is often necessary to maintain or restore self-confidence.<sup>131</sup> Would hope be a better counsellor?

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<sup>131</sup> R. Pieterman, *De voorzorgscultuur. Streven naar Veiligheid in een Wereld vol Risico en Onzekerheid* [The Precautionary Culture. Striving for Safety in a World full of Risks and Uncertainty] (The Hague: Boom Juridische Uitgevers 2008) at 200.

