



# postnote

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## HANDLING UNCERTAINTY IN SCIENTIFIC ADVICE

**Handling risk and uncertainty in the fields of science and technology (S&T) underpins much of the work of government and its scientific advisory system. There have recently been moves to develop a more sophisticated understanding of scientific uncertainty and its treatment. This POSTnote looks at how uncertainty is best handled in the provision of scientific advice, in decision-making and in communicating with the public.**

### Key points:

- Risk assessments are invariably subject to a range of uncertainties.
- There are different types of uncertainty, which may derive from a variety of sources.
- Numerous approaches can be applied to assist in the consideration of uncertainty.
- Scientific uncertainties may be underplayed or overplayed for political advantage.
- Official guidance suggests that uncertainties should be made explicit and their implications transparently taken into account in decision-making.

### Background

The number of UK deaths attributed to variant CJD is 141<sup>1</sup>, while internationally the wider financial costs of the disease continue to accumulate. In the run-up to the BSE crisis in 1996, uncertainties were insufficiently acknowledged, with advisers and ministers representing the lack of any 'sound scientific' evidence for a risk as evidence that it could not occur. It was thus common for politicians to deliver unequivocal assurances of safety. The Phillips Inquiry into BSE recommended a shift in the relationship between scientific advice and policy-making. Increased emphasis has since been placed on the explicit

and systematic handling of scientific uncertainties by advisers, officials, ministers and parliamentarians.

### Scientific advice

Uncertainties in scientific advice arise from various sources including:

- Difficulties in making predictions about complex systems. 'Climate change' is a good example.
- Uncertainty over the assumptions adopted throughout the analysis (these may be tentative or too narrow) or over how best to frame the questions being addressed (which may fail to address all relevant factors).

When science informs policy-making, it is also subject to wider uncertainties over:

- Financial, legal, ethical and political considerations
- Different interpretations of numerical values (either inputs or outputs) in scientific analyses by various interest groups. For example, EU rules permit the unintended presence of up to 0.9% genetically modified (GM) material in a crop without it needing to be labelled as GM. This figure is acceptable to the National Farmers' Union, but is seen as unacceptable by some organic growers.

Developments in the understanding of types of risk and uncertainty are discussed in box 1.

### Communicating uncertainty to decision-makers

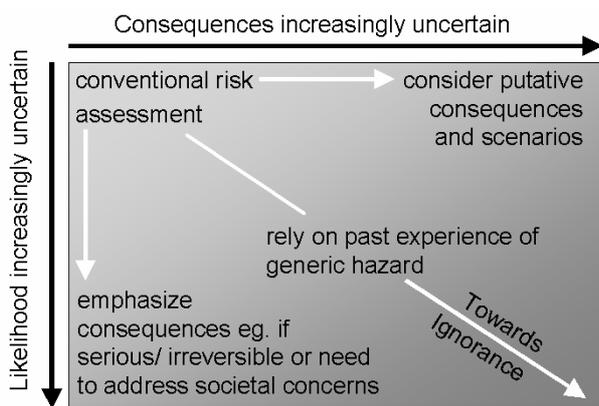
The Office of Science and Technology (OST) works to improve policy-making on the basis of scientific evidence (see POSTnote 196). Building on the lessons learned from BSE and updating guidelines from 1997, the Chief Scientific Adviser (head of OST) made recommendations to departments in *Guidelines 2000* on the use of scientific advice in policy-making. OST's *Code of*

### Box 1. Developments in risk and uncertainty

Risk is commonly understood as the product of the likelihood (or probability) of a particular outcome and its impact. The distinction between risk and uncertainty has traditionally centred on the following difference.<sup>2</sup>

- risk – situations where both the likelihood of a particular outcome, and the nature of its impact, are well understood (such as in a fair game of roulette).
- uncertainty – situations in which there is no sufficient basis for assigning a precise and accurate likelihood to a particular outcome (such as predicting the price of copper in 20 years' time).

More recent developments have begun to acknowledge the difficulties involved in predicting the consequences and evaluating the impacts of particular outcomes. A scheme drawing upon this distinction is shown below.<sup>3</sup>



Types of uncertainty have also been distinguished on the basis of:

- ambiguity arising from different value-judgements about the existing scientific data, for example in the debate over GM thresholds mentioned in the text
- ignorance of the relevant factors and relationships to be taken into account in risk assessment. For example, there was ignorance of the effects of chlorofluorocarbons (CFCs) on the ozone layer when the chemicals were first introduced. Ignorance is likely to be highest when dealing with novel and complex systems.

*Practice for Scientific Advisory Committees* (the Code) in 2001 provided explicit instructions on the reporting of uncertainty and divergent opinions. The Code recommends that scientific advice to decision makers should make clear the sources and extent of uncertainty. This includes the assumptions on which judgements are based as well as alternative scenarios and interpretations of the data.

Several approaches can be used to ensure that advice is more systematic in its treatment of uncertainties:

- **Conventional risk assessment** – used where there is a firm basis for predicting both likelihood and impact. For example, rail operators will sometimes be asked by the Health and Safety Executive (HSE) to submit quantified risk assessments (QRAs) before they implement proposed risk control measures that make changes to existing infrastructure or practices. This type of QRA uses historical data on frequency and impact (fatalities and injuries) from previous accidents to calculate the likelihood of similar events under existing conditions and after proposed measures. Rail operators then multiply likelihood and impact to obtain

an estimate of risk, and calculate the number of 'equivalent fatalities' that would be prevented by proposed risk control measures. (Currently one fatality is equated with 10 major, or 200 minor, injuries) Rather than delivering decisions on whether the measures are adequate, the QRA process provides a basis for dialogue and judgement about the possible options. Within risk assessment, uncertainties arise from variability in data or from only limited amounts of data being available. These types of uncertainties can be further examined through sensitivity analysis.

- **Sensitivity analysis** – used in situations where the relationship between the cause and effect for risks are relatively well defined. This investigates the effect of altering the questions asked, the assumptions made and the data used. For example, in the safety case produced for the channel tunnel rail link where historical data was lacking, sensitivity analysis was used to test the effect on the assessed risk of varying a number of parameters (such as the passenger loading of trains and the various events that could lead to derailment). By altering these assumptions the appropriate degree of confidence in the risk assessment could be determined.
- **Scenario analysis** – used systematically to investigate the potential impacts of different possible outcomes. This was one of the approaches taken by the Strategy Unit in the economic strand of the GM Dialogue.<sup>4</sup> Here, five scenarios were developed based on two main factors: the strength of public reaction to GM crops and food and the extent of regulation specific to GM crops. At one extreme, there was public antagonism and tight regulation of GM; at the other, public support and non-specific regulation.
- **Wide consultation and deliberation** – allows questions and assumptions to be scrutinised, especially when issues are sensitive. Ideally, if applied early on, it lessens the chance that pertinent information and perspectives (such as from the public's 'lay' knowledge) are neglected. The GM Science Review and the current Royal Society/Royal Academy of Engineering study on nanotechnology have attempted to achieve this by involving interested parties early on.

### Scientific uncertainty in the GM debate

As part of the GM Dialogue,<sup>4</sup> the government received scientific advice on GM crops from the Advisory Committee on Releases to the Environment (ACRE) and from the GM Science Review Panel in January 2004. Uncertainties were considered differently by each group:

- ACRE's advice focussed specifically on farm-scale evaluations (FSEs) of three GM crop varieties. Based on the FSE results, ACRE concluded that cultivation of two of the GM crops evaluated (beet and oilseed rape) under the specific management conditions used in the FSEs would result in adverse effects, whereas cultivation of GM fodder maize under FSE conditions would not. The committee explicitly specified conventional agriculture as the comparator. ACRE also recognised the sources of variation mentioned by the FSE authors and other uncertainties identified at open meetings where the FSEs were discussed.

- The GM Science Review Panel attempted to adopt a systematic approach to identifying uncertainties by analysing the quality of the evidence considered, different interpretations of that evidence and key assumptions on which the panel's conclusions relied. Gaps in knowledge were explicitly acknowledged, and the ways in which research and/or risk management measures might address these were discussed. The Department for Environment, Food and Rural Affairs (Defra) has considered the GM Science Review, and based on the findings has begun to develop new lines of research, such as looking at gene flow between plants and soil fungi.

### Decision-making under uncertainty

Risk management decisions can respond to some of the uncertainties in conventional risk assessment by applying appropriate safety margins that take this variation into account. Wider uncertainties can be addressed by building in resilience to potential crises through contingency planning and/or by applying the 'precautionary principle'. The latter has several conflicting interpretations and concerns have been raised that it may be applied inappropriately and act as a barrier to scientific progress. The most widely-used definition is that from Principle 15 of the 1992 Rio Declaration on Environment and Development, which states, "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."

More recently, the European Commission has outlined its approach to the principle<sup>5</sup>, while the European Council endorsed a resolution to use it at the Nice Summit in December 2000. The now-disbanded Interdepartmental Liaison Group on Risk Assessment (ILGRA) produced similar guidance on its application across UK government departments in 2002.<sup>6</sup> This recommends that the precautionary principle should be invoked when, "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 public health case studies in box 2 describe instances where the level of scientific uncertainty was at specific times viewed as sufficient (blood safety, HRT) or insufficient (MMR) to justify precautionary action.

The case studies go beyond systematically applying the precautionary principle in decision-making and raise wider issues of continuous research and improved engagement with the public. Accordingly, a more sophisticated view of precaution sees it as a process incorporating:

- ongoing risk research and monitoring
- transparent consideration of multiple options, including the risks of action and inaction
- genuine engagement with minority and lay concerns
- a shift in the burden of proof for safety to proponents of new technologies, while acknowledging the impossibility of proving zero risk.

### Box 2. Public health case studies

#### *Blood supply safety for transfusions*

Based on advice from the Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT), the government announced that, from April 2004, it would exclude anyone who had received a blood transfusion since 1980 from donating blood. This step was the latest in a series of precautionary measures against the spread of vCJD through donated blood, after the first victim thought to have contracted the disease by this route died in late 2003. The Health Secretary explicitly recognised that the department was following a "highly precautionary approach" in response to an "uncertain but slight risk".<sup>7</sup>

#### *Hormone replacement therapy (HRT)*

Although the possibility of side-effects has long been recognised, new scientific evidence has emerged over the past few years on the health impacts of HRT.<sup>8</sup> As new data have been published, the Committee on the Safety of Medicines (CSM) has updated its advice to health professionals, and the Medicines and Healthcare Products Regulatory Agency (MHRA) has relayed associated information to the public.<sup>9</sup> Following a Europe-wide review of the data, notice was sent to health practitioners in December 2003 that the balance of risk and benefit for all conventional oestrogen-only and combined (oestrogen plus progestogen) products was unfavourable for the long-term prevention of osteoporosis. Without explicitly acknowledging uncertainties on this occasion, this CSM advice was implicitly a precautionary extrapolation from data on a limited sample of products (as made clear in earlier CSM communications and in product information).

#### *MMR Vaccine (see POSTnote 219)*

The response to early concerns over the proposed association between MMR vaccine and autism was to review and commission research on the possible link. The body of evidence is under regular review by CSM and by the Joint Committee on Vaccination and Immunisation (JCVI), both of which have consistently concluded that the data do not support a causal association, and thus have not introduced any scientific uncertainties into their advice. While the Department of Health (DH) is open about known risks associated with MMR (for example the slight risk of a condition which affects blood clotting), its response to claims of links with autism has been to reassure parents of the safety of the vaccine. DH's decision not to offer single vaccines as an alternative to MMR also takes into account uncertainties over the effectiveness of such a regime.

### The politics of precaution

Decisions over when and how to apply the precautionary principle are not based entirely on scientific considerations, but also draw on questions about the wider financial, legal and ethical implications of different policy options. Without an open, transparent and accountable approach to articulating and addressing these matters, uncertainties may be taken out of context or:

- underplayed - with uncertainties represented as scientific certainties or even well-understood risks, for example, when the focus of a risk assessment is too narrow and ignores (or underplays) pertinent issues
- overplayed - through inappropriate claims that uncertainty is sufficient to justify a particular decision or to delay a decision pending further research.

- avoided – through transferring responsibility for managing risks or uncertainties to others while failing to ensure that the public is protected.

*Guidelines 2000* stresses that departments should also explain their interpretation of advice, carefully presenting the issues, uncertainties and policy options to the public. For example, the government responded publicly to the various strands of the GM Dialogue, attempting to clarify how it weighed each of the outputs and how its decision was constrained by its legal obligations.

## Engagement with the public

It is widely acknowledged that public concerns should be taken into account by government at an early stage, before seeking scientific advice. While some argue that public participation can dilute valuable scientific inputs, many believe that it promotes a more rigorous framing of scientific questions and also helps to build a more trustworthy regulatory system. The ways in which members of the public perceive risks is linked to their trust in regulatory institutions, so openness and transparency are widely proposed as a necessary, although not sufficient, step towards rebuilding trust in the government's use of science.

Risk amplification is where risks are perceived to be significantly greater than their scientific assessment would indicate and is more likely when risks possess certain characteristics related to 'fright factors' or 'media triggers'.<sup>10</sup> Risk amplification may result in knock-on effects, for example, the decrease in immunity to measles following the drop in vaccine uptake caused by the MMR scare. Conversely, 'risk attenuation' may also result in risks not receiving the attention they warrant (for example exposure to radon gas).<sup>11</sup>

## Public dialogue and the GM debate

Through GM Nation? and other strands of the GM Dialogue, scientific uncertainties were explicitly examined with opportunities for stakeholder input provided through social research, open public meetings, a web site and written consultation. The March 2004 government decision to allow cultivation of the GM maize subject to strict conditions largely reflected scientific advice. Wider commitments outlined in the government's response, which cited a "precautionary and evidence-based approach",<sup>12</sup> addressed several of the issues raised in the public debate and other advice on coexistence and liability.<sup>13</sup> Partly because of these changes, the company that owns the GM maize announced that it would not proceed with commercial growing of this maize in the UK on economic grounds.

## Government handling of risk and uncertainty

In recent years, there has been increased attention given to risks and uncertainties in the context of building resilience to major emergencies. The Civil Contingencies Secretariat in the Cabinet Office provides guidance and support in preparation for, and response to, potential crises including natural disasters such as flooding, and emergencies, such as threats from terrorism.

Improved approaches to the day-to-day handling of risks to delivery were outlined in a 2002 Strategy Unit report,<sup>14</sup> the recommendations of which are currently being followed up within the Treasury by the Risk Programme. This focuses on embedding a culture of risk management into government at all levels and has developed the following five principles of managing risks to the public:

- openness and transparency – about the government's understanding of risks and its approach to handling them.
- involvement – of those concerned in the decision process.
- proportionality and consistency – in the level of protection needed to address different risks.
- evidence – from a range of perspectives, where possible quantified, should be the basis for decisions.
- responsibility – should be allocated to appropriate individuals for managing specific risks.

The Treasury's programme will finish at the end of 2004, when the National Audit Office will also report on progress made. The implementation of OST's *Guidelines 2000* and the Code was last followed up across government in 2001 and 2002 respectively. OST currently has no plans to produce another government-wide review on the issue. Instead, it is committed to assess implementation by individual departments further, through its Science Reviews.

## Endnotes

- 1 National CJD Surveillance Unit, 3rd May 2004 data on deaths from definite and probable vCJD - see <http://www.cjd.ed.ac.uk/>
- 2 Examples taken from J.M. Keynes (1937) *Quarterly Journal of Economics*, Vol. 51, p.209-23
- 3 Based on HSE (2002) Reducing risks, protecting people
- 4 The national dialogue on GM issues consisted of three main strands – the GM Science Review, the Strategy Unit's review of costs and benefits and the GM Nation? public debate (see POSTnote 211).
- 5 Communication from the Commission on the precautionary principle. Brussels, 2/2/2000
- 6 ILGRA (2002) *The Precautionary Principle: Policy and Application*
- 7 DH press release 16<sup>th</sup> March, reference number 2004/0104
- 8 HERS Study, WHI Study, Million Women Study
- 9 <http://medicines.mhra.gov.uk/> - see CSM link
- 10 DH (1998) Communicating about Risks to Public Health: Pointers to Good Practice
- 11 HSE Contract Research Report 329/2001
- 12 The GM Dialogue: Government response, 9th March 2004
- 13 AEBC (2003) *GM Crops? Coexistence and Liability*
- 14 Cabinet Office (2002) *Risk: Improving government's capability to handle risk and uncertainty*

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