Paper Number: ILGRA/MAY/01/03 /Supplement

Meeting Date: 15 May 2001

Open Government Status: *Fully Open*

INTERDEPARTMENTAL LIAISON GROUP ON RISK ASSESSMENT

DRAFT HSC COMMENTS TO MAFF ON "THE INTERIM RESPONSE TO THE REPORT OF THE BSE INQUIRY"

A paper by the Secretariat

The Government's Interim Response to the Report of the BSE Inquiry invited comments from interested parties by 11 May. The attached document is a draft Health and Safety Commission response. **It has not yet been cleared by the HSC.** Nevertheless we thought that it could provide a basis for discussion of paper ILGRA/MAY01/03**.**

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Background

The Commission has already discussed and accepted the specific recommendations in the Philips report relevant to its responsibilities. Its response on these specific recommendations forms part of the Government's Interim Response. The Health and Safety Executive has put work in hand to address the lessons to be learnt and will report the outcome to the Commission.

The purpose of this letter is to consider the Government's Interim Response in its broader context against the very wide responsibilities of the Commission and Executive as regulator across a wide range of risks arising from work - from traditional, well known risks such as injuries from machinery, to major catastrophic risks in the nuclear industry, to emerging health risks such as stress with complex and uncertain causation.

The Commission welcomed the Philips report and it welcomes the Government's response. We firmly support the general principles set out in the response, in particular on "Science and Government", "Openness", and "Risk and Uncertainty". We welcome the opportunity to contribute to the debate and would wish to continue to be actively engaged. Our comments are intended to extend the debate and explore the issues surrounding and underlying the Government's Interim Response.

Science and Government

The Commission fully supports the general principles and policies set out in "Guidelines 2000 - Scientific Advice and Policy Making" and the draft "Code of Practice for Scientific Advisory Committees". However we would like to draw your attention to two related areas of concern which are not addressed by the Government's Interim Response nor the Guidelines nor draft Code. The first of these is the way in which science or scientific advice is separated from other issues which policy makers have to address (only touched on in para 20 of the Guidelines). The second is the challenge in securing the effective implementation of the Guidelines. This requires policy makers to be fully competent and motivated - and to be fully engaged in the debate. Our broad concern is that the current wider debate on Philips has engaged the scientific community but not the policy makers whose roles and responsibilities are critical but little understood and rarely debated including by the policy makers themselves.

Before I come back to these two issues, I think it is worth asking what we now expect of the policy maker - ultimately the Government, but including bodies like the Commission and officials of the Health and Safety Executive. First we expect them to ensure that policy making is based on robust and rigorous evidence. This means in the areas we are talking about not just an understanding of the political, social, legal and financial constraints and consequences but also an understanding of the scientific evidence in its widest sense - evidence from the hard sciences of biology, chemistry, toxicology, material science and from the social sciences of sociology, economics and psychology.

We expect the policy maker to anticipate what evidence will be required for decisions 2, 5 or even 10 years down the line and to put systems and research in place to collect, analyse and report on that evidence. We expect the policy maker to make decisions or recommendations in the meantime which are effective, practicable and acceptable. The policy maker needs to reach these decisions against a rigorous and analytical framework increasely based on outcomes, with baselines, monitoring and evaluation - and to achieve these outcomes in innovative and novel ways. And normally against tight deadlines.

Finally it is the policy maker's responsibility to ensure that at every point in this process, the best advice, including scientific advice, is available to help the policy process.

The responsibilities of the policy maker are therefore primary in the process of bringing scientific advice to bear on the policy making process. However the expectations placed on the policy maker and the competences required are high. How many policy makers have the scientific understanding to see what questions need asking and to realise the implications of the scientific advice available?

The Commission believe that, whatever we do to improve the scientific base via external expertise or research, we will not improve the scientific underpinning of our policy making unless we place the responsibilities firmly on the policy maker and ensure they have the necessary understanding of their role and the competence to carry it out.

Implementing Guidelines 2000

To return to the Commission's concern about implementing Guidelines 2000, the Commission believes it to be a major corporate governance/risk management issue for all Government Departments and should be covered by assessments required by the Turnbull report.

The Health and Safety Executive intend to develop a quality management system and procedures for securing implementation of the Guidelines. This will set out the roles and responsibilities of everyone concerned, particularly the policy makers. It will establish the competences required and provide training and coaching. For policy makers this will include being able to identify the appropriate scientific and technological experts and working with them to define the issues/questions which need to be addressed. It would be useful if appropriate training courses could be made available across Whitehall eg run by the Civil Service College or the Centre for Management and Policy Studies. HSE would be pleased to contribute to the development of such courses. HSE will also be developing and implementing appropriate monitoring and review arrangements to ensure all parties fulfill their obligations.

What will be important in this process is the integration of the implementation of the Guidelines into the work of the policy maker, not as an add on, and the acceptance of the organisation corporately of its responsibilities, and not to delegate them solely to the organisation's Chief Scientist or equivalent.

Integration of Scientific Advice

It is against this background that the Commission views the separation of science and scientific advice from non-scientific advice with some concern. This is not just because of difficulties with definitions (what would fall under the definition of scientific advice and scientific advisory committees and thus under the Guidelines and/or the draft Code?) It is, more importantly, because separating scientific advice from other advice is often not justified, does not reflect the way in which policy formulation generally is, and should, be carried out, and could in some cases divorce the scientific advice from the mainstream of policy making. Much of what is said in the Guidelines and draft Code for example is just as applicable to

"non-scientific" advice provided to policy makers - the degree to which advice should for example be open or peer reviewed should be based on proportionality ie the importance of the decision and the criticality of the advice to the decision.

For many years, the Commission has had a broad range of advisory committees covering particular industries or sectors or particular subjects. The Commission is currently conducting a review of these advisory committees including their functions and structures. Whatever the conclusions of the review, the Commission will continue to need a wide range of advice from a range of different stakeholders via advisory committees of some sort.

None of its existing advisory committees are solely scientific advisory committees; all of them are expected to provide policy advice which goes wider than the scientific. The Commission would expect them for example to consider the political and social implications of what they recommend, the practicalities and the economic impact. We would of course expect the membership of the committees and their competence to reflect this wide role and responsibility.

As part of this process, we would also expect the advisory committees to base their advice on the best available evidence, including scientific evidence where appropriate. Our existing advisory committees obtain this scientific advice in a variety of ways. Some ensure that the necessary expertise can be provided by some of the members. Some committees have set up separate committees to advise on the underlying (generally hard) science. Some rely on HSE to provide the necessary scientific advice. And some obtain their scientific advice from a mix of these methods.

Whether scientific advisory committees are to be treated separately or not, the Commission would urge the Government to recognise the need for flexibility; what is effective in an area where a deep, but relatively narrow, expertise is required may not be effective where a broad range of perhaps less specialised expertise is required. HSC's experience is that representation of scientific experts, stakeholder representatives and lay members on the same committee promotes trust, inclusivity and transparency as well a scientific and technical excellence. **The key is to be clear about the functions being performed at any one time and the roles and**

responsibilities of members at that time. [Sentence in bold to emphasise its importance]

The Commission would also suggest that in some areas high quality scientific advisors are unlikely to be completely independent and may have links with industrial or other organisations with particular agendas. The aim should be to take such affiliations into account, recognise where conflicts of interest may occur and establish how to resolve them. We would not wish to see these experts become less acceptable as members of advisory committees giving scientific advice. Our policy making would be the worst for it.

Research

The Commission would also suggest, under the proposals for managing the research programmes, that the Government again sets out clearly the central role of the policy maker. For the purpose of policy making, it is the responsibility of the policy maker to determine the research needs, ensure that suitable research is commissioned and that the results are fed into the policy process. Often this is done with the help of scientific and technological experts but it is the policy maker who has to demonstrate the foresight and determination to put the research in place. All too often, we suggest, the impetus for taking forward the research falls by default to the scientist, which increases the risk that research becomes divorced from the policy needs and the strategic priorities of Government. The issue is one of communication between policy maker and scientist so that ideas, knowledge and concerns can be shared during the drawing up of the research programme. This is not just a matter of process but of understanding, skills and behaviour.

HSC/Es draft Science and Innovation Strategy recognises that our research is intended to support the full range of our needs as a regulatory body, including policy making, and to help meet our business objectives. In line with the Philips report, this means increasing the amount of social, economic, behavioural and operational research so that our policies take full account of these factors alongside physical scientific and technical advice.

<u>Openness</u>

The Commission has a publicly stated commitment to openness. We are working hard to emulate its standards. For example, we are considering seeking agreement of ministers to publish our advice as the FSA do.

The Interim Response invites comments on other ways in which Government can engender the trust of the public. We are shortly to consult on a framework for prioritising a range of our work that impacts on public health and safety. The criteria for deciding on priorities includes the degree and extent of societal concern. The framework raises a number of issues which we will need to bottom (how do we systematically assess societal concern on fairground safety or domestic gas safety or legionella?). However we feel that this is one way forward in gaining trust and credibility in deciding our priorities.

Risk and Uncertainty

HSC/E decision-making process

We believe that assessing risk and tackling uncertainty are essential parts of a decision-making process. The decision-making process set out in our discussion document '*Reducing risks, Protecting People'* has six stages:

i) Deciding whether the issue is primarily one for HSC/E.

ii) Defining and characterising the issue, including an assessment of the risk and tackling uncertainty.

iii) Examining the options available for addressing the issue, and their merits.

iv) Adopting a particular course of action for addressing the issue efficiently and in good time, informed by the findings of (ii) and (iii) above.

v) Implementing the decisions.

vi) Evaluating the effectiveness of actions taken and revisiting the decisions and their implementation if necessary.

The above stages are not independent of each other and going through the stages is an iterative process. Furthermore, we involve our stakeholders at all stages. Some caution is necessary for those looking for their universal application in our past, present and future decisions. Because the system was developed over time previous regulatory decisions may not be in full accord with them. Moreover, there are often many constraints which prevent the system from being applied fully. For example, most health and safety at work legislation originates from the European Union in the form of directives and their transposition requires the adoption of procedures not entirely compatible with our system. Furthermore, the arrangements are also applied proportionately and with discretion. Finally, there may be time when the need to act quickly may circumvent some of the stages, nor will there be any need to go through the stages if information and knowledge from past decisions can be transposed to inform new decisions.

Role of risk Assessment

We see risk assessment as playing an important role in the above process. There have been some disagreements about the role that risk assessment should play in the regulation of risk. Indeed it has become a recent fashion by some to campaign

against the use of risk assessment in the decision-making process, particularly for large scale risks. Many of the criticisms voiced about the role of risk assessments are based on mistaken beliefs about how such assessments are undertaken and applied. For example, it is often argued that an approach based on assessment of the risks:

- is inadequate since it often reduces the characteristics of what is in many instances a complex issue to a single number and is therefore weak in taking into account societal concerns or other important factors such as the degree of trust between regulators and their stakeholders (see para 21 above);
- often underestimates the true impact of a problem overall. For example, a risk assessment is always undertaken for a specific purpose and with a specific population in mind and may therefore ignore risks to another population;
- is used capriciously to legitimise decisions, for example, to allow an unpopular development in one area but not in another;
- can be misused to present a particular problem as being primarily one of risk and could thereby undermine the adoption of a precautionary approach based on anticipating and averting harm.

However, we hold the counter view that there is overwhelming evidence that, properly used, the results of a risk assessment often provide an essential ingredient in reaching decisions on the management of hazards. The proper use of a risk assessment does not rule out the results of a risk assessment being expressed in terms of a qualitative value rather than a number (this is the case more often than not). It also requires inter alia that:

- the risk problem is properly framed;
- the nature and limitations of the risk assessment are clearly set out and understood; and
- the results of the risk assessment are used to inform rather than to dictate decisions and are only one of the many factors taken into account in reaching a decision.

Uncertainty

In terms of tackling uncertainty, our policy is inherently precautionary and in line with the precautionary principle. Our policy is that the precautionary principle should be invoked where:

- there is good reason, based on empirical evidence or plausible causal hypothesis, to believe that serious harm might occur, even if the likelihood of harm is remote; and
- the scientific information gathered on the nature and magnitude of a hazard, reveals such uncertainty that it is impossible to evaluate conclusively the different outcomes and move to the next stages of the decision-making process.

Good reason to believe that serious harm might occur could be demonstrated by showing that an activity, product or situation is similar to others which are known to carry a substantial adverse risk; or by adducing a sound theoretical explanation (tested as necessary by peer review) as to how harm might be caused.

Though we invoke the precautionary principle for hazards where, because of the uncertainty involved, it is not possible to apply the conventional techniques of risk assessment to assess the risks involved whatever the circumstances, it is possible in practice, to use such techniques for operationalising the precautionary principle. Uncertainty is overcome by constructing credible scenarios on how the hazards could be realised and thereby making assumptions about consequences and likelihoods. The credible scenarios can range from a 'most likely' worst case to a 'worst case possible' depending on the degree of uncertainty. For example, by assuming that exposure to a putative carcinogenic chemical will cause cancer the chemical becomes subject to a very stringent control regime. Though such risk assessments made on scenarios are inevitably narrower in scope than a full blown risk assessment, this may not be a serious limitation if the scenarios are carefully chosen to reflect what could happen in reality.

In addition to invoking the precautionary principle as above there are many other ways in which our approach is inherently precautionary. For example our risk assessment procedures:

- do not take 'absence of evidence of risk ' as 'evidence of absence of risk';
- require that the effects of the assumptions made to cover gaps in knowledge be tested through recognised methods, eg sensitivity analysis;
- build safety factors into the assessment process where appropriate, eg in assessing toxic substances, safety factors are used depending on the quality of data, severity of effect, and whether data from animals or *in vitro* experiments are being extrapolated to humans;
- attach more weight to consequences where a hazard has attributes which makes it likely that it will give rise to societal concerns, such as the potential to affect future generations, or the potential for severe detriment, eg a major explosion in a built-up area;
- make use of comparative risk assessment for novel hazards that bear a similarity with existing hazards, requiring a stringent control regime for reducing risks to tolerable levels.

Turning to some of the questions that you have raised, we have the following comments.

Whether there are benefits from departments developing and managing a more structured system of responsibility for risk management decisions that relate to public health. If so, how might such systems be audited?

We believe that departments would indeed benefit from a more structured system of responsibility for risk management decisions not only to those relating to public health but to health, safety and welfare in general. Departments have already started the process by publishing their framework on how they manage risks. What is now needed are mechanisms for ensuring that those frameworks dovetail with each other and are applied within departments. In undertaking those tasks as far as HSC/E are concerned we benefited from the creation of a unit within HSE for promoting coherence and consistency within divisions in the different directorates of HSE. The unit scrutinises policies from other divisions and has the authority to

challenge policies that do not conform to the framework that HSC/E have adopted. We commend this approach.

Whether the Government takes sufficient account of decision-making procedures that are used in the private sector to cover risk and uncertainty in these areas.

We described earlier the decision-making process used by HSE for deciding how risk should be managed - an approach that has evolved from an HSC requirement in 1983 that all new proposals should be accompanied by a cost benefit analysis. To test the robustness of our approach we commissioned in 1997 AEA technology to undertake research to elicit the practices in different walks of life by which judgements are exercised in making decisions and to explore whether there were any common approaches which decision makers could use to make their decisions robust, consistent and explicable. One of the conclusions of their report1. was that there was no clear correlation between the attributes of decisions and the approaches to making them. Nor was the researcher able to draw any clear conclusions on best practice.

Our approaches for assessing risks etc draws a lot from industry. However, we have been able to use our position as regulator for risks in the workplace to extract good practice from various sectors and make use of this information when developing our risk assessment techniques, protocols, criteria etc. HSC/E are not unique in that respect. A similar approach has been used by some Departments and other regulators. There is enough evidence that the approach works to recommend its adoption within Government. Indeed HSC/E nowadays both at home and abroad are seen as being in the forefront in the development of protocols, criteria and procedures for assessing risks and integrating them together with other inputs such as cost benefit analysis in the decision-making process.

Ways of ensuring transparency of the process that Departments use to take risk-based decisions

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1. "Expert Judgement. An investigation of approaches. A report by AEA Technology for the UK Health and Safety Executive (April 1997). Available from the Risk Policy Unit, Health and Safety Executive, Rose Court, London SE1 9HS.

We believe that this could be achieved by ensuring that the frameworks developed by departments meet the conditions set by ILGRA in their second report, namely:

- Ensuring that the potential or current problem is framed as stakeholders see it, ie shedding the long default assumption that identifying the root of the problem is a matter only for the Departments or Agencies involved;
- Obtaining the necessary data and knowledge for informing decisions, such as the results of an assessment of the risks, the options available for solving the problem and the constraints attached to them;
- Adopting decisions, including the criteria used for ensuring that the residual risks that remain after preventative and protective measures have been introduced are tolerable to those affected and to society at large;
- Implementing the decisions using the range of instruments available to regulators and enforcers for that purpose, education, information, assistance, persuasion, promotion, economic incentives, regulation and enforcement ;
- Evaluating the effectiveness of the action taken to make sure that the action taken resulted in what was intended and to identify lessons to be learned to guide future risk management decisions;
- Actively engaging stakeholders in all stages of the above process so that they can influence the assumptions and value judgements that permeate the whole procedure, and hence concur more readily with decisions emanating from it.

How best to communicate low risks, when there is uncertainty associated with the assessment.

Communicating low risks when there is uncertainty represents a challenge for regulators. However, since there is no such thing as an activity with zero risk, we would advocate an approach where the use of the word ‘safe’ could not be misconstrued as implying an absence of risk, or a guarantee of safety, particularly in circumstances where the communications are under our control, eg press releases.

Our favoured approach is to provide stakeholders with the information about the risks and the benefits of a particular activity and to emphasise the concept of tolerability as described in our discussion document '*Reducing Risks, Protecting People.*

On the other hand, there will be situations where the risk is not as low as we would wish it to be but where we believe the risks can be reduced without having to resort to shutting down the activity concerned. In such circumstances, we have a role as regulator in providing reassurance to the public by explaining that the situation is "safe enough for the time being" and spelling out the degree of risk and the benefits of continuing the activity albeit with some restrictions, whilst ensuring that the duty-holder takes action to reduce the risks to the level we require.

How the Government might best develop guidance on contingency planning and for assessing policy options

Approach advocated

1. We believe that guidance can be developed requesting departments to:

a. set up mechanisms for identifying potential emerging risks;

b. share with other departments their findings and control measures for identifying the potential risks identified;

c. Identifying options and their merits for addressing these emerging risks;

d. In undertaking (iii) above take account that risks is not a 'respector' of the boundaries of responsibility amongst departments. This makes it necessary to ensure that an integrated view is taken across all departments of the risks associated with a particular hazard. Very often an option which looks tolerable from a narrow departmental view might not be so when view across Government as whole because the option would create or increase another type of risk that is the responsibility of another department.

2. Currently HSC obtains information about emerging risks from the following sources:

Statistical intelligence

Statistics obtained from notification systems

3. These include:

Notifications required under health and safety at work legislation[2].

Dutyholders are required to notify certain:

- injuries (e.g. fatalities, amputations, loss of sight of an eye, or accidents where the injured person is admitted to hospital for more than 24 hours);
- dangerous occurrences (e.g. failures of pressure vessels or pipelines, collapses of scaffolding or buildings under construction, unintentional ignition of explosives); and
- ill-health conditions diagnosed by a medical practitioner (e.g. poisoning by mercury, methyl bromide or lead; occupational asthma from work involving isocyanates or platinum salts; asbestosis; and vibration white finger in various occupations).

4. In 1999/2000 HSE received approximately 150,000 reports of injuries. These statistical data are studied eagerly for trends, undetected hazards etc.

The Pesticides Incident Appraisal Panel.

5. This panel collates the pesticide incident data from cases investigated by HSE and Local Authority inspectors and shows a picture of emerging problems; for example a cluster of cases related to a particular pesticide.

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[2] **Notifications of incidents come to HSE from duty holders under the Health and Safety at Work etc. Act 1974 by virtue of requirements in The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995.**

The disease specific notification systems.

6. These involve occupational physicians notifying the HSE of cases of illness they believe to be occupational in causation (ODIN, the Occupational Disease Information Network).

Surveys

7. The population surveys (eg Labour Force Surveys) to which HSE contributes questions once a year. These complement the data from notifications, as there is known to be a significant level of under-reporting. Again these provide major contributions for assessing trends and risks that should be tackled both from the point of view of the public and the regulator (eg the need for action on stress and musculoskeletal injury);

Operational intelligence

8. HSW Act inspectors are a formidable source for detecting new risks. During the course of their duties they acquire considerable information about new developments and changes that have implications for health and safety. For example HSE alone conducts 185,000 inspections, and investigations of accidents, disease and complaints. Inspectors are encouraged to report new/unusual findings to Sector Groups so that 'patterns' can be established and further investigation made and risk control policy developed.

Analysis of trends

9. HSE scans horizons for trends and the hazards that advances in technology etc can give rise to. Typical exercises of this kind comprise:

- The scanning of Technology Trends databases. HSE scans these databases for health and safety implications of scientific and technical developments. This has proved useful for predicting:

- The accelerating pace of change in automation, computer and information technology and communications and how they impact on workplace equipment and processes but also on wider working and leisure patterns and practice;
- The use of computer based design and modeling and their associated risks as a replacement for the traditional build, pilot and 'test to destruction' approach;
- The increasing pressures for recycling, brown site development and greater push towards decommissioning, decontamination and reclamation of land.

- Analysis of trend in occupational mortality and morbidity, e.g., The 'Decennial Supplement' that HSE publishes with the Office of National Statistics (ONS). This produces hypotheses that HSE then explores to see whether there really is an emerging health risk (e.g. prostate cancer and occupation). In this example HSE shares its analyses with the Department of Health. HSE always take steps to bring its science of relevance to the attention of others in Government, and routinely publish.

Advisory Committees

10. Early warning of risk issues is also provided by a series of advisory committees established to advise the Health and Safety Commission. These committees are multi-partite, comprising representatives of employers, employees, NGOs and independent specialists. They provide forums in which members can raise concerns and share good practice.

11. Some of the advisory committees cover an industry sector such as agriculture or railways; others cover a specialist topic, e.g. genetic modification, nuclear safety and toxic chemicals. Most will have, as a standing item on their agendas, a forward look, which is intended to provide early warning of risk issues on the horizon to the Commission and HSE. The outcome may be, for example, research to investigate further, or a particular inspection/compliance initiative.

Research

12. HSE also uses the results of research to identify and evaluate the significance of new hazards and their potential impact. For example:

- HSE has established a specific programme of research based on inviting ideas from outside HSE. The programme has been designed to invite proposals aimed at identifying and evaluating newly emergent risks.

- HSE (in collaboration with other Government Departments) has commissioned four separate research projects examining the role of the media in the amplification and attenuation of risk issues among the public. These projects are just coming to an end. They have identified some of the mechanisms and factors which influence public opinion - in particular why hazards and events that experts regard as presenting relatively low risk become a focus of social and political concern; and conversely why other risks, which experts consider present a high risk, do not catch the public imagination.

Sharing with other Departments

13. We share a lot of our findings with other departments. For example:

- Our analysis of trend on occupational mortality and morbidity with the Department of Health;
- The findings of the Pesticide Incident Appraisal Panel is fed back into the pesticide approval system;
- Relevant research findings;
- Work is about to begin to turn the findings of the research on the amplification and attenuation of risk into practical guidance for policy makers in Government Departments to enable them to recognise and plan for the processes of amplification and attenuation, and should provide a way of predicting hazards and risks likely to create a socio-political response. The guidance will be developed by the original sponsoring Departments and co-ordinated for Government-wide use through the "Interdepartmental Liaison Group on Risk Assessment (ILGRA)."

14. Nevertheless, we believe that the Government would benefit from the setting up of more formal systems for sharing findings on emerging risks, monitoring the likelihood of their actual emergence and planning commensurate measures to possible threats.

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