

**REVIEW OF RISK PROCEDURES
USED BY THE GOVERNMENT'S
ADVISORY COMMITTEES DEALING
WITH FOOD SAFETY**

Report of the group led by Sir Robert May, Chief Scientific Adviser

July 2000

Introduction

1. At the end of March, I was asked by the Prime Minister to conduct a review into the way in which risk is handled by those scientific advisory committees which advise the Government on food safety, together with Professor Liam Donaldson (Chief Medical Officer) and Sir John Krebs (Chairman of The Food Standards Agency). Additional members of the review group, acknowledging the involvement of the devolved administrations in the interests of their Parliament and Assemblies, and our terms of reference are set out in annex 1.

2. We asked the Chairmen of the relevant committees (annex 2) to describe to us (annex 3):

- the way in which their committee approaches risk assessment;
- how information about risk is communicated; and
- the role of their committee in risk management.

Their responses are summarised at annex 4.

3. We also met the Chairmen to discuss how their committees used risk assessment and tested out on them our own ideas about the robustness of the ways in which risk is currently assessed, managed and communicated. Finally, members of the Review group met to discuss our findings and to agree the text of our report.

4. We were greatly helped in producing this report by the assistance of the committee chairmen and hope that it will be of use to them and their committees, as well as to policy makers in Government. Advisory committees are generally following good practice and have a strong record of providing the government with valuable advice, which is widely respected, both here and abroad.

The nature of the issue

5. Risk and food safety are complex and emotive issues. Hard evidence of the risks involved can often be incomplete or even absent. The scientific committees that advise Government on food safety have a key and valued role to play through their consideration of evidence and assessment of risks. Their work may involve a study with no direct precedent, or be part of a routine approval process, or be in response to departments faced with an emergency situation and needing urgent advice. Our key findings were:

- Committees' risk practices vary considerably, largely reflecting differences in their tasks.
- The stages of the risk analysis process (risk assessment, risk communication and risk management) are closely linked and cannot be neatly separated.
- Advisory committees' openness has increased, but communication could still be better.

Risk Analysis

Risk assessment

6. Risk assessment practice varies. Some committees carry out formally structured assessments (see annex 5 for definitions), while others rely more on expert judgement. Our view is that while no single risk assessment formula can be applied to all problems, we believe that carrying out a systematic risk assessment is the best way of approaching risk. There are occasions when this is not practicable, because the information is not available, but a transparent and structured framework to examine, display and debate the nature of the risk, the relative importance of the different components and the options for risk control is nearly always helpful. Most of the committees are systematic in their approach, but we believe that a more rigorous framework for assessment would be beneficial in some cases. It can be particularly helpful where:

- We simply don't know enough about the risk concerned and there is no recognised good practice in risk control; (as for example BSE/vCJD, where so little is known about the transmissible agent);
- existing practice has not kept pace with the scientific understanding of the risk;
- existing practice may be unbalanced, with too much attention paid to some areas and neglect in others; and
- society's expectations of food risks have changed.

7. It is sometimes, but by no means always, appropriate for risk assessments to be highly complex exercises. The value of formal risk assessment lies in the rigour with which the hazards and the populations exposed are identified, risks are estimated and uncertainties exposed. However, the outcomes of some risk assessment exercises may appear to provide clear and precise information about the level of risk, when this is not the case. If little hard scientific data was available for the risk

assessment process, then the outcome will be as imprecise as the assumptions and judgements that went into it.

8. When carrying out risk assessments, committees should therefore bear in mind the principles set out in the Office of Science and Technology (OST) guidelines on “The Use of Scientific Advice in Policy Making”. These principles are particularly relevant where there is scientific uncertainty, a range of scientific opinion and/or potentially significant implications for sensitive areas of public policy.

9. Advisory committees deal with very different kinds of risk problems in varying legislative frameworks, both national and international. Nevertheless, food safety will benefit from achieving more consistent and coherent approaches to risk assessment across committees. Formal and informal communication and links between committees need to be strengthened so that they can be sure that they are taking as consistent an approach as is feasible.

10. Improvements in consistency can only be achieved by detailed comparisons of risks and approaches to them. The work of the Interdepartmental Liaison Group on Risk Assessment (ILGRA) is an essential contribution. Its reports are necessarily detailed and technical, but they need more attention from Ministers and senior officials. Summary guidance is practicable and approachable, and we recommend its widespread use.

Risk Management

11. Historically it has not always been clear where the responsibilities of the advisory committees end and those of the Government begin. Sponsoring departments have not always been sufficiently precise about exactly what risks they were asking Committees to assess or the scope of the risk management work commissioned. The choice of risk management options has always been the

responsibility of Government, and the Food Standards Agency will now have a clear role in evaluating such options and making the decisions, as it is the body responsible for risk management in relation to food safety. It receives advice from the advisory committees covered in this review (some of the committees also advise other Government departments) and uses this advice for implementing risk management or making recommendations to Ministers.

12. It is helpful to distinguish broadly – if necessarily roughly – between two kinds of food risks to the public. Where risks are voluntary, with well understood and accepted implications for society (e.g. eating certain types of shellfish), the role of Government is to put underpinning control regulation in place, then to ensure that individuals are given sufficient information and advice to enable them to make their own choices, with the assurance that a regulatory environment exists to limit the risk (e.g. by banning the harvesting and marketing of shellfish under certain conditions). There are cases where the person who makes the choice is not the one exposed to the risk (e.g. when the choice is made by parents or carers), and particular care needs to be taken to ensure that adequate information is available. In the second kind of food risk, there may be wider or more serious public health or societal concerns, or an individual may have no meaningful choice or vulnerable groups (e.g. children) are involved. The Government then intervenes to protect the public. The banning of particular additives or ingredients provides a good example of cases where the risk can be removed by a simple change of practice in the food industry (e.g. the ban on adding tryptophan to foods and supplements)

13. Where Committees are asked to advise on regulatory options, they will of course be aware that inadequate regulation can have serious consequences for public health or result in damaging long term loss of consumer confidence in a product. But too heavy-handed an approach can impose costs and excessive burdens across society

and ultimately erode confidence by so doing. It is the responsibility of Government to evaluate all the pros and cons of a particular approach. Committees therefore need to put forward a range of options to their sponsoring Department or agency, and spell out their different implications, bearing in mind the principles recommended by the “Better Regulation Task Force” of consistency, transparency, targeting, proportionality and accountability.

14. Risk management is inextricably linked to the other parts of the risk analysis process. This means that some consideration of the ways in which a risk might be managed is necessarily part of assessment and communication. So while committees are not responsible for risk management as such, it may often be appropriate to ask them to consider and advise on options for managing the risk. It is also important that committees make clear to policy makers the assumptions and uncertainties underlying their advice. These principles are especially important for policy makers when evaluating options for risk management and the consequent implications of emerging evidence from monitoring activities.

Risk Communication

15. Transparency throughout the processes of risk assessment and management is essential to ensure public confidence and that the best possible decisions are made. The Food Standards Agency is setting new standards in openness and transparency, for example by holding all its Board meetings in public. We were encouraged that many of the advisory committees are taking steps to open up their procedures and are embracing the principles of openness and transparency set out in the OST guidelines on “The Use of Scientific Advice in Policy Making” and further amplified in “The Review of the Advisory and Regulatory Framework for Biotechnology”.

16. Committees need to be able to communicate well. They need to explain complex ideas to a lay audience and also to listen to what people are saying. This two way process starts with consultation, and continues, with as much openness as possible, at all stages of examining a risk. Committees need to be open from the outset about what is, and is not, known about the risk they are considering and about how the assessment will be carried out, so that the right questions can be asked. This is an iterative process where dialogue with the public (which is not a homogeneous group), as well as policy makers, will help to refine the questions. The outcome of the analysis should be published, and even if there are commercial confidentiality considerations, every effort should be made to be as open as possible. Some committee members and secretariats are already trained to ensure that they communicate effectively and professionally, especially when their conclusions are a “best guess”, rather than a scientifically secure assessment. We believe that more should receive such training.

Conclusions

17. The work of the many committees which advise the Government on food safety is complex and diverse. In the time available to us, we have been able to take only a broad overview. We believe that, in general, the system is working well. But it seemed to us that there were a number of areas where clearer responsibilities and processes, as set out in OST’s guidelines on “The Use of Scientific Advice in Policy Making”, and greater openness would help to strengthen it further. Our conclusions fell into two categories:

The relationship between the Government and committees

- Departments and agencies should ensure that the right questions are asked of their advisory committees when seeking advice on the assessment of a particular risk.

- Departments and agencies should set out any constraints, when asking advisory committees to advise on risk management options.
- Government, and not its advisory committees, is responsible for taking decisions on the management of risk, and needs to take an abiding interest in matters of risk, although committees may be best placed to advise on management options.
- The distinction between voluntary and involuntary risks, the needs of vulnerable groups, as well as the implications for risk management standards need to be fully recognised by both Government and advisory committees.

Best practice for committees

- Advisory committees will usually be helped by following a formal structure for the process of risk assessment, even when the scientific facts are cloudy, disputed or even unknown.
- Advisory committees should be open at all stages of the risk assessment process and in their consideration of options for risk management, and find ways of being as open as possible when there are commercial confidentiality constraints.
- Training should be made generally available to the members and secretariats of advisory committees to enable them to convey the complexities and uncertainties surrounding some food safety issues. We are asking the Cabinet Office to facilitate this.
- Advisory committees dealing with food safety issues should establish better links and lines of communication with each other in order to ensure a coherent and consistent approach to risk. These might be achieved through cross-membership, occasional joint meetings, circulation of papers or discussions between the secretariats.
- Advisory committees should, when appropriate, set out a range of risk management options for policy makers, together with their implications, to avoid placing unnecessary constraints upon the decision-making process.

ANNEX 1

TERMS OF REFERENCE FROM “STRATEGY FOR AGRICULTURE: AN ACTION PLAN FOR FARMING”

The Government’s aim is to use proportionate measures to protect the consumer from risks associated with food. The scientific committees that advise Government on food safety have a key and valued role to play through their assessment of risk. The transfer of responsibility for food safety matters to the new Food Standards Agency provides us with an opportunity to look again at how risk assessment can best be managed across the committees.

The Prime Minister has asked that a review should be conducted by Sir Robert May (the Government’s Chief Scientific Adviser), Professor Liam Donaldson (Chief Medical Officer for England) and Sir John Krebs (Chairman of the Food Standards Agency). The terms of reference are:

- To review the principles and procedures of risk assessment used by the Government’s scientific committees that deal with food safety;
- To consider and recommend, in the light of this review, what strengthening of risk assessment procedures could beneficially be implemented by the committees;
- To consider and recommend improvements to the committee’s risk management and risk communication practices that follow from recommendations on risk assessment.

Membership

The Chief Medical Officer for Wales (Dr Ruth Hall), the Deputy Chief Medical Officer for Scotland (Dr Andrew Fraser), the Principal Medical Officer, Department of Health, Social Services and Public Safety, Northern Ireland (Dr Liz Mitchell) and the Chief Veterinary Officer (Jim Scudamore) were members of the Review group. Dr Jim McQuaid, an independent expert on risk and formerly Chief Scientist at the Health and Safety Executive and Chairman of ILGRA was also asked to join the group

ANNEX 2

Scientific Advisory Committees covered in review and their role

Advisory Committee on Animal Feeding-Stuffs

Advisory Committee on Novel Foods and Processes

Advisory Committee on Pesticides

Advisory Committee on the Micro-biological Safety of Food

Advisory Group on Veterinary Residues (becoming Veterinary Residues Committee)

Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment

Committee on Medical Aspects of Food Nutrition Policy (being established as the Scientific Advisory Committee on Nutrition)

Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

Expert Group on Vitamins and Minerals

Pesticides Residues Committee

Spongiform Encephalopathy Advisory Committee

Veterinary Products Committee

The committees were established by the Ministry of Agriculture, Fisheries and Food and/or the Department of Health to provide scientific advice to the departments to help them carry out their responsibilities for managing food safety. Their primary role has always been the assessment of risk; Government is responsible for decisions on how to manage risk, although sometimes Departments have sought the committees' advice.

The Food Standards Agency was created partly in response to public concern that these processes were not being carried out effectively or transparently. The Agency is now responsible for both risk assessment, on which it will rely heavily

on the advice of Advisory Committees, and risk management decisions (or recommendations on such decisions to Ministers). Close interaction and feedback between the assessment process and the evaluation of risk management options are essential and this is part of the Agency's responsibility. Responsibility for communication of all parts of the process will therefore be shared between the Advisory Committees and the Agency.

ANNEX 3

LETTER TO COMMITTEES

19 April 2000

Dear Chairman

You may be aware that, together with Professor Liam Donaldson and Sir John Krebs, I have been asked by the Prime Minister to conduct a review into the way risk assessment is used by Government scientific advisory committees. The Chief Veterinary Officer, James Scudamore, and Dr Jim McQuaid are also members of the group. Our formal terms of reference are attached.

We need your assistance in carrying out this work. As a first step, it would be useful if you could provide a brief note about ways in which your committee has handled questions of risk. The sort of questions which occur to us include:

- the way in which your committee approaches risk assessment;
- how information about risk is communicated; and
- the role of your advisory committees in risk management.

A member of our secretariat (Carolyn Coote 020 7271 2062) would be happy to expand on our initial thinking, if you would find this helpful.

We will be contacting you shortly to arrange a meeting with my group towards the end of May. I hope that you will be able to attend, or, if you cannot, that a deputy will be able to do so.

I would be grateful if you could provide a response by 19 May. I do realise this is work for you, and I recognise that the deadline is tight, but you will be aware that the Government is anxious for this work to be completed as quickly as possible.

Your response will be really helpful.

Thanking you in advance.

Yours

Sir Robert May

ANNEX 4

SUMMARY OF COMMITTEE RESPONSES

Name of committee	Role in risk assessment	Role in risk management	Role in risk communication	Future Plans/other notes
Advisory Committee on Pesticides (ACP)	Final risk assessments of consumer exposure to pesticides residues and mammalian toxicity are carried out. Also involved in dietary risk assessment. Work closely with PRC.	Is responsible for risk management. Options include withholding/revoking approval or restricting use of pesticide.	Recommendations are published for Ministers. Annual report and minutes of meetings are published.	A guide for lay reader and an annual meeting to hear public opinion in planning stages. First one to be held in September
Advisory Committee on Animal Feedingstuffs (ACAF)	Adopted FAO/WHO risk analysis system as the basis of its approach to animal feed and feeding practises with regards to human safety issues, although little experience as committee is relatively new (set up in June 1999). Liaises with other committees (e.g. ACRE, ACNFP) as required.	Not as yet involved.	Minutes of meetings are published. Reviews and annual reports will be published in due course.	Risk management and risk communication are areas where the committee propose to have a positive role. Also want to discuss the Precautionary Approach at a future meeting.
Advisory Committee on Novel Foods and Processes (ACNFP)	The primary role of the Committee is to identify and assess risks in relation to novel, including GM, foods. It advises the FSA on all novel food safety issues. The EC procedures for assessing risk in these instances are based on the ACNFP's approach. When necessary the ACNFP seeks advice from other committees including COT, COC and COM, and COMA.	The ACNFP's approach helps to inform the risk management process, which under the EC Novel Foods Regulation 258/97 is addressed at Community level by the Standing Committee on Foodstuffs.	The committee plays an important part in risk communication. Its Annual Reports are published and it also produces a user-friendly brochure with inserts that are updated regularly. It also provides advice to Ministers and meeting papers and minutes are available on the Internet. These are all open to comment and there is the opportunity to feed pre-meeting comments into the committee and for responses to be fed back. Press releases announce clearances of individual novel foods.	Committee plans to include observers at regular meetings in addition to current policy of allowing observers at meetings regarding generic issues such as post market monitoring of novel foods
Advisory Committee on the Microbiological Safety of Food (ACMSF)	Principal role is risk assessment. It reports to the FSA and provides the Government with advice in reports, which are used in these areas.	Suggests risk management measures to the Government.	Provides Government with experts for media interviews and would like to be more proactive in risk communication. Ministers publish reports, along with the Government's responses to the committee's recommendations. Website developed to improve openness. Reports, minutes of meetings etc are published on this.	Will consider why risk control is not universally used applied by small to medium size enterprises.

Name of committee	Role in risk assessment	Role in risk management	Role in risk communication	Future Plans/other notes
Advisory Group on Veterinary Residues (AGVR)	Where results of surveillance programmes are above the Maximum Residue Limit (MRL), AGVR will seek advice from FSA and VMD as to whether the concentration poses a risk to human health. Risk assessment involves an exposure assessment and comparisons with results of pharmacological, microbiological and toxicological studies to gauge margins of safety. Also liaises with COT.	Proposes action to manage risk, such as leaflets and posters setting out good practice. AGVR also receives reports on all follow-up activities carried out on positive samples above the MRL and advises on the action taken. Also approves Differential Action Level (DAL) for certain substances where the residues pose no toxicological risk to the consumer.	The AGVR communicates evaluations of risk and risk management measures taken in the VMD's Annual Report on Surveillance for Veterinary Residues. The results are also published quarterly in the VMD's Medicines Act Veterinary information service.	The AGVR will be replaced by the Veterinary Residues Committee from 2001.
Committee on Carcinogenicity (COC)	Remit of COC and COM to give scientific advice to Government on chemicals, mutagens and carcinogens in numerous sectors including mutagenic or carcinogenic effects of chemicals on humans, and on the methodology for investigations. Advice given to DH, FSA and OGD's/Agencies on request. Major part of work looks at hazards of chemicals to humans. Advises on research including carcinogenic risk assessment. Food-related work amounts to approx. 25% of total.	COC has no role in risk management	Openness is encouraged and statements and conclusions of the COC are published and also placed on the Internet, as is their Annual Report.	
Committee on Mutagenicity of Chemicals (COM)	Provides advice on genotoxic chemicals at request of Government. Departments and Agencies. Undertakes independent assessment of the available datasets on specific chemicals and mixtures and provides statements on their hazards. Advice that departments operate on a precautionary principle. Food-related work is about 25% of total.	No role in risk management as they have an advisory role to the Government.	Minutes of the meetings, and assessment of a chemical by the COM are published on the DH website. Reviews of all the assessments of the COM are published in an Annual Report.	COM and COC hold joint meetings on specific topics related to hazard and risk assessment. Reports on these discussions are published in scientific literature.

Name of committee	Role in risk assessment	Role in risk management	Role in risk communication	Future Plans/other notes
Committee on the Medical Aspects of Food and Nutrition Policy (COMA)	Used largely epidemiological concepts of risk formulated in terms of incidence rates, odds ratios and relative and attributable risks	Limited role in use of advice to policy makers	Reports were published	Feels communication between public, policy makers and scientific advisers calls for a national programme of scientific education and acculturation.
Committee on Toxicity (COT)	Uses procedures recognised by EC's Scientific Committee on Food or FAO/WHO Expert Committee on Food Additives for risk assessment. These involve identification of possible adverse effects on humans by toxic elements present in the agent of concern	Have an advisory role to the Government and no specific role in risk management.	Improving openness and transparency of the way in which they operate. They publish reports on their views on chemicals and other related issues and also hold open meetings.	
Expert Group on Vitamins And Minerals	The role of the Group is risk assessment. Detailed scientific risk reviews of each investigated nutrient are prepared and detailed, then released on the Expert Group's website so that other external parties from industry and a parallel EU working group are able to scrutinise and respond as they wish to the reviews before the final risk assessments are made. All separate risk assessments will be re-examined over the 2-year life of the Group to ensure consistency of approach.	Although the Group works closely with the Food Advisory Committee (FAC) who are responsible for risk management and risk communication, the Group may comment on possible risk management options in their report to the FAC due out in Spring 2001.	Minutes and risk reviews are published for public consultation/ feedback.	The Group proposes to use an uncertainty factor of 10 on data derived from animal studies to allow for inter-species differences. Where the pharmacokinetics or pharmacodynamics of a nutrient is known then they may tailor the uncertainty factors to the particular case and use the WHO model(EVM/99/14) as a starting point.
Pesticides Residue Committee (PRC)	Limited involvement in risk assessment relying heavily on methodologies provided by the ACP. Initial risk assessments of consumer exposure to pesticide residues in food carried out. Work closely with ACP. In 1997-1999 updated its consumer exposure modelling with respect to long term and short-term intakes by adopting WHO/FAO recommendations.	Relatively limited because they do not deal with product approvals	Residues surveillance programme results are published in an annual report and also appear on the PSD website. Also publishes a 'consumer' leaflet, and members give presentations to public interest groups to improve openness.	Over next two years moving towards quarterly publication of results.

Name of committee	Role in risk assessment	Role in risk management	Role in risk communication	Future Plans/other notes
Spongiform Encephalopathy Committee (SEAC)	<p>Analysis and assessment of the risk to public health from exposure to TSEs, particularly BSE. Whilst much work is done internally SEAC also commissions advice from external contacts on specific issues.</p> <p>Its main area is risk assessment, which is informed by regularly reviewing research and drawing on scientific expertise. Use quantitative and qualitative, systematic risk assessment procedures.</p>	<p>SEAC informs rather than drives decision-making. Risk management decisions may be influenced by factors that cannot be built into a formal quantitative risk assessment. SEAC offers advice on risk management.</p>	<p>After each meeting, a summary of discussions is published and any advice put to Ministers. Also holds a press briefing after each meeting to improve public understanding of how conclusions were reached, and publishes an Annual Report. Has also published summaries of the SEAC sub-groups and their findings.</p>	
Veterinary Products Committee (VPC)	<p>The VPC considers all aspects of safety, quality and efficacy of veterinary medicinal product. EU derived MRLs are used by the VPC in setting withdrawal periods to protect those consuming products from treated animals.</p> <p>The procedures for establishing ADIs and MRLs are used by WHO/FAO Expert Committee on Food Additives and the EU CVMP. Well established principles of risk assessment based on EU guidelines are applied for safety of veterinary medicinal products contaminating the environment, and less formal procedures are used for in the assessment of risks to persons applying the product to animals, such as organophosphate sheep dips.</p>	<p>Part of risk management is the Committee's recommendations of veterinary medicines sale and supply (i.e. design of packaging etc and whether medicine should be Prescription Only Medicine – POM -, etc).</p>	<p>Information about risk is communicated to the users of veterinary medicines through Summary of Product Characteristics. The results of compulsory and non-statutory surveillance programmes are published quarterly in the VMD Medicines Act Veterinary Information Services (MAVIS) newsletter and the VMD's Annual Report is also published. Summary minutes of its meetings on a VPC website which is expected to go online by 31 July 2000.</p>	<p>VPC intend to place summary minutes of its meetings on a VPC website which is under construction.</p>

ANNEX 5

RISK ANALYSIS

In relation to food safety risk the Codex Alimentarius (the joint Food and Agriculture Organisation and World Health Organisation body responsible for setting international food standards) has the following definitions for risk analysis terms:

Risk - a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard in food;

Hazard - a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Risk Assessment - a scientifically based process consisting of::

- hazard identification;
- hazard characterisation
- exposure assessment; and
- risk characterisation

Risk Management - the process distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed selecting appropriate prevention and control options.

Risk Communication is the interactive exchange of information and opinions throughout the risk analysis process concerning risks, risk related factors and risk perceptions, among risk assessor, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

The Rio Declaration defines a **precautionary** approach as ‘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’. Application of the **precautionary principle** may shift the burden of proof from those who wish to prohibit or constrain an activity, to those who would allow it. However the term has been used rhetorically to justify action based on concerns for which there is no scientific basis. There is a debate about whether precautionary action needs to include the appraisal of costs and benefits of that action.

The European Commission adopted a Communication in February 2000 which underlined that the precautionary principle forms part of a structured approach to the analysis of risk, as well as being relevant to risk management. It covers cases where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU. Where action is deemed necessary, measures should be proportionate to the chosen level of protection, non-discriminatory in their application and consistent with similar measures already taken. They should also be based on an examination of the potential benefits and costs of action or lack of action and subject to review in the light of new scientific data and should thus be maintained as long as the scientific data remain incomplete, imprecise or inconclusive and as long as the risk is considered too high to be imposed on society. They may assign responsibility - or the burden of proof - for producing the scientific evidence necessary for a comprehensive risk assessment. These guidelines are intended to guard against recourse to the precautionary principle as a disguised form of protectionism.

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