INTERDEPARTMENTAL LIAISON GROUP ON RISK ASSESSMENT

THE PRECAUTIONARY PRINCIPLE: POLICY AND APPLICATION

The purpose of ILGRA is to help secure coherence and consistency within and between policy and practice in risk assessment as undertaken by Government, and help disseminate and advance good practice. ILGRA reports to Ministers.

Ministers have agreed that this paper should be published on the ILGRA website.

ILGRA welcomes comments on this paper - please send your comments to the ILGRA Secretariat, robert.wellens@hse.gsi.gov.uk by 30 September 2002.

Summary

This paper outlines policy guidelines on the precautionary principle agreed by the Interdepartmental Liaison Group on Risk Assessment (ILGRA). The key points are:

- The purpose of the precautionary principle is to create an impetus to take a decision notwithstanding scientific uncertainty about the nature and extent of the risk.
- Although there is no universally accepted definition, the Government is committed to using the precautionary principle, which is included in the 1992 Rio Declaration on Environment and Development.
- The precautionary principle should be invoked when:
  - there is good reason to believe that harmful effects may occur to human, animal or plant health or to the environment; and
  - the level of scientific uncertainty about the consequences or likelihood of the risk is such that the best available scientific advice cannot assess the risk with sufficient confidence to inform decision-making.
- The precautionary principle should be distinguished from other drivers that require caution such as society's view on the extent of protection afforded to children or others considered to be vulnerable, or the wish to ensure that conventional risk assessment techniques deliberately over rather than under-estimate risk.
- Action in response to the precautionary principle should accord with the principles of good regulation, i.e. be proportionate, consistent, targeted, transparent and accountable.
- Applying the precautionary principle is essentially a matter of making assumptions about consequences and likelihoods to establish credible scenarios, and then using standard procedures of risk assessment and management to inform decisions on how to address the hazard or threat.
- Decision-making should bring together all relevant social, political, economic, and ethical factors in selecting an appropriate risk management option.
- Invoking the precautionary principle shifts the burden of proof in demonstrating presence of risk or degree of safety towards the hazard creator. The presumption should be that the hazard creator should provide, as a minimum, the information needed for decision-making.
- Decisions reached by invoking and applying the precautionary principle should be actively reviewed, and revisited when further information that reduces uncertainty becomes available.

Contents

Introduction – need for a consistent approach

1. Intuitively, precaution should be easy – the proverbial 'better safe than sorry'. However, for regulators precaution is often controversial, with no simple answers.

2. Precaution is controversial because the 'why', 'when' and 'how' of precautionary intervention goes to the heart of the regulation of hazardous activities and their place in society. For example, a view that risks should be managed and hazardous activities banned only as a last resort would not be shared by those who favour risk avoidance and so would prefer to remove the hazard altogether.

3. Annex 1 develops this into a spectrum of contrasting views on the precautionary principle, ranging from 'weak' to 'strong' precaution. In practice the position adopted should reflect the commitment to sustainable development that gives full weight to economic, social and environmental factors. The precautionary principle should not, therefore, be an obstacle to innovation. Properly applied it is a positive, proportionate policy tool to encourage technological innovation and sustainable development by helping to engender stakeholder confidence that appropriate risk control measures are in place.

4. Although it is widely accepted that the precautionary principle should be invoked in deciding how hazardous activities should be addressed, there is considerable debate about what the principle means, and about how it should be applied in practice. There is an obvious need for consistency between Departments. Ministers endorsed ILGRA's second report (December 1998) [1], which included a remit to "develop a consistent policy on a precautionary approach". This initiative was picked up in the commitment in the Sustainable Development White Paper [2] (May 1999) "to develop a more consistent approach to the principle across Government" and to "report on this work in forthcoming reports on this Strategy". ILGRA's work on the precautionary principle is also noted in the Government's response to the Phillips Inquiry on BSE [3].

5. The policy proposed in the following paragraphs seeks to clarify and develop existing understanding, and should underpin domestic application of the precautionary principle by Departments. The policy is broadly consistent with, but elaborates on, the European Commission's Communication [4] on the precautionary principle, which was broadly endorsed by EU Heads of Government in a European Council Resolution at Nice in December 2000 [5]. The main elements of the Resolution are summarised in Annex 2. As with any policy, however, its application is subject to constraints such as the requirements of

existing international treaties or agreements. Nevertheless, the policy is intended to be forward-looking and should inform the UK line in negotiating these treaties and agreements as they evolve.

Definition of the precautionary principle

6. There is no universally accepted definition of the precautionary principle. The Sustainable Development White Paper, set out the Government's commitment to use the precautionary principle by reference to the 1992 Rio Declaration on Environment and Development [6]:

'Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation.'

Since 'Rio', however, the UK has signed a number of international agreements which include different formulations of the precautionary principle, reflecting the context and negotiating circumstances.

7. Although the precautionary principle was originally framed in the context of preventing environmental harm, it is now widely accepted as applying broadly where there is threat of harm to human, animal or plant health, as well as in situations where there is a threat of environmental damage.

8. However, the definition is only a starting point. Policy guidelines are needed to indicate when, for example, the precautionary principle should be invoked, how a risk-based approach can continue to be followed when the scientific uncertainty is such that conventional risk assessment cannot in itself determine the level of risk, and how decisions should be made on appropriate precautionary measures.

Purpose of the precautionary principle

9. The definition makes clear that where there is scientific uncertainty the precautionary principle establishes an impetus to make a decision that seeks to avoid serious damage if things go wrong.

Key Point

The purpose of the Precautionary Principle is to create an impetus to take a decision notwithstanding scientific uncertainty about the nature and extent of the risk, i.e. to avoid 'paralysis by analysis' by removing excuses for inaction on the grounds of scientific uncertainty.

Invoking the precautionary principle

10. The precautionary principle should be applied when, on the basis of the best scientific advice available in the the time-frame for decision-making:

- there is good reason to believe that harmful effects may occur to human, animal or plant health, or to the environment; and
- the level of scientific uncertainty about the consequences or likelihoods is such that risk cannot be assessed with sufficient confidence to inform decision-making.

11. Such criteria are inevitably judgmental. Nevertheless:

– 'good reason' to believe that harmful effects may occur could be demonstrated by empirical evidence; by analogy with another activity, product or situation which has been shown to carry a substantial adverse risk; or by showing that there is a sound theoretical explanation (tested as necessary by peer review) as to how harm might be caused; and

– 'harmful effects' could be gauged by reference to factors such as severity, irreversibility, uniqueness, numbers affected, temporal and spatial extent, and knock-on effects [7].

Key point

The precautionary principle should be invoked when:

i. there is good reason, based on empirical evidence or plausible causal hypothesis, to believe that harmful effects might occur, even if the likelihood of harm is remote; and

ii. a scientific evaluation of the consequences and likelihoods reveals such uncertainty that it is impossible to assess the risk with sufficient confidence to inform decision-making.

12. Clearly care is needed in making judgements on whether there is good reason to believe that harmful effects might occur, and on the extent of scientific uncertainty. 'Absence of evidence of risk' should never be confused with, or taken as, 'evidence of absence of risk'. An immediate and likely consequence of invoking the precautionary principle is research that seeks to reduce uncertainty. However, where appropriate and thorough research still finds no evidence of risk, this should be taken into account in the judgements made.

The precautionary principle and other cautionary policies

13. The focus on scientific uncertainty brings out an important distinction between:

- the precationary principle; and
- other drivers for caution.

14. For example, even where there is little scientific uncertainty, Government Departments may be cautionary in situations where:

a) the nature of a hazard, or those exposed to a hazard, reduce the extent of society's toleration of risk, e.g. where
   - the consequences of a hazard are known to be serious or catastrophic, or are associated with high levels of dread/aversion (e.g. failure of containment in a nuclear power station, or exposure to products known to be carcinogenic or highly toxic);
   - the hazard is novel;
   - those exposed to a hazard are considered to be vulnerable or disadvantaged (e.g. children);
   - reliance on individual choice on the basis of information provided (e.g. via warnings or labels) is impossible or unreasonable (e.g. air pollution);
   - the benefits from tolerating a hazard are not considered to be justified. This could arise because society considers that the benefits can be forgone, or because there are acceptable alternatives with lower risk (e.g. the ban, with very limited exceptions, on the supply and use of asbestos);

b) there is a wish to ensure that conventional risk assessment techniques do not knowingly underestimate risk. Examples of cautionary conventions in risk assessment include:
   - the use of uncertainty factors in the assessment of the health risks from chemicals;

– ‘over-engineering’ of bridges and other major structures.

15. The precautionary principle, therefore, will not be relevant when acting to address, for example, hazards from a major chemical plant handling well-known flammable or toxic products. The regulatory approach to such a plant, however, is cautionary because: risk is imposed on the general public living around the plant; the consequences, if the hazard were to be realised, are potentially serious; such plants are known to produce relatively high levels of dread/aversion; and the conventional techniques to estimate risk contours around the plant tend to overestimate rather than underestimate risk. On the other hand, issues such as BSE and genetic modification are examples of hazards where scientific knowledge, even when pushed to the limit, cannot presently provide conclusive answers about the nature and extent of the risks.

16. In short, the precautionary principle is narrower than ‘being cautionary’. At first sight this is counterintuitive because ‘principle’ implies universality.

Key point

The Precautionary Principle:

- is narrower than ‘being cautionary’; and
- is <u>not</u> relevant unless scientific uncertainty is a significant factor and there is good reason to expect harmful effects.

Extent of precaution – good regulation

17. The ‘Rio’ definition of the precautionary principle (paragraph 6) is silent on the extent of precaution required, other than noting that measures should be cost effective. However, the extent to which the principle requires action erring on the side of caution is not unlimited - precaution has to be balanced against other principles that shape the response to risk. In practice precaution is bounded by application of the principles of good regulation [8]. In addition, invocation of the precautionary principle should be non-discriminatory [9].

Key point

Action in response to the precautionary principle should accord with the principles of good regulation, i.e. invocation of the precautionary principle should:

a) lead to action that is
   - proportionate to the required level of protection;
   - consistent with other forms of action;
   - targeted to the risk; and

b) be invoked in a process that is:
   - transparent; and
   - accountable to stakeholders and ultimately to the political process.

Applying the precautionary principle

18. Although invoking the precautionary principle means taking action when scientific uncertainty rules out sufficient information for risk assessment, it doesn't mean that a risk-based approach is abandoned – decisions continue to be informed by the best available scientific advice, taking into account the uncertainties. A risk-based approach is preserved by establishing credible scenarios.

Credible scenarios

19. The precautionary principle is applied in practice by making assumptions about consequences and likelihoods to establish credible scenarios. Risk assessment and management can then proceed on the basis of the assumptions made. In practice a range of alternative scenarios is usually established. Where possible, the range should include the most likely and worst case scenarios. Annex 3 describes the approach in more detail.

20. Application of the precautionary principle requires considered judgement in selecting the appropriate scenarios on which to base risk management decisions. In particular:

- the assumptions made about consequences and likelihoods should err on the side of caution and so seek to avoid harmful effects if things go wrong; but
- the bias towards caution should be tempered by application of the principles of good regulation, particularly proportionality and consistency in the assumptions made and the risk management measures selected.

21. In practice erring on the side of caution usually means giving more weight to the consequences of the risk than to the likelihood, especially when the consequences are irreversible.

Key point

Applying the Precautionary Principle is essentially a matter of making assumptions to establish credible scenarios, and then using standard procedures of risk assessment and management to inform decisions on how to address the hazard.

Decision-making

22. Decision-making requires all relevant factors to be brought together in selecting the appropriate risk management option – in the words of the Nice European Council Resolution (reference 5) "risk management measures must be taken by the public authorities responsible on the basis of a political appraisal of the desired level of protection". This presupposes examination of the benefits and costs of action and inaction, and that "the examination must take account of social and environmental costs and of the public acceptability of the different options possible".

Openness and transparency

23. Transparency, openness and engagement of stakeholders are essential in any process of risk assessment and management. Key aspects of the process include sensitivity to stakeholder views in framing the risk issue, and stakeholder input in clarifying uncertainties and contributing to risk management options. However, where the precautionary principle is invoked and applied, openness becomes critically important in achieving an outcome that stakeholders regard as valid. Openness demands candour in exposing, for example:

- the information on which risk assessment was undertaken;
- the scientific uncertainties and reasoning for invoking the precautionary principle, and any uncertainty factors already built into the risk assessment;
- the assumptions made in establishing credible scenarios;
- the many factors that influence the choice of risk management measures.

24. Transparency and openness also help to ensure proportionate outcomes by exposing where judgements have been made at each stage of the decision-making process.

Burden of proof

25. The general presumption in western societies is that the regulator has to demonstrate reasonable grounds to intervene (Annex 1). However, invocation and application of the precautionary principle carries a general presumption that the burden of proof shifts away from the regulator [10] having to demonstrate potential for harm towards the hazard creator having to demonstrate an acceptable level of safety.

26. One consequence is that invoking the precautionary principle shifts the onus to provide the scientific evidence for risk assessment from the regulator to the hazard creator. This is exemplified in licensing or approval regimes imposed to address more serious hazards considered to merit a strongly precautionary approach, such as nuclear power generation and pesticides. In such permissioning regimes the requirements on applicants or holders of licences or approvals to provide scientific evidence can be onerous, and can include action to reduce scientific uncertainty.

27. However, in practice the extent to which a permissioning regime shifts the burden of proof away from the regulator is variable, reflecting a mixture of policy and scientific factors. For example, the UK regimes for licensing nuclear power stations and approving pesticides both require applicants to provide the scientific evidence needed to assess risk. However, in the nuclear regime the applicant does a risk assessment and the regulator challenges why risks cannot be reduced further [11]. In contrast, in the pesticide regime the regulator undertakes the risk assessment and demonstrates an acceptable level of safety [12]. In short, flexibility is needed and the extent to which the burden of proof shifts towards the hazard creator is determined case-by-case.

28. There are, however, exceptions to the general rule that invoking the precautionary principle puts the onus on the hazard creator to provide the scientific information needed for risk assessment (paragraph 26 above). Where there is significant value for society in reducing uncertainty, yet there is little or no prospect of the work being done by the private sector, it may be appropriate for Departments to act in the public interest by, for example, undertaking research to plug information gaps. Examples of such situations include research to establish the nature and extent of any adverse effects resulting from climate change, or to investigate a generic range of pharmaceuticals that has the potential to address a prominent disease or condition.

Key point

Unless there are constraints, the presumption should be that:

- as a general rule, the hazard creator should provide, as a minimum, the information needed for decision-making; but
- Departments should retain flexibility to determine 'regime-by-regime' the extent to which the burden of proof should shift towards the hazard creator in demonstrating presence of risk or degree of safety.

Hierarchy of control measures

29. Invocation of the precautionary principle should trigger consideration of the whole range of risk management options, which could include, for example, information and guidance, publicity campaigns, stronger enforcement and/or larger penalties, and of course, research to reduce uncertainty. An outright ban on an activity or product should be a last resort.

30. Nevertheless, within this position regulators should be able to impose on hazard creators a preferred hierarchy of controls that follows established good practice in risk reduction. For example, good risk management practice in health, safety and environmental protection starts from the position that, wherever practicable, it is better to avoid hazards by substitution or careful process/equipment design than to 'bolt-on' measures to reduce the risks. This would be particularly true for hazards where there are considerable uncertainties in the estimates of the risks attached to them.

Review

31. Decisions reached by invoking and applying the precautionary principle should be:

- kept under active review;
- revisited when further information that reduces uncertainties becomes available, and modified as appropriate [13].

Key point

Decisions reached by invoking and applying the precautionary principle should be actively reviewed to:

- ensure that the action taken resulted in what was intended; and
- check whether decisions previously reached need to be modified to take account of, for example, advances in technology, new knowledge about the risks from research, or any other information which may reduce uncertainty in the nature and likelihoods of potential consequences.

Annex 1

Contrasting views of precaution (paragraph 3)

'Weak' precaution	**'Moderate' precaution**	**'Strong' precaution**
Presumption of unfettered market-led development and technological innovation	Underlying presumption of unfettered market-led development and technological innovation but recognition that this can sometimes be overthrown where there are high levels of societal concern	No presumption of either market led or technologically driven development
Regulators intervene only where there is positive scientific evidence of risk and intervention demonstrably cost-effective	Presumption of intervention as under 'weak', but case by case flexibility to shift the onus of proof towards the risk creator	Risk creator demonstrates safety of activity. Little credence in cost effectiveness
Presumption of risk management Banning very rare	Underlying presumption of risk management Banning possible, but a last resort	Presumption of risk avoidance Banning likely
Presumption of free trade on the basis of objective scientific criteria. Individual preferences and societal concerns given no weight	Underlying presumption of free trade on the basis of scientific criteria. Recognition that individual preferences and societal concerns matter	No automatic presumption of free trade Individual preferences and societal concerns dominant

Annex 2

European Resolution on the precuationary principle (paragraph 5)

In summary, the Resolution on the precautionary principle, which was endorsed by Heads of Government at a General Affairs Council at Nice in December 2000, provides that:

- use should be made of the precautionary principle where the possibility of harmful effects on health or the environment has been identified and preliminary scientific evaluation proves inconclusive for assessing the level of risk
- the scientific assessment of the risk must proceed logically in an effort to achieve hazard identification, hazard characterisation, appraisal of exposure and risk characterisation
- risk management measures must be taken by the public authorities responsible on the basis of a political appraisal of the desired level of protection
- all stages must be conducted in a transparent manner, civil society must be involved and special attention must be paid to consulting all interested parties as early as possible
- measures must observe the principle of proportionality, taking account of short-term and long-term risks; must not be applied in a way resulting in arbitrary or unwarranted discrimination; and should be consistent with measures already adopted in similar circumstances or following similar approaches
- measures adopted presuppose examination of the benefits and costs of action and inaction, and the examination must take account of social and environmental costs and of the public acceptability of the different options possible
- decisions taken in accordance with the precautionary principle should be reviewed in the light of developments in scientific knowledge.

Annex 3

Credible scenarios (paragraph 19)

1. The essence of the approach is shown in Figure 1. The horizontal axis represents increasing uncertainty in the consequences of a hazard; the vertical axis represents increasing uncertainty in the likelihood that the hazard will be realised (including uncertainty as to impacts over time, e.g. climate change).

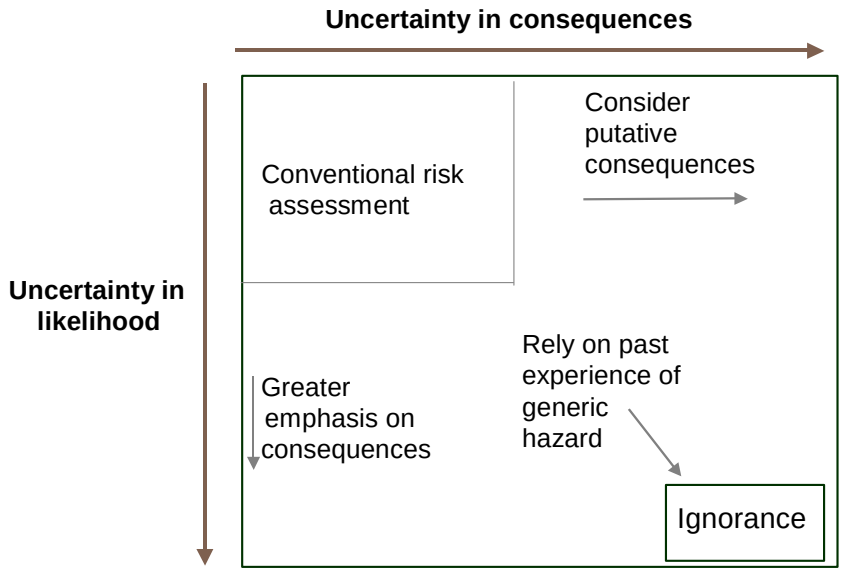

Figure 1

2. In the upper left-hand corner of Figure 1 - in the box labelled conventional risk assessment - consequences and likelihoods can be established and their robustness checked. Here conventional risk assessment gives an estimate of the risk generally accepted as valid by the stakeholders – the precautionary principle is not relevant. However, moving along the axes in Figure 1 the uncertainties increase, and the precautionary principle has to be invoked and applied to move to a decision. In these circumstances, reasonable assumptions have to be made about consequences and likelihoods. Moving towards the far right of the horizontal axis, for example, credible consequences are assigned, and moving towards the bottom of the vertical axis the assumption is made that the assumed consequences will occur (i.e. the risk will be realised). Each set of assumptions establishes a credible scenario.

3. The risk assessment undertaken in this way will obviously not be as full as that resulting from conventional risk assessment but, with good judgement applied case-by-case in establishing the scenarios, this will not be a serious disadvantage. Once the scenarios have been established, conventional means can be used to identify and evaluate, so far as possible, the benefits and costs (advantages and disadvantages) of risk management actions to inform, but not determine, decision-making. Where elements are difficult or impossible to express in monetary terms, they should be carried forward qualitatively in decision-making.

References

1 *Risk assessment and risk management: improving policy and practice within government departments*, second ILGRA report to Ministers (December 1998), http://www.hse.gov.uk/dst/ilgra/minrpt2.htm

2 *A better quality of life: a strategy for sustainable development for the UK*, White Paper (May 1999), http://www.sustainable-development.gov.uk/uk_strategy/

3 *Response to the report on the BSE inquiry*, Cm 5263 (2001), http://www.defra.gov.uk/animalh/bse/general/response.pdf

4 The Communication can be found at http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf

5 Presidency Conclusions, Nice European Council Meeting 7, 8 and 9 December 2000, http://europa.eu.int/council/off/conclu/dec2000/dec2000_en.htm

6 *Rio declaration on environment and development*, made at UNCED 1992, ISBN 9 21 100509 4, http://www.unep.org/Documents/Default.asp?DocumentID=78&ArticleID=1163

7 These criteria have been developed by the Environment Agency.

8 *Principles of good regulation*, Better Regulation Task Force (October 2000), http://www.cabinet-office.gov.uk/regulation/taskforce/2000/PrinciplesLeaflet.pdf

9 The European Commission's Communication on the precautionary principle (reference 4 above) explains non-discrimination as meaning that "comparable situations should not be treated differently and that different situations should not be treated in the same way, unless there are objective grounds for doing so."

10 Or whoever is entitled to challenge the hazardous activity.

11 The high level of dread/aversion associated with radiation, and the absence of a threshold of exposure for mutations that may lead to cancer, results in a regime based on keeping exposure as low as reasonably practicable.

12 For pesticides the basis of approval is to screen out genotoxic carcinogens and establish (usually on the basis of animal tests) acceptable intakes at which no effects would be expected.

13 Where there is confidence that further information, e.g. from a research programme, will reduce uncertainty within a fixed timescale, consideration should be given to making a commitment in advance to review after this period.