Regulatory Policy Committee

RPC guidance note on 'using the precautionary principle'

Background and purpose of this note

A decision to invoke the precautionary principle to support a propostion is a policy decision; however, the RPC has an interest in validating the evidence being used to support such a decision. This note seeks to clarify some of the issues that the RPC will consider in assessing the evidence used to justify use of the precautionary principle.

At the final stage, the RPC does not red-rate on the rationale for intervention, only the small and micro-business assessment and the direct business impacts of a policy. However, the Committee will provide commentary on all aspect of the impact assessment, including the use of the precautionary principle.

This document does not comment on policy nor seek to add to the better regulation framework or RPC expectations. Whether or not to invoke the precautionary principle in support of the rationale for intervention is a decision for departments. If they do, they should demonstrate that their rationale for intervention is robust, appropriate proportionate and fit for purpose; this guidance aims to assist departments in demonstrating evidence for the rationale for intervention.

Policy guidance on the precautionary principle is set out in the Interdepartmental Liaison Group on Risk Assessment's (ILGRA) guidance ('the ILGRA guidance"). This explains that the purpose of the precautionary principle is to allow a policy decision to be made notwithstanding scientific uncertainty about the nature and extent of the risk.

The ILGRA guidance notes that the precautionary principle should be applied only 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 likelihoods is such that risk cannot be assessed with sufficient confidence to inform decision-making.

The ILGRA guidance acknowledges that '…*the precautionary principle was originally framed in the context of preventing environmental harm* [however] *it is now widely accepted as applying broadly where there is threat of harm to human, animal or plant health*…' (p. 5). The principle is therefore applicable across a wide range of policy areas.

The ILGRA guidance is clear that the precautionary principle is narrower than just being precautionary and is only relevant where scientific uncertainty is a key factor, and there is a good reason to expect harmful effects. The above criteria, if taken without a full understanding of the ILGRA guidance, could be used to support any intervention where there is little evidence that a problem exists, or where the causal link between the target of the intervention and the problem is unsupported.

This RPC guidance note sets out the factors that the RPC will look for, when the precautionary principle is cited as a key rationale for intervention. It aims to provide policy makers and analysts with a concise tool to assist them in presenting evidence that will be relevant to the department's application of the precautionary principle and is appropriate to their specific circumstances.

Stages for the application of the precautionary principle

In deciding whether to invoke the precautionary principle, it is helpful to consider issues in four stages. The RPC will use these stages to structure our comments on the robustness of the evidence presented in support of proposals that invoke the precautionary principle in the context of specific measures.

Stage 1 – Evidence for harmful effects

The ILGRA guidance notes that there should be '*good reason*' to believe harm could occur. Based on the evidence available, policy makers should draw on:

1. empirical evidence of the actual harm;
2. empirical evidence of an analogous harm or analogous activity/product/situation causing harm; and/or
3. a strong theoretical argument.

The RPC consider that, where possible, '*good reason*' should be supported with empirical evidence, for example recorded instances of past harm. If a policy maker cannot provide any direct empirical evidence for the possibility of harm occurring, the guidance suggests using evidence from analogous activities, products or situations as a proxy. In cases where none of this is possible, for example in a highly novel area, the ILGRA guidance states that policy makers may draw on '*a sound theoretical explanation (tested as necessary by peer review)*' (p. 6) which outline how harm could occur. In an ideal world, an impact assessment would draw on all three; however, in practice, the evidence base may not accommodate this, and they should, therefore, be seen as a hierarchy of evidence.

Stage 2 – Irreversible harmful effects

At stage 2, policy makers should determine whether the possible impacts of inaction, i.e. what could happen under the *status quo*, warrant the proposed action when the risks and likelihood of harm are unknown. The ILGRA guidance notes that *harmful effects* can be gauged with reference to severity, irreversibility, numbers affected, uniqueness, temporal and spatial effects, and knock-on effects.

With reference to *numbers affected* and *severity,* the Green Book describes the type of harms that warrant the use of the principle as those which have the 'potential for devastating impact'. The decision to invoke may be straightforward in situations where the impacts of inaction could severely affect a broad base of individuals, such as significant harm to a large number of individuals or significant loss of life. However, for some policy proposals, it will be less clear-cut and should be influenced by the prevailing political level of risk tolerance.

Where a department justifies the principle on the basis of *irreversible* harms, the RPC will expect to see sufficient evidence to support this. For example, the Department could present evidence that, in the absence of intervention, the level of harm would change in such a way as to render it impossible (or very difficult/expensive) to return to the previous baseline, or so that future interventions would have a greatly reduced effect. Ultimately, it falls on departments to assess the specific harms and determine whether they justify the application of the precautionary principle. The RPC will expect to see a clear rationale for invoking the principle based on robust evidence of *numbers affected*, *severity* and *irreversibility* of harms.

When determining whether the harms warrant the use of the principle, departments should also consider how the proposed intervention will impact innovation, investment and

competition. The ILGRA is clear that 'the precautionary principle should not…be an obstacle to innovation'. It will ultimately be for departments to consider possible trade-offs between taking a precautionary approach and fostering innovation, investment and competition.

Stage 3 – Level of scientific uncertainty

In stage 3, policy makers need to determine whether the level of scientific uncertainty about the consequences or likelihoods is such that risk cannot be assessed with sufficient confidence to inform decision-making. The relevant part of the ILGRA guidance states that the principle can be invoked when '*a scientific evaluation of the consequences and likelihoods reveals such uncertainty that it is impossible to assess the risk*' (p. 6).

The RPC interprets this to mean that a weak evidence base alone is not enough to justify the use of the precautionary principle; rather a policy maker must demonstrate that the state of evidence is such that it is unlikely to be able to assess the risk and likelihood of harm or to assess it sufficiently before it is too late to intervene effectively. This includes situations where there may be some knowledge of the risks but not enough to properly assess them with sufficient confidence to inform decision making. Where evidence is limited, every effort should be made to reduce uncertainty before reverting to the precautionary principle.

Stage 4 – Review

If, after stage 3, a policy maker is still content that the precautionary principle is an appropriate justification for government intervention, they should consider the ILGRA guidance's suggestions on appropriate plans for review.

The ILGRA guidance notes that '*Decisions reached by invoking and applying the precautionary principle should be actively reviewed, and revisited when further information that reduces uncertainty becomes available*.' (p. 2). In stage 3, policy makers are encouraged to make every effort to reduce uncertainty. While the results of research programmes may not be available in time, policy makers should review the decision in the light of any change in the evidence base. In support of the this, the Green Book states that '*The recommended approach in situations where expensive precautionary actions have been taken is to monitor continually the situation and to build in specific review points, being prepared to act quickly on the basis of better information*'. (Managing Risks to the Public Appraisal Guidance, p. 32)

The ILGRA guidance also notes that reviews should '*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*.' (p. 13)

Where the precautionary principle is used, the RPC, therefore, expects to see high-quality monitoring and evaluation plans. It may be appropriate to include commitments to review the policy earlier than the five-year time horizon commonly used for secondary legislation. For post-implementation reviews, the RPC will expect to see a thorough assessment of the original decision to invoke the principle.