EUROPEAN POLICY CENTRE

EPC WORKING PAPER N° 17

Enhancing the role of science in the decision-making of the European Union

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March 2005

In strategic partnership with the King Baudouin Foundation

With the support of the European Commission

BETTER REGULATION

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BETTER REGULATION

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About the author

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Foreword

Europe's citizens in the new Millennium share an unprecedented level of both concern and high expectations. Politicians and regulators are increasingly called upon to make complex decisions in the face of scientific uncertainty and crises, often having to react to strong external pressures. It is paramount that the European Union meet these new challenges in the most legitimate, accountable and efficient manner possible.

Through its Risk Forum and its Integrated Work Programme on Better Regulation, the European Policy Centre has substantially contributed to the debate on improving the quality of regulatory decisions in the EU over the past decade. Science is a critically important component of most regulatory processes. Science helps society achieve higher living standards in a safer, healthier, economically dynamic and more sustainable environment.

I am particularly delighted that the EPC Risk Forum chose "Enhancing the role of science in the decision-making of the European Union" as its core research project in 2004. This impressive publication complements previous studies on the Precautionary Principle (2001), Regulatory Impact Analysis (2001) and Risk Communication (2003). It also marks a further tangible step towards achieving two of the declared objectives of the Risk Forum: to help decision-makers and opinion-formers improve their understanding of the risk analysis process at EU level and to promote improved communication between scientists, policy-makers, stakeholders and citizens.

Some five years ago, in the EPC Occasional Paper on the Politicisation of Science (1999), we wrote that "Governments cannot eliminate all risks on behalf of society. They can only seek to reduce the risks faced by society to an acceptable level (…)." We continue to hope that European society will once again trust its politicians because it can rest assured that public concerns are adequately taken into account, while progress and innovation are also encouraged.

I warmly commend this Working Paper to you.

Stanley Crossick
Founding Chairman
European Policy Centre

Acknowledgements

As principal author of this Working Paper, I would particularly like to thank the members of the Steering Group established by the Risk Forum of the European Policy Centre for their help.

Christopher Proctor (British American Tobacco) chaired the Steering Group. The members of the Steering Group were: Dirk Hudig (FIPRA EU); François Lafond (Policy Network); Giuseppe Malinverno (Solvay); Richard Moore (Eucomed); Mia Nybrant (Scientific-Alliance); Scott Ratzan (Johnson and Johnson); Nico Van Belzen (ILSI Europe); Johan Vanhemelrijck (EuropaBio); Susanne Zänker (IFAH Europe); and David Zaruk (Risk Communications Consultant).

I would like to thank the observers from the European Commission: Michael Rogers in the Group of Policy Advisors, and Mark Cantley and Dorian Karatzas in DG Research.

I am grateful to the stakeholders who agreed to be interviewed – MEPs, officials from Commission services, and representatives of companies, business organisations and NGOs.

I would like to warmly acknowledge the assistance of my colleagues on the project team for their help in researching and writing the report: Lorenzo Allio from the European Policy Centre; Bethan Devonald and Richard Meads from Business Decisions Limited; and our academic expert advisor, Professor Ragnar Löfstedt from the Centre for Risk Management at King's College, London. Finally, I would like to thank our editorial advisor, Alex Ballantine, for her advice and assistance. However, responsibility for the final report is mine alone.

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Executive Summary

Used well, science provides effective ways of identifying potential risks, protecting citizens and using resources wisely. It enables government decisions to be based on evidence and provides a foundation for a rules-based framework that supports global trade.

To ensure that the best available science becomes a key input in the decisions made by EU institutions, this Working Paper considers how science is currently used in the policy and decision-making processes of the EU, what the limitations of scientific evidence are, and how a risk assessment process based on scientific 'good practices' can be advantageous. Finally, the paper makes recommendations on how to improve the use of science by EU institutions.

Advantages and Limitations of Scientific Evidence

In managing risks to the environment and to human health, scientific evidence is a key knowledge input for decision-making in all stages of the regulatory cycle:

- It leads to better-informed and more effective legislative and regulatory decisions.

- It provides decision-makers with the opportunity to base decisions on evidence derived from transparent, rational processes designed to eliminate bias.

- It has been highly effective in providing theories with explanatory and predictive power.

Scientific evidence does, however, have its limitations:

- Policy-makers and decision-makers are often unable to make use of scientific advice.

- There is a lack of public confidence in the utility of scientific evidence, particularly in managing risks to human health, which limits its effectiveness.

- There are often difficulties in obtaining 'independent' and 'excellent' scientific advice, and in obtaining it quickly enough to deal with emerging risks.

- Some influential groups do not accept that scientific evidence is an appropriate input.

Scientific Good Practices

A series of interviews and a structured analysis of the approaches of different governments and organisations provided the basis for the development of a set of scientific good practices that underpin the effective use of science in decision-making:

- Legislative requirements oblige regulators to base policy decisions primarily on the best available scientific evidence of risk.

- Clear, binding policies are drawn up for the use of scientific evidence for risk management that apply throughout government and that are supported politically.

- Government-wide mandatory guidelines for the operation of the scientific advice system are in place.

- Definitions of the roles and responsibilities of the key participants in the process of collecting, assessing and using scientific advice are published.

- An independent Chief Scientific Advisor or Scientific Advisory Group ensures the integrity, quality and effective operation of the scientific advisory system.

- An independent body provides high quality scientific advice to help legislators make policy and legislative decisions.

- Officials and advisors responsible for producing or using scientific advice receive regular training.

Weaknesses in the Use of Science in Decision-making by the EU

Since the mid-1990s, the EU institutions have taken steps to improve the quality and credibility of scientific evidence used in decision-making at EU level. Major reforms include the creation of independent scientific committees; the creation of independent risk assessment agencies for medicines and food; and the introduction of a Commission-wide policy for the collection and use of expertise. There are, however, gaps in the EU approach when compared to the good practice framework:

- The EU Treaty imposes certain legal obligations to make use of scientific evidence when making some decisions on the development of environmental policy. However, it does not extend the requirement to take account of scientific data to other policy areas or to the implementation of policy. The Treaty contains no requirement to base decisions on the 'best available science' and legislation on evidence of risk rather than hazard.

- EU legislation satisfies many elements of a good risk analysis policy. However, there is no comprehensive statement of risk management principles; and the risk analysis policy can only be constructed by amalgamating policies included in separate documents.

- EU guidelines for the collection and use of scientific advice meet many of the good practices. However, the guidelines are not mandatory and do not provide a comprehensive and common set of key concepts and definitions for use in the provision of scientific advice; guidelines can only be established by amalgamating the requirements included in various Commission documents; there is no definition of the quality of information to be used; and findings from major scientific assessments used in policy-making are not subject to peer review.

- EU guidelines for the use of scientific evidence are limited and not mandatory. Moreover, they do not provide EU institutions with a coherent policy for the use of evidence in decision-making.

- EU guidelines for the selection of scientific advisors meet many of the requirements of the good practices framework. However, those volunteering for appointment as scientific advisors are, to a large extent 'self-selecting'; there is no peer review of potential advisors by external experts; selection processes are opaque; and there are restrictions on the use of advisors from outside the EU.

- EU guidelines for the briefing and use of scientific advisors do not require officials to consult widely when framing policy-related questions; and the use of scientific advisors is not limited to questions that are capable of being answered by scientific evidence.

- EU reporting guidelines have major gaps in comparison with the good practices framework. There is no mandatory requirement to ensure that advice is comprehensive, informative, consistent or understandable; opinions are not required to cover factors such as relevant peer reviewed studies, methodologies used to reconcile inconsistencies or estimates of risk for each relevant population; facts, judgements and opinions do not have to be distinguished clearly; and value judgements do not have to be avoided.

- Evidence from EU Member States and other countries suggests that roles and responsibilities are frequently defined within the national policy for scientific advice. However, none of the documents that describe the EU scientific advice policy provide a definition of roles and responsibilities. At EU level there is no independent Chief Scientific Advisor or a Scientific Advisory Group; and the Commission does not have a central unit that supports the Chief Scientific Advisor.

Recommendations

Short-term Actions (to be implemented in the next two to three years):

A. The Commission should publish a Decision containing a new formal and binding policy statement covering risk analysis in policy-making.

B. The EU institutions should issue a joint Communication affirming that high quality science will have a principal role in policy-making and decision-making processes.

C. The Commission should establish a new, coherent policy for the collection and use of scientific advice. The policy should be applied by all institutions to all stages of the regulatory cycle and to all sources of scientific advice.

D. The Commission should establish Chief Scientific Advisors or Scientific Advisory Groups in all relevant services or agencies with responsibility for ensuring the integrity, quality and effective operation of the scientific advisory system in the service/agency concerned.

E. The Commission should also establish an independent Chief Scientific Advisor or Scientific Advisory Group, reporting directly to the President of the European Commission, with responsibility for ensuring the integrity, quality and effective operation of its overall scientific advisory system.

F. The Commission should establish a central unit in the Secretary General's Office in support of the Chief Scientific Advisor or Scientific Advisory Group.

G. The Parliament should review the provision of independent scientific advice available to MEPs and ensure that it is able to support the development and updating of technical legislation.

Long-term Actions (that may require eight to ten years to achieve):

1. The creation of a 'European Academy of Sciences' should be encouraged.

2. The creation of a 'Science Watch,' not-for-profit organisation should be encouraged.

3. The Commission should ensure that a single set of mandatory operational guidelines is developed for the collection and use of scientific advice.

4. The Commission should amend the criteria for the selection of members of Scientific Advisory Committees to ensure that members are nominated by their peers and are selected on the basis of excellence.

5. The Commission should draw up mandatory operational guidelines for the briefing and utilisation of scientific advisers.

6. The Commission should establish mandatory written principles that define the quality of information to be used in scientific assessments.

7. The Commission should draw up mandatory guidelines that describe the tools, techniques and processes to be used when conducting different forms of risk assessment.

8. The Commission should seek to harmonise the process of risk assessment internationally.

9. The Commission should draw up mandatory detailed guidelines for the presentation of scientific advice to policy-makers and decision-makers.

10. The Commission should update the Regulatory Policy and the Impact Assessment Guidelines to ensure that Impact Assessments and Explanatory Memoranda explain relevant scientific evidence.

1. Introduction

1.1. Background

"The advances in pure science during the 20th Century – particularly in physics (…) and biology (…) – have completely changed the relationship between science and society. Science has become a dominant element in our lives. It has brought enormous improvements to the quality of life, but it has also created grave risks."[1] As a result, "the European public perceives the consequences of science and technology in a highly diverse way. The overall view of science remains positive…but it is no longer considered a panacea for a series of problems."[2]

Used well, science provides effective ways of identifying potential risks, protecting citizens and using resources wisely. It enables government decisions to be based on evidence and provides a foundation for a rules-based framework that supports global trade. Moreover, legislative decisions based on scientific evidence produce regulatory frameworks that encourage creativity, stimulate innovation and facilitate investment in knowledge.[3]

During the last two decades, however, new ideas based on values, beliefs and moral dichotomies have begun to emerge about the best way to protect mankind and the planet from risks. Proponents of these new approaches argue that, "policy-makers must let citizens choose between different potential risks if they are to retain public trust in the event of a crisis."[4] Science, it is claimed, "makes many futures possible, but whether these are acceptable or not should be a social and ethical issue, not a scientific one."[5]

Opponents of science argue that, due to its lack of certainty, it is unable to help policy-makers deal with new, uncertain threats. Moreover, expertise is being increasingly contested as official, industry and counter-experts often contradict and challenge each other.[6] Science is also increasingly confronted with the ethical, environmental, health, social and economic implications of its technical applications.

At the same time, regulatory failures and media coverage have undermined public trust in the competence of policy-makers, industrialists and even scientists. Examples of significant regulatory failures that have attracted considerable media coverage include the tainted blood scandal in France in the 1980s,[7] the BSE crises of the early 1990s,[8] the foot and mouth problems in the

UK in the late 1990s[9] and the Belgian dioxin crisis in the summer of 1999.[10] The precautionary principle,[11] which has emerged in recent years as one of the main regulatory tools of environmental[12] and health policy in the European Union, has also influenced the debate on the use of science in decision-making.

The Communication by the European Commission on the precautionary principle[13] aims to build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate adequately. It requires that implementation of an approach based on the precautionary principle should start with a scientific evaluation that is as complete as possible and identifies the degree of scientific uncertainty. However, there remains "great concern about how invoking the precautionary principle can cause conflict with scientific-based risk analysis."[14]

1.2 The need for further improvements

Problems resulting from this shift away from using scientific evidence to guide decisions in the EU are becoming apparent:

- Policy initiatives, such as the REACH proposal,[15] have emerged that lack robust scientific evidence of risk.[16] This limits the likely effectiveness of action and accountability.

- Technical legislation has been enacted that lacks scientific justification.[17] This limits the potential effectiveness of government action.

- Regulatory decisions based on non-scientific evidence, or what is said to be 'precaution,' have been made.[18] This reduces predictability, undermines business confidence and increases administrative discretion.

- Trade tensions with countries outside the EU have emerged because they consider that the EU has made regulatory decisions based on non-scientific evidence.[19] This limits the scope for international co-operation, invites legal disputes and threatens global growth.

A review of the literature and a structured analysis of a sample of recent Extended Impact Assessments and Explanatory Memoranda published by the European Commission, combined with in-depth interviews with stakeholders, provided additional insights into the use of scientific evidence in EU decision-making.

Four Extended Impact Assessments[20] and ten Explanatory Memoranda[21] were reviewed. These covered a range of policy areas, and focused on the protection of public health and the environment. The reviews concluded that, in general:

- The extent to which scientific advice was taken into account was not clearly specified.
- Hazard and risk characterisations were qualitative and poor.
- There were no references to peer reviewed studies.
- Scientific uncertainties and minority/diverging scientific opinions were not reported.
- Scientific advice provided by experts was often confused with opinions obtained through consultation meetings with stakeholders.

More than 30 interviews were carried out with Commission officials, MEPs and other stakeholders (representatives of businesses and Non-Governmental Organisations). There were a number of major differences in the responses of the different groups but there were some common themes:

- The policy framework for risk analysis is subject to different interpretations by different Commission services; the formal scientific committees such as the European Medicines Evaluation Agency (EMEA) and the European Food Safety Authority (EFSA) have, however, built up a good reputation with stakeholders.
- During the process of designing policies and legislation, scientific evidence has been used poorly on some occasions. This has been caused by some European Commission officials not having the necessary skills and expertise to make effective use of scientific evidence, and existing support mechanisms within the European

Parliament providing insufficient scientific guidance to help MEPs make good quality technical decisions.

- The Commission guidelines on the use of expertise have helped to improve the transparency, independence and excellence of scientific advisers, but enforcement mechanisms are weak. For example, Technical Working Groups composed of Member State representatives, are not required to meet the standards of operation and composition established for the formal Scientific Advisory Committees of the European Commission. Moreover, there is no standard mechanism to ensure the ex-post assessment of EU legislative and regulatory decisions, even if new scientific evidence emerges.

Delivering sustainable development, more employment and greater wealth depends on making properly informed regulatory decisions that are based on evidence, target risks and use resources effectively without undermining prosperity. Action is now needed to overcome the weaknesses highlighted and to ensure that the EU achieves its economic, environmental and social goals.

In making the changes needed to achieve these goals, the EU needs to ensure that scientific advice conforms to the highest standards and that the process is open to public scrutiny. The reforms do, however, need to recognise that science is not the only input used by policy-makers and decision-makers to inform risk management decisions; cultural, moral, political, environmental, social and economic factors, as well as scientific ones, influence such decisions. Scientific expertise must, therefore, interact with other types of expertise in the policy-making and decision-making stages of the legislative and regulatory processes.

The EU institutions have already taken some initial steps to improve the utilisation of science within their policy-making and decision-making processes. However, on their own, these changes are not enough; there is a continuing need to further strengthen the role of scientific evidence in decision-making at EU level.

1.3 Objectives

The principal aim of this project is to ensure that the best available science is a key input to the legislative and regulatory decisions made by the EU institutions responsible for risk management. This Working Paper makes recommendations that, if implemented, will assist the institutions in realising the objectives agreed at the European Council Summit in Lisbon in 2000,[22] including the implementation of the recommendations of the so-called Kok Report,[23] covering issues such as the 'knowledge society,' the 'business climate' and 'sustainable development.'

2. Scientific Evidence and Regulatory Decision-Making

2.1 Science and scientific method

'Science' is defined as the systematic study of the nature and behaviour of the material and physical universe based on exploration, observation, experiment and measurement. It is a way of looking at the world by testing hypothetical explanations of the behaviour of natural or man-made systems. Through inductive and deductive reasoning, science seeks to establish cause-and-effect relationships based on evidence rather than belief or superstition.[24]

Science also refers to the community of scientists. It is guided by a series of methodological applications, a 'scientific method.' This refers to an organised approach to the acquisition of knowledge, which seeks to be objective and to avoid bias.

The scientific method is based on a number of key principles:

- Hypotheses must be developed that provide provisional explanations of underlying causes. These hypotheses are then used to develop predictions that are capable of being tested through experiment or observation.

- It must be possible to test and, if necessary, reject a hypothesis based on the scientific method.

- Findings from one set of experiments must be reproducible by other independent scientists, and must be subject to independent peer review before they become accepted as part of the existing body of knowledge.

- Findings based on the scientific method remain provisional and subject to challenge.

2.2 Scientific evidence and the regulatory cycle

In managing risks to the environment and human health in modern economies, scientific evidence is a key knowledge input for decision-making in all stages of the 'regulatory cycle.' It creates three types of beneficial outcomes:

- It leads to better-informed and more effective legislative and regulatory decisions because it enables policy-makers and decision-makers to:

  › Identify the existence of current, future and emerging hazards;
  › Determine which hazards pose the greatest risks to human health or the environment;
  › Develop effective strategies to manage risks;
  › Identify the benefits of government action;
  › Identify the existence of new, unintended risks that might be created through government action (the 'risk-risk' paradigm); and
  › Allocate resources rationally and effectively.

- It provides decision-makers with the opportunity to base decisions on evidence derived from transparent, rational processes designed to eliminate bias.

- It has been highly effective in providing theories with explanatory and predictive power. These theories have revealed links between hazards on the one hand, and human health or the environment on the other, and have enabled decision-makers to anticipate problems and to develop effective solutions.

2.3 Scientific evidence: the process

Most scientific evidence is provided to policy-makers and decision-makers through a process of 'scientific assessment.' This involves an expert assessment of the state of knowledge, and the implications of 'known' scientific evidence. Assessments are undertaken by experts and frequently require the application of judgement, but the best assessments distinguish clearly between evidence, analysis, judgement and opinion.

Scientific evidence is used for different purposes in different stages of the regulatory cycle:

- The review of existing scientific data, including the interpretation of scientific research from different sources and the application of expert judgement where data is lacking or inconclusive.

- The collection and analysis of new scientific data.

- The completion of formal risk assessments of new or existing technologies, products or substances.

- The identification of the health and environmental impacts of differing regulatory options, such as limit values, process controls or fiscal incentives.

- Support for submissions for the approval of new or existing products or substances.

- The identification of policy options.

- The provision of expert scientific advice to help with the ex-ante assessment of different policy options.

- The assessment of the effectiveness and impacts of legislative and regulatory decisions.

2.4 Limitations of scientific evidence

As an input into the regulatory cycle, science, along with all other forms of evidence used by policy-makers and decision-makers, has its limitations:

- **Structural limitations in the nature of scientific evidence reduce its utility for policy-makers**. These include the need to apply judgement and express opinions in the preparation of scientific assessments, which may lead to potential bias in the evidence presented to policy-makers. Moreover, the presence of uncertainties in scientific findings may also give the impression of a lack of certainty in the evidence presented to policy-makers. In addition, scientific evidence is not able to answer 'value-based questions.'

- **Some policy-makers and decision-makers may be unable to make use of scientific advice**. Many policy-makers and decision-makers have only limited 'scientific literacy.' In addition, most scientists lack an understanding of how policy-makers make use of scientific evidence. As a result, there tends to be a cultural and a capability gap between scientific advisors on the one hand, and policy-makers and decision-makers on the other. This gap can lead to two types of problem: some policy-makers and decision-makers may place too much reliance on scientific evidence, while other policy-makers and decision-makers may fail to understand scientific evidence.

- **Lack of public confidence in the utility of scientific evidence limits its effectiveness in managing risks to human health and the environment**. In recent years, public confidence in science has declined in most developed countries. This has been caused, at least partly, by media coverage of controversial and high profile topics that has focused on regulatory failures and scientific disagreements. Increasing use of business funding to support fundamental research may undermine the perceived integrity of scientific evidence.

- **Difficulties in obtaining 'independent' and 'excellent' scientific advice limit its effectiveness**. Increasingly, the scientific expertise needed to manage many of today's risks resides in the private sector or outside the EU. Existing restrictions on the selection of scientific advisors mean that the EU may not have access to the best available science to enable it to take effective action. In fact, the relevant knowledge-base is not limited by administrative or geographical boundaries.

- **Difficulties in obtaining good quality scientific advice quickly enough limit its ability to deal with emerging risks**. Scientific advice cannot be supplied quickly enough, on occasion, because the 'scientific method' involved in producing good quality scientific evidence is a lengthy process.

- **Lack of acceptance amongst influential groups of the appropriateness of scientific evidence limits its effectiveness**. Some groups believe that long-term threats to human health and the environment can only be managed by decisions based on values rather than scientific evidence, as the stakes are too high to rely on evidence that is unable to provide certainty of the absence of harm from new or existing threats. In addition, some groups claim that traditional science is unable to deal with the threats posed by complex hazards, such as prolonged low levels of exposure to multiple hazards or the impact of economic activity on the environment.

2.5 The use and abuse of science

Examples of the use and abuse of science in recent years include, 'the Brent Spar controversy,' the 'Belgian dioxin crisis' and the 'Swedish acrylamide alarm.'

The Brent Spar case study highlights the damage that Shell suffered to its reputation because it was unable to respond effectively to 'emotional' challenges to science.

The Brent Spar controversy[25]

In early 1994, Shell and Exxon, partners in the exploration of the UK sector of the North Sea, encountered problems in relation to the disposal of the Brent Spar oil storage platform. The platform, originally commissioned in 1976, had been non-operational for five years and was considered redundant in 1994.

Shell, the operator, commissioned 30 separate studies to consider the technical, safety, and environmental implications of its disposal. As a result of these studies, Shell decided to dump the platform in deep water as this was felt to be both a low cost strategy and one that would have only a minor environmental impact.

The UK Department of Trade and Industry granted permission to dispose of the platform in the deep sea, and there were no protests from the other North Sea nations. However, as the platform was being towed to the spot for deep-water disposal, Greenpeace occupied the Brent Spar. As a result, the Brent Spar controversy hit the media headlines. The crisis was not resolved until Shell abandoned its plans to dump the platform in deep water and decided to dismantle it on land.

With hindsight, science was on the side of Shell. An independent group of experts (the Scientific Group on Decommissioning Off-Shore Structures) broadly confirmed the scientific assessment of Shell's analysis that the platform itself did not contain the levels of toxic materials that Greenpeace had claimed. In addition, the group concluded that dumping the platform in the deep sea would pose little risk to underwater flora and fauna. Despite the group's assessments, Shell lost credibility as the company was perceived to be greedy. There was also the moral issue of dumping the platform in the sea, and the fact that the media, social networks and a number of international meetings amplified the effect of the story.

The dioxin case study highlights the political damage that the Belgian government suffered because it delayed reporting a potentially serious scientific problem that might have affected the public, and because it delayed conducting high quality scientific studies.

The Belgian dioxin crisis[26]

Dioxins are by-products of industrial chemical processes that are released into the environment via chemical reactions. They are bio-accumulative and stored in fatty tissues. They are considered by some NGOs to be 'super poisons.'

Dioxins have been highly stigmatised by the media,[27] e.g. the supposed contamination of the Hudson River in New York State, the high levels of dioxin found in blood samples of healthy European adults[28] and the emissions of dioxin in Seveso, Italy in 1976[29] (leading to the formulation of the 'Seveso Directive'[30]). It is little wonder, therefore, that the Belgian government's decision to withhold information from the public led to media amplification and raised public concern.

In the spring of 1999, dioxin was introduced into the Belgian food supply, via contaminated animal fat used in animal feeds supplied to Belgian, French, and Dutch farms. The scandal led to government investigations and the removal and destruction of tonnes of eggs and meat products.

From a risk communication perspective, the major mistake in this case was that the Belgian government only went public on 29 May 1999, when it had known about the problem since mid-March. This delay worsened the crisis, resulting in accusations of a self-serving cover-up, led to the resignations of two cabinet ministers and contributed to the defeat of the ruling party in a national election.

From a scientific perspective, however, the real risks posed by this scare were minimal. Scientific studies comparing levels of dioxins in Belgian blood donors before and after the scare indicated that there was no significant difference, and that the dioxin levels remained within the average of the European blood mix.

The acrylamide case study highlights the damage to the reputation of trusted researchers and regulators because the results of research were publicly communicated before all the relevant scientific studies had been checked.

The Swedish acrylamide alarm[31]

In April 2002, regulators at The Swedish National Food Administration (SLV) and researchers at Stockholm University (SU) faced a dilemma. SU had found high levels of acrylamide (a substance widely believed to cause cancer) in carbohydrate foods cooked at a high temperature. SLV had verified the research and SU's paper summarising the results had been accepted for publication by a peer-reviewed journal.

SLV wanted the information to become publicly available as soon as possible as the agency took the view that the findings were of paramount importance to the health of the Swedish consumer. SU, however, took the view that there was no real rush and that it would be better to publish the paper first and see what response was received from the wider international scientific community. Because of pressure from SLV, however, it was decided that SLV and SU should hold a joint press conference, which was widely covered by the media.

But, immediately after the press conference, doubts began to emerge as to whether the publication of the results had been handled in the best way. Some commentators criticised SLV for amplifying risks, while others saw it as a PR coup.

Arguably, in this case, not enough scientific advice had been taken. Although the research by SU was robust and met the highest peer review standards, SLV was wrong to present the findings on the international stage in the way it did. There was no evidence that acrylamide (which was cancerous in rats) was cancerous in humans as well. Indeed, epidemiological studies conducted in Sweden and the United States after this 'alarm' indicated the rates of cancer suffered by those individuals who consumed high levels of fried food were no greater than the rates suffered by those who did not.

3. Good Practices

Many governments have introduced changes to ensure that more effective use is made of scientific evidence throughout the regulatory cycle. These provide the basis for the development of a set of good practices, which, taken together, underpin the effective use of science in decision-making. They are based on a review of initiatives undertaken by national governments in Australia, Canada, Denmark, France, Germany, Italy, New Zealand, Norway, Sweden, the UK and the USA, to improve the use of scientific evidence in decision-making.[32]

These good practices are interlinked and are designed to change behaviours and the attitudes that underpin them. Good practices fall into three main categories:

3.1 Overall policy and legislative context

These good practices provide the framework that is needed to ensure that science is used effectively when making strategic decisions. They also ensure long-term adherence to guidelines and the sustained provision of political support and financial resources:

- Legislative requirements for the management of risks to human health, public safety and the environment require regulators to base implementation and policy decisions primarily on the best available scientific evidence of risk.

- Clear, binding policies are drawn up for the use of scientific evidence for risk management that apply throughout government, are supported politically, and form part of a wider commitment to evidence-based decision-making.

3.2 Guidelines for the operation of the scientific advice system

These good practices describe, in detail, the new processes that must be followed. They reassure citizens that action is being taken and provide a mechanism for ensuring the effective external oversight of activities by individual departments and agencies. Guidelines also help to improve coherence of activity and to define expected behaviours:

- Government-wide mandatory guidelines for the operation of the scientific advice system are in place. These apply to traditional ministries and independent agencies at all levels of government, and encompass the collection and provision of scientific advice used in legislative and regulatory decisions. The guidelines cover the selection of scientific advisers; the operation of scientific committees; the briefing and utilisation of scientific advisers; information quality and evaluation of evidence; risk assessment reporting; and the range of scientific advice included in Impact Assessments and Explanatory Memoranda.

3.3 Roles, responsibilities and resources

These good practices define the institutional architecture that will ensure that the strategy and its goals are achieved and that new process standards are met. They also identify the appropriate levels of resources:

- Definitions of the roles and responsibilities of the key participants in the process of collecting, assessing and using scientific advice are published.

- An independent Chief Scientific Advisor or Scientific Advisory Group, reporting directly to the head of government, is responsible for ensuring the integrity, quality and effective operation of the scientific advisory system.

- Each agency and ministry (or equivalent) that produces or uses scientific advice has a Scientific Advisor or Scientific Advisory Group responsible for overseeing the operation of the scientific advisory process and for ensuring its compliance with government-wide policies and guidelines.

- An independent body provides high quality scientific advice to help legislators make policy and legislative decisions.

- Officials and advisors responsible for producing or using scientific advice receive regular training.

4. Scientific Evidence and EU Regulatory Decision-Making

4.1 Improving the use of scientific evidence at EU level

The EU uses science as one of a number of sources of evidence to support decision-making across a wide range of policy areas, including fishing quotas, emission limits, food safety, environmental protection, animal health, worker safety and consumer protection.

Since the mid-1990s, the EU institutions have taken a series of steps to strengthen the quality and credibility of the scientific advice it uses:

- The creation of independent scientific committees, which are structurally separated from risk managers, and which provide scientific advice for the preparation of policy, as well as regulatory advice required by legislation.

- The creation of two science-based risk assessment agencies (EMEA and EFSA), which make use of independent scientific committees to provide advice to risk managers in the European Commission.

- The introduction of policies and guidelines for the use of scientific advisors throughout the Commission, which cover planning, preparing for the collection of expertise, identifying and selecting experts, managing the involvement of experts and ensuring openness.

- The expansion of access to sources of scientific advice through the Scientific Information Advice in Policy Support (SINAPSE) programme, which, it is hoped, will provide Commission officials with electronic access to scientific advice produced in Member States.

- Political support from the Commission for the use of scientific evidence to inform decisions about the best way to manage risks to human health and the environment.

4.2 Principal sources of scientific advice

Most scientific advice is provided to EU policy-makers and decision-makers through a process of 'scientific assessment.' This involves an expert assessment of the state of knowledge and implications of known scientific evidence, including published and unpublished studies.

There is, however, no single, common system for providing scientific assessments to EU policy-makers and decision-makers. Scientific advice is provided through a range of different mechanisms that differ by policy area, Directorate General and agency. Moreover, sources of advice used for policy and legislative decisions tend to be different from those used for regulatory decisions. In many cases, scientific advice mechanisms for regulatory decisions are set out in relevant legislation.

- Sources of advice used to support EU policy and legislative decisions include: formal scientific committees supported by the Health and Consumer Protection Directorate General (DG SANCO); scientific committees associated with EFSA and EMEA; reports by advisory agencies, such as the European Environmental Agency (EEA); bespoke reports by external contractors; reports from scientific advisory bodies in Member States; in-house analyses by Commission officials; reports by the Joint Research Centre (JRC) and the Scientific and Technical Options Assessment group in the European Parliament (STOA); and 'ad hoc' expert groups. This range of sources reflects, in part, the lack of an explicit model that describes how the EU institutions should use science to inform policy and legislative decisions.

- In contrast, a more limited range of sources of scientific advice is used to support regulatory decisions. These are scientific committees supported by DG SANCO, EFSA, and EMEA, and Technical Working Groups made up of representatives of Member States.

- In most cases, legislation prescribes the process of regulatory decision-making, including, where appropriate, the need for, and sources of, scientific advice. There is, however, no common approach.

4.3 Policies, guidelines and the organisation of scientific evidence at EU level

The following define, structure and control the collection and use of scientific advice by policy-makers and decision-makers in the EU:

- The policy and legislative framework.

- Guidelines for the operation of the scientific advice system.

- The institutional architecture.

Policy and Legislative Framework

The **legislative requirements** are established by Articles 95, 153 and 174 of the EU Treaty.

Article 174 requires that the Union, "in preparing its policy on the environment, shall take account of: (i) available scientific and technical data; (ii) environmental conditions in various regions of the Community; (iii) the potential benefits and costs of action or lack of action; and (iv) the economic development of the community as a whole and the balanced development of its regions."

Articles 95 and 153 of the EU Treaty refer to the use of scientific evidence. Article 95 identifies scientific evidence as one of the ways in which the EU may learn about new threats to citizens. Article 153 requires Member States to use scientific evidence if they wish to introduce national restrictions that exceed EU measures to protect consumers or the environment.

Although these requirements impose legal obligations on the EU to make use of scientific evidence when making some policy decisions, they do not satisfy fully the requirements set out in the good practice framework:

- *The requirement to take account of scientific data is limited to the development of environmental policy, but does not extend to other policy areas or to the implementation of policy.*

- *The Treaty does not require decisions to be based on the 'best available science.' It merely requires officials to take account of available scientific data, i.e. there is no 'quality threshold.'*

- *The Treaty does not require legislation to be based on evidence of risk.*

In a number of instances, however, specific pieces of legislation have been produced that overcome these weaknesses. The EU Regulation setting up EFSA,[33] for example, requires EFSA to provide the EU institutions and the Member States with the best possible scientific opinions.

The EU risk analysis policy is defined by two key documents: the Communication on Consumer Health and Food Safety (1997)[34] and the Communication on the Precautionary Principle (2000).[35] Both Communications cover decisions relating to the best way to manage threats to human health and the environment.

Although these requirements satisfy many elements of a good risk analysis policy, there are some gaps:

- *They do not highlight the need to make decisions based on risk rather than hazard.*
- *There is no comprehensive statement of risk management principles to be used in situations when the precautionary principle is not appropriate.*
- *The 'policy' can only be constructed by amalgamating requirements included in two separate documents.*

The **scientific advice policy** of the EU is contained in three key documents: the Science and Society Action Plan (2002),[36] the Commission Communication on the Use and Collection of Expertise (2002)[37], and the Commission Decision to set up scientific committees in the fields of consumer safety, public health and the environment (2004).[38]

Collectively these documents highlight the importance of using sound and timely science as an essential requirement for risk management in the areas of consumer safety, public health and the environment. They also provide a set of guiding principles for the collection and use of scientific expertise: independence, pluralism, excellence, impartiality, proportionality and transparency.

However, compared to the framework of good practices there are some gaps in the area of scientific advice policy:

- *The documents do not provide clear information about the benefits of scientific evidence for policy-making, and they do not provide a comprehensive and common set of key concepts and definitions for use in the provision of scientific advice.*
- *They also fail to describe the key processes that underpin the process of collecting and assessing scientific evidence, and to require policy and regulatory decisions to demonstrate links between scientific evidence and proposed government action.*

The principal requirement to make use of **evidence** is set out in the EU Regulatory Policy Guidelines (1996).[39] These require the European

Commission to disclose the justification for any measure in the Explanatory Memorandum. They also require a measure to be based on an assessment, including an evaluation of the common interest.

Further references to the value of providing evidence to justify policy actions are included in the technical guidelines of the Communication on Impact Assessment (2002).[40] However, there is no explicit requirement for assessors to review the evidence for action or to ensure that it is highlighted.

Moreover, two further Communications deriving from the White Paper on Governance (2001)[41] – on Simplifying and Improving the Regulatory Environment (2002)[42] and Better Lawmaking (2002)[43] – do not include a requirement to base decisions on evidence.

Hence, on balance, there are a number of gaps in EU policies in the area of evidence compared with the list of good practices:

- *Formal, explicit requirements to base EU policy decisions on evidence are limited and not binding.*

- *The statements do not provide the EU with a coherent policy for the use of evidence in decision-making.*

Guidelines for the Operation of the Scientific Advice System

The EU has two principal sets of guidelines for the collection and use of **scientific advice**. They are set out in the Communication on the Collection and Use of Expertise (2002)[44] and in the Commission Decision setting up scientific committees in the field of consumer safety, public health and the environment (2004).[45] Scientific committees within EFSA are also governed by the guidelines set out in the 2004 Decision.

Although these requirements meet many of the good practices, there are some gaps in the system for providing scientific advice:

- *Technical Working Groups that are composed of Member State representatives are not included within the scope of the guidelines.*

- *Guidelines can be established only by amalgamating the requirements included in various Commission documents.*

EU guidelines for the **selection of scientific advisors** require the use of 'open calls for tender' to select members of formal scientific committees; selection on the basis of excellence; and selection from a wide range of backgrounds and from a broad geographic spread within the EU. They also require advisors to act independently and to disclose conflicts of interest.

Although these requirements meet many of the good practices, there are gaps in the approach of the EU to the selection of scientific advisors:

- Those volunteering for appointment as scientific advisors are, to a large extent, 'self-selecting.'
- There is no peer-review of potential advisors by external experts.
- Selection processes are opaque.
- There are, in practice, restrictions on the use of advisors from outside the EU.

EU guidelines for the **operation of scientific committees** meet all of the major good practices in this area. They require access to different and relevant types of experts; rules of procedure for committees; the treatment of private meetings of committees as confidential; and the provision of information regarding the membership, activities and outputs of committees to citizens.

EU guidelines for the briefing and use of scientific advisors only meet a limited number of the standards set by the good practice framework. Most importantly, the guidelines do require formal scientific committees to operate within a transparent framework.

*However, there are gaps in the **guidelines for the briefing and use of scientific advisors**:*

- *Officials are not required to consult widely when framing policy-related questions or to work with committee members when dealing with issues characterised by high levels of scientific uncertainty.*
- *The use of scientific advisors is not limited to questions that are capable of being answered by scientific evidence.*

Formal EU guidelines for the operation of scientific committees and for **the collection and use of scientific advice** do not contain explicit requirements for information quality and the evaluation of evidence.

As a result, there are a number of gaps in the EU framework of operational guidelines for the collection and use of scientific advice:

- *There is no definition of the quality of information to be used in scientific assessments.*
- *Evidence and analyses do not have to be based on the 'weight-of-evidence' approach.*
- *Mandatory protocols for identifying and reporting uncertainty are not established.*
- *Findings from major scientific assessments used in policy-making are not subject to peer review.*

The risks posed by these gaps were highlighted in a letter sent by DG Enterprise and DG Environment to the members of the Working Groups on Classification and Labelling at the end of 2003.[46] This reminded members of risk assessment committees of the need to base recommendations on solid science, and not to make use of the precautionary principle at the risk assessment stage.

A report by the EU Scientific Steering Committee in 2000[47] also highlighted problems and inconsistencies in information quality and in the evaluation of evidence by formal scientific committees.

Recommendations and detailed guidelines on the harmonisation of **risk assessment procedures** are set out in a report produced by the EU Scientific Steering Committee.[48] However, this report is purely advisory, as each scientific committee is independent and draws up its own rules of procedure; other scientific committees are not, therefore, obliged to follow its recommendations.

It appears likely, therefore, that there is a lack of detailed risk assessment guidelines available for EU scientific advisors.

EU guidelines contain only limited **reporting guidelines**. They require opinions to be published; divergent opinions to be identified and reported; evidence on which experts base their advice to be highlighted; and any persisting uncertainties to be highlighted.

However, by comparison with the good practices framework, there are major gaps in the EU reporting guidelines:

- *Advice does not have to be of publishable quality.*
- *There is no requirement to ensure that advice is comprehensive, informative and understandable.*
- *Opinions are not required to cover factors such as peer reviewed studies that are relevant, minority opinions of scientists and risk assessors, methodologies used to reconcile inconsistencies or estimates of risk for each relevant population.*
- *Facts, judgements and opinions do not have to be distinguished clearly, and value judgements do not have to be avoided.*
- *Scientific committees are not required to use a standard specification for the form and content of opinions.*

EU guidelines for the collection and use of expertise recommend that any legislative proposal submitted by the Commission should be accompanied, in the Impact Assessment and the Explanatory Memorandum, by a **description of the expert advice considered**.

However, the Regulatory Policy Guidelines[49] that define what must be included in an Explanatory Memorandum merely require the justification for a proposal to be included, and do not require expert evidence to be disclosed. Moreover, the Guidelines for Impact Assessments[50] are purely advisory.

In overall terms, EU guidelines do not meet the standards included in the framework of good practices for the description of the expert advice considered:

- EU Explanatory Memoranda are not required, for example, to explain the scientific evidence that underpins the overall justification for

government intervention, the policy options considered, the reasons for the policy option recommended, or the benefits to public health and the environment.

'Institutional Architecture' – Roles and Responsibilities

Evidence from EU Member States and other countries suggests that **roles and responsibilities** are frequently defined within the national policy for scientific advice.

However, none of the documents that describe the EU scientific advice policy provide a definition of roles and responsibilities at EU level.

A member of the Group of Policy Advisors provides the President of the European Commission with **scientific advice** about significant current and emerging scientific policy issues that cut across departmental boundaries.

At EU level, however, there is no independent Chief Scientific Adviser, or a Scientific Advisory Group, with responsibility for ensuring the integrity, quality and effective operation of the scientific advisory system.

Nor does the Commission have a **central unit**, which supports the Chief Scientific Advisor, with responsibility for developing an overall scientific advice policy and guidelines; enforcing compliance with guidelines; producing an annual review of the effectiveness of the advisory system; providing expert support; and commissioning periodic external evaluations.

Responsibility for the implementation of the Commission cross-Directorate guidelines on the collection and use of expertise lies within each Directorate. DG Research is responsible for commissioning an external evaluation of the effectiveness of the guidelines. The Commission reports annually on progress towards implementation of its Better Regulation Action Plan.

Despite these recent changes, the standards set out in the good practices framework are not met at EU level.

Since 1992, the Scientific and Technological Options Assessment (STOA) has provided scientific and technological **advice to the European Parliament**. Its original aim was to ensure that the Parliament had access to timely, high quality, independent assessments of scientific and technological

issues that were relevant to their work as legislators. To achieve this, STOA responded to information requests from parliamentary committees and undertook selected projects on its own initiative. Independent consultants carried out the work after projects were approved by the Members of the European Parliament (MEPs) on the STOA Panel.

The work of STOA was, however, subject to criticism from MEPs and, in response, the Parliament adopted a new set of rules in 2004.[51] These require STOA to focus on assessing the medium and long-term impact of technological developments on society; carry out studies on the basis of open-minded scientific enquiries; use independent contractors from scientific institutions in several EU Member States, who have relevant expertise and are selected on the basis of open tender, to carry out all studies; require contractors to present results in a manner understandable to a layperson; and carry out an independent review of reports produced by contractors.

These new requirements meet the standards set out in a number of the good practices: reports are to be published and must meet a basic standard of literacy. Moreover, peer review of scientific assessments is explicitly considered, although its use is to be determined, on a case-by-case basis, by the STOA Panel.

In a number of areas, however, further improvements are needed to the 'new' STOA if the scientific and technical advice provided to the European Parliament is to meet the standards set out in the framework of good practices:

- *STOA should ensure that an explicit statement of the quality of scientific evidence is provided.*
- *The principal criterion for the provision of advice should be 'excellence.'*
- *Scientific advice should be available to support the European Parliament in creating and up-dating 'technical' legislation.*

5. Conclusions

Living standards, employment and quality of life depend increasingly on the exploitation of investment in scientific knowledge. At the same time, there is an ever-increasing requirement from policy-makers for scientific advice because of increasing demands from citizens for protection against risks, and because of the emergence of new and more complex threats to human health and the environment.

Scientific evidence has helped governments to manage risks because it has enabled them to make better and more effective legislative and regulatory decisions. It has played an essential role in identifying hazards and risks; developing technologically effective strategies to manage risks; identifying the benefits of government action; and reducing uncertainties in decision-making. Scientific evidence has also helped governments to avoid targeting inconsequential problems, whilst ignoring greater risks.

There is, however, an emerging debate as to the appropriate role of scientific evidence in determining the outcome of legislative and regulatory decisions. This has been caused by rising concerns about the limitations of science and the importance of 'non-scientific' factors.

Hence, a challenge facing all governments is to ensure that science retains its central role in policy-making and decision-making processes, whilst taking appropriate account of the structural limitations of scientific evidence and the increasing importance of non-scientific factors.

Many governments have managed to undertake reforms to improve the credibility, quality and effective use of scientific evidence. Taken together, these changes have created a framework of good practices that can be exploited by other governments.

Since the mid-1990s, the EU institutions have taken steps to improve the quality and credibility of scientific evidence used in the EU decision-making. Major reforms include the creation of independent Scientific Advisory Committees, the creation of two independent risk assessment agencies for medicines and food, and the introduction of a Commission-wide policy for the collection and use of expertise.

There are gaps, however, in the EU approach, when compared to the good practice framework:

- There is a limited and equivocal political commitment to the importance of good science as an essential input into policy, legislative and regulatory decision-making.

- There is a poorly structured and incomplete policy framework for risk analysis and the use of evidence in policy-making.

- There are gaps in the scope of operational guidelines for the inclusion of scientific evidence in the legislative process, the effective use of scientific advisers, information quality, the interpretation of evidence and the reporting of results.

- There is a lack of institutional mechanisms to ensure the integrity, quality and effective operation of the scientific advisory system.

There are weaknesses, therefore, in the effective use of scientific evidence in policy-making and regulatory decision-making processes by the European Union.

Accordingly, a structured programme of reform is proposed that will, if implemented fully, improve the framework of policies, guidelines and institutional structures at EU level. This will help to improve the effective use of science in all decision-making processes by the EU institutions.

6. Recommendations

Achieving change in any large organisation is difficult. In recognition of this, the recommendations have been grouped into two time-periods:

- A number of actions that, if implemented fully in the next two to three years, will move the process of change, irrevocably, towards achieving improvements in the decision-making processes of the EU.

- A larger number of actions that may require eight to ten years to achieve.

6.1 Short term actions

Recommendation A. *The European Commission should publish a Commission Decision containing a new formal and binding policy statement covering risk analysis in policy-making, in the creation and review of legislation and in the implementation of regulations.*

The policy statement should:

- Highlight the need to make decisions on the basis of risks rather than hazards.

- Define appropriate mechanisms for achieving a transparent interface between risk assessment and risk management at different stages of the regulatory cycle.

- Require high quality and widely accepted scientific evidence and scientific procedures to inform risk assessments.

- Define key risk management principles.

- Integrate the precautionary principle into a wider framework for risk management decision-making that takes account of different types of risk and different levels of scientific uncertainty.

- Define clearly the roles and responsibilities of scientific advisors, regulators, decision-makers and stakeholders within the risk analysis process.

- Incorporate extensive and relevant communication with stakeholders.

Recommendation B. *The EU institutions should issue a joint communication affirming their collective commitment to ensuring that high quality science will be a principal source of evidence to inform all policy-making and decision-making processes designed to protect citizens and the environment from risks.*

Recommendation C. *The European Commission should establish a new, coherent policy for the collection and use of scientific advice. The policy should be applied by all EU institutions to all stages of the regulatory cycle and to all sources of scientific advice, including formal Scientific Advisory Committees and other advisory bodies such as agencies and STOA.*

The policy statement should:

- Define a set of guiding principles for the collection, assessment and provision of scientific advice.
- Describe clearly the benefits and limitations of using scientific evidence to manage risks to human health and the environment.
- Provide a comprehensive set of key concepts and definitions used in the provision of scientific advice, including definitions of 'best available science,' the 'scientific method,' 'uncertainty,' 'hazard' and 'risk.'

Recommendation D. *The European Commission should establish Chief Scientific Advisors or Scientific Advisory Groups in each Commission service or agency that makes extensive use of scientific advice. These advisors or groups should report to the head of each service or agency.*

Recommendation E. *The European Commission should also establish an independent Chief Scientific Advisor or Scientific Advisory Group, reporting directly to the President of the European Commission, with responsibility for ensuring the integrity, quality and effective operation of its overall scientific advisory system.*

Recommendation F. *The European Commission should establish a central unit in the Secretary General's Office in support of the Chief Scientific Advisor or Scientific Advisory Group.*

The unit should be responsible for:

- Developing the overall scientific advice policy and the specific guidelines that underpin the operation of the advisory system.
- Providing additional expert resources, advice and support to Scientific Advisory Committees and officials.
- Enforcing compliance with common guidelines.
- Auditing the extent to which science is used effectively in policy-making and decision-making processes.
- Commissioning periodic external evaluations of the operation of the overall scientific advisory system.
- Producing an annual review of the effectiveness of the scientific advisory system.

Recommendation G. *The European Parliament should review the provision of independent scientific advice available to MEPs and ensure that it is able to support the development and updating of technical legislation. Any new system should meet the guidelines and process standards used by the independent scientific committees supported by the European Commission.*

6.2 Long Term Actions

Sources of Scientific Advice

Recommendation 1. *The EU institutions should encourage the creation of a 'European Academy of Sciences,' consisting of experts who are able to address critical issues in the areas of science, engineering, medicine and research, and give advice to the institutions and the public.*

Recommendation 2. *The EU institutions should encourage the establishment of a 'Science Watch,' not-for-profit organisation to evaluate policy and legislative proposals put forward by the EU, to ensure that they meet the highest scientific standards.*

Operational Guidelines

Recommendation 3. *The European Commission should ensure that a single set of mandatory operational guidelines is developed for the collection and use of scientific advice. This should be applied by all EU institutions to all stages of the regulatory cycle and to all sources of scientific advice.*

Recommendation 4. *The European Commission should amend its criteria for the selection of members of Scientific Advisory Committees. Members should be nominated by their peers and should only be selected on the basis of excellence, using a transparent, objective, consistent and systematic process. Selection decisions should be subject to peer review.*

Recommendation 5. *The European Commission should draw up mandatory operational guidelines for the briefing and utilisation of scientific advisers.*

The guidelines should require:

- Scientific Advisory Committees and advisors to operate within a transparent framework with publicly available terms of reference.

- Officials to consult widely with stakeholders and Scientific Advisory Committees when framing policy-related questions to be answered by Scientific Advisory Committees, particularly when dealing with issues characterised by high levels of scientific uncertainty.

- The use of Scientific Advisory Committees should be confined to questions that are capable of being answered using scientific evidence.

Recommendation 6. *The European Commission should establish mandatory written principles that define the quality of information to be used in scientific assessments.*

The guidelines should require:

- The information used in assessments to be based on the best available science. Supporting studies should be conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science.

- Evidence and analyses to be assessed using the 'weight-of-evidence' approach.

- Protocols to be developed for the identification and reporting of significant uncertainties.

- Written instructions to clarify the separation of risk assessment and risk management, and to ensure that the use of risk management tools (such as the precautionary principle) is confined to policy-makers and decision-makers.

- Findings from reviews by scientific advisers, which will have a clear and substantial impact on important public policies or private sector decisions, to be subject to peer review.

Recommendation 7. *The European Commission should draw up mandatory guidelines that describe the tools, techniques and processes to be used when conducting different forms of risk assessment, and should ensure that these are available to all relevant officials and Scientific Advisory Committees. These include guidelines for risk characterisation, human health risk assessments and ecological risk assessments.*

Recommendation 8. *The European Commission should seek to harmonise the process of risk assessment internationally.*

Recommendation 9. *The European Commission should draw up mandatory detailed guidelines for the presentation of scientific advice to policy-makers and decision-makers. Guidelines should emphasise the need for advice to be understandable to policy-makers and to be of publishable quality. Limitations of scientific advice should be recognised.*

The guidelines should require:

- Each population addressed by any estimate of risk and each risk assessment end-point to be identified, along with the expected and (appropriate) upper and lower bound estimates of human health or environmental risk.

- Peer reviewed studies that are relevant to the subject to be highlighted.

- Facts, judgements, opinions and studies that have not been peer reviewed to be distinguished.
- Methodologies used to reconcile inconsistencies in scientific data to be explained.
- Assumptions and analytical methods to be described.
- Significant uncertainties to be identified and explained.
- New evidence that might alter conclusions to be highlighted.
- Value judgements to be avoided and comments restricted to science and scientific advice.

Recommendation 10. *The European Commission should update the Regulatory Policy and the Impact Assessment Guidelines to ensure that Impact Assessments and Explanatory Memoranda for proposals to manage risks to human health, public safety and the environment explain relevant scientific evidence.*

The mandatory guidelines should require evidence to include:

- Overall justification for government intervention, including distinctions between evidence of hazard and assessment of risk.
- Statements of the levels of uncertainty.
- A list of the policy options rejected and a list of the policy options recommended.
- Benefits to human health or the environment arising from the implementation of the recommended policy option.
- Causal linkages between hazard and risk, the recommended policy option and societal benefits from government action.
- The sources of scientific advice, including peer reviewed studies that support the arguments set out in the Impact Assessment and the Explanatory Memorandum.
- Recommended review periods for scientific conclusions.

[1] Joseph ROTBLAT, "The Social Conscience of Scientists," in: *Physics World*, December 1999.

[2] European Commission, *Europeans, Science and Technology*, Eurobarometer No.55/2, 2001.

[3] See, for example, David LANDES, *The Wealth and Poverty of Nations: Why Some Are So Rich and Some So Poor*, W.W. Norton & Company, 1999.

[4] Andrea LORENZET/Frederico NERESINI, "Science, Risks and Social Representations," in *European Commission IPTS Report*, Vol. 82, 2004.

[5] Professor George GASKELL as quoted in Ben DUNCAN, "Public Risk Perception and Successful Risk Communication," *European Commission IPTS Report*, Vol. 82, 2004.

[6] European Commission, *Democratising Expertise and Establishing Scientific Reference Systems*, Report of Working Group 1b on the White Paper on Governance, 2001.

[7] Monika STEFFEN, "The Nation's Blood: Medicine, Justice and the State in France," in: Ronald BAYER/Eric FELDMAN (eds.), *Blood Feuds: Aids, Blood, and the Politics of Medical Disaster*, Oxford University Press, 1999.

[8] Scott RATZAN, *The Mad Cow Crisis: Health and Public Good*, Routledge, 1998.

[9] Abigail WOODS, *A Manufactured Plague: The History of Foot and Mouth Disease in Britain*, Earthscan, 2004.

[10] Corie LOK/Douglas POWELL, *The Belgian Dioxin Crisis of the Summer of 1999: A Case Study in Crisis Communication and Management*, Technical Report 13, Department of Food Science, University of Guelph, 2000.

[11] The most commonly used definition of the precautionary principle is the 1992 Rio Declaration: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." See United Nations (General Assembly), *Rio Declaration on Environment and Development*, New York, 1992.

[12] The EC Treaty (Article 174) provides that the Community environmental policy shall be based on a number of policy principles, including the precautionary principle.

[13] European Commission, *Communication from the Commission on the Precautionary Principle*, COM(2000) 1 final of 2 February 2001.

[14] Ragnar LÖFSTEDT, "The Precautionary Principle: Risk, Regulation and Politics," in Trans IchemE, Vol. 81, Part B, January 2003. See also European Policy Centre, Towards a Proportionate Implementation of the Precautionary Principle, Occasional Paper, September 2001.

[15] European Commission, *Proposal for a Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) (on Persistent Organic Pollutants)*, COM(2003) 644 final of 29 October 2003.

[16] In the case of REACH, no credible scientific evidence has been advanced to support the need for additional legislation on the scale proposed by the EU. Recent legislation covering disposal of electrical and electronic waste provides an additional example. Legislative

requirements were based primarily on examples of theoretical hazards rather than exposure and risk.

17 Some safety testing requirements for existing veterinary medicine products are, for example, based on human pharmaceuticals or pesticides standards rather than relevant scientific evidence of risk.

18 Well-known examples include decisions to phase out the use of antibiotics as growth promoters in food-producing animals and restrictions on the use of phthalates in children's toys.

19 Examples include hormones in beef and agricultural biotechnology.

20 The Extended Impact Assessments reviewed are those attached to the following Commission Proposals: *Proposal for a Directive on the protection of groundwater against pollution* (COM(2003) 550 final); *Proposal for a Regulation concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) (on Persistent Organic Pollutants)* (COM(2003) 644 final); and *Proposal for a Directive on batteries and accumulators and spent batteries and accumulators* (COM(2003) 723 final).

The assessment of the Proposal for a Regulation relating to cadmium in fertilizers was still to be finalised when the analysis took place. It can be consulted at: http://www.europa.eu.int/comm/enterprise/chemicals/legislation/fertilizers/cadmium/impact_assessment.pdf (last visited on 2 February 2005).

21 The Explanatory Memoranda reviewed are those attached to the following Commission proposals: *Proposal for a Directive on waste electrical and electronic equipment (WEEE) and Proposal for a Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment* (COM(2000) 347 final); *Proposal for a Council Decision on material presenting risks as regards transmissible spongiform encephalopathies* (COM(2000) 378 final); *Proposal for a Directive on emission of gaseous and particulate pollutants from internal combustion engines in non-road mobile machinery* (COM(2000) 840 final); *Proposal for amending Directive 76/769/EEC on the marketing and use of certain dangerous substances and preparations (c/m/r)* (COM(2002) 70 final); *Proposal for a Directive on Control of High Activity Sealed Radiation Sources* (COM(2002) 130 final); *Proposal for a Directive on the conditions of use for a food additive E 425 konjac* (COM(2002) 451 final); *Proposal for amending Directive 1999/32/EC on the sulphur content of marine fuels* (COM(2002) 595 final, Vol.2); *Proposal for a Directive relating to arsenic, cadmium, mercury, nickel, polycyclic aromatic hydrocarbons in ambient air* (COM(2003) 423 final); *Proposal for a regulation on incidental catches of cetaceans in fisheries* (COM(2003) 451 final); and *Proposal for a regulation on certain fluorinated greenhouse gases* (COM(2003) 492 final).

22 Presidency Conclusions, *Lisbon European Council* (23/24 March 2000) at: http://ue.eu.int/ueDocs/cms_Data/docs/pressData/en/ec/00100-rl.en0.htm.

23 High Level Group chaired by former Dutch Prime Minister Wim Kok, *Facing the challenge. The Lisbon strategy for growth and employment,* November 2004, at:

http://europa.eu.int/comm/lisbon_strategy/pdf/2004-1866-EN-complet.pdf.

[24] S. WOLF, *Scientific Method,* 1998; and Christopher PRESTON, *The Scientific Method,* University of Adelaide, 2004.

[25] Ragnar LÖFSTEDT/Ortwin RENN, "The Brent Spar Controversy: An Example of Risk Communication Gone Wrong," in: *Risk Analysis*, Vol. 17/2, 1997; and Chris ROSE, *The Turning of the Spar*, Greenpeace, 1998.

[26] Corie LOK/Douglas POWELL, 2000, see Endnote 10 above.

[27] Theo COLBURN/Dianne DUMANOSKI/John PETERSON MYERS, *Our Stolen Future: Are We Threatening Our Fertility, Intelligence and Survival? A Scientific Detective Story*, EP Dutton, 1996; and US Environment Protection Agency, *Estimating Exposure to Dioxin-like Compounds*, 1994.

[28] Gwynne LYONS, *Chemical Trespass: A Toxic Legacy*, WWF, 1999.

[29] Brian WYNNE (ed.), *Risk Management and Hazardous Waste: Implementation and the Dialectics of Credibility*, Springer-Verlag, 1987.

[30] The original 'Seveso Directive' (Council Directive 82/501/EEC on the major-accident hazards of certain industrial activities, OJ L 230 of 5 August 1982) was replaced by Council Directive 96/82/EC on the control of major-accident hazards, the so-called 'Seveso II Directive' (OJ L 10 of 14 January 1997). For more information, see *http://europa.eu.int/comm/environment/seveso/*.

[31] Ragnar LÖFSTEDT, "Science Communication and the Swedish Acrylamide Alarm," in: *Journal of Health Communication*, Vol.8, 2003.

[32] Good practices are described in a range of studies, reports, and guidelines, including: US Office of Management and Budget (OMB), *Proposed Draft Peer Review Standards for Regulatory Science*, 2003; Frederick ANDERSON, "Improving Scientific Advice to Governments," in: *Issues in Science and Technology*, Spring 2003; US EPA, *Guidelines for Ensuring and Maximising the Quality, Objectivity, Utility and Integrity of Information Disseminated by the EPA*, 2002; UK Office of Science and Technology (OST), *Code of Practice for Scientific Advisory Committees*, 2001; Steven GLYNN (et al.), *Science and Governance: Describing and Typifying Scientific Advice Structures*, Report for the European Commission, 2001; Government of Canada, *A Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government Decision-making*, 2000; Oxford Economic Research Associates; *Policy, Risk, and Science: Securing and Using Scientific Advice*, Report for the UK government, 2000; US National Research Council, *Strengthening Science at the US EPA*, 2000; William SMITH/Janet HALLIWELL, *Scientific Advice in Government Decision-making*, Report for the Government of Canada, 1999; William SMITH/Janet HALLIWELL, *Principles and Practices for Using Scientific Advice in Government Decision-making: International Best Practices*, 1999.

[33] *Regulation EC/178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing EFSA and laying down procedures in matters of food safety*, in OJ L 31 of 1 February 2002, p.1.

[34] European Commission, COM(97) 183 final of 30 April 1997.

[35] European Commission, COM(2000) 1 final of 2 February 2000.

[36] To be found at: http://www.europa.eu.int/comm/research/science-society/pdf/ss_ap_en.pdf.

[37] European Commission, COM(2002) 713 final of 11 December 2002.

[38] European Commission, Decision (2004/210/EC) of 3 March 2004, in OJ L 66, 4 March 2004, p.45.

[39] European Commission, *Regulatory Policy Guidelines*, Internal document, 1996.

[40] European Commission, COM(2002) 276 final of 5 June 2002. The technical guidelines can be found at: http://www.europa.eu.int/comm/sustainable/docs/ia_guidelines_en.pdf.

[41] European Commission, COM(2001) 428 final of 25 July 2001.

[42] European Commission, COM(2001) 726 final of 5 December 2001.

[43] European Commission, COM(2002) 275 final of 5 June 2002.

[44] See Endnote 37 above.

[45] See Endnote 38 above.

[46] See *Joint Views of Directorates-General Environment and Enterprise, and the European Chemicals Bureau*, ECBI/55/03, September 2003.

[47] European Commission, *Report of the Scientific Steering Committee's Working Group on Harmonisation of Risk Assessment Procedures in the Scientific Committees Advising the European Commission in the Area of Human Health and Environmental Health*, 2000.

[48] European Commission, *Harmonisation of Risk Assessment Procedures*, Opinion of Scientific Steering Committee, 2000.

[49] See Endnote 39 above.

[50] See Endnote 40 above.

[51] See http://www.europarl.eu.int/stoa/info/rules_en.htm.

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Mission Statement

The European Policy Centre (EPC) is an independent, not-for-profit think-tank, committed to making European integration work. The EPC works at the 'cutting edge' of European and global policy-making providing its members and the wider public with rapid, high-quality information and analysis on the EU and global policy agenda. It aims to promote a balanced dialogue between the different constituencies of its membership, spanning all aspects of economic and social life.

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