

A European Food and Public Health Authority.

The future of scientific advice in the EU

December, 1999.

PREFACE

This report is in response to a request by the then Director General of DGXXIV, H. Reichenbach to undertake a reanalysis of the organisation of scientific advice in the light of the last two years experience with the new system of expert recruitment and working procedures. Our report has evolved over several months in response to a number of inputs, public hearings and discussions with organisations and individuals in Europe and elsewhere. We have greatly benefited from the administrative support of our colleagues in DG SANCO: Takis Daskaleros, Daniele Dotto, Stephen Hutchins and Jeannie Vergnettes. The views presented in this report are our own.

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Appendix 1 Mandate

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Executive Summary

The mandate for this report is set out in Appendix 1. The mandate relates to arrangements for providing scientific advice to the Commission. The system changed markedly in 1997 and has been further developed in October 1999 during the course of our deliberations. The recent success of the EU in establishing its scientific advisory system within Directorate General XXIV, now termed SANCO, with its responsibility for public health and consumer protection now needs to be developed further for many reasons as listed in the Table below.

The need for restructuring the arrangements for scientific scrutiny and action within the EU.

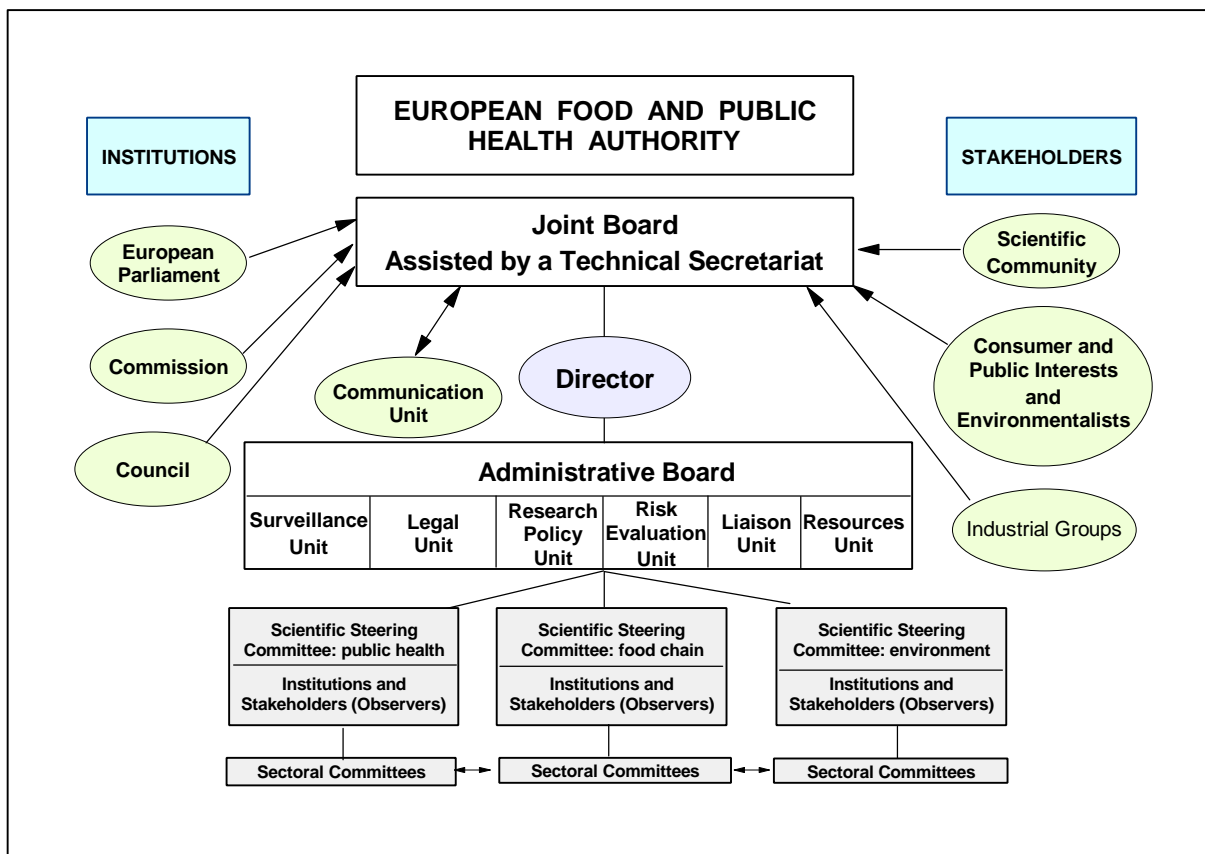
- ❖ The Amsterdam Treaty emphasised the need to include health issues in policy making and action at a European level.
- ❖ The health of children and adults is markedly different within societies and across Europe and is explained by, social and environmental conditions, diet and smoking habits.
- ❖ The EU's enlargement will amplify these differences because the markedly greater burden of ill health in Central and Eastern Europeans will highlight public health problems of the EU.
- ❖ There is currently no coherent EU surveillance system dealing with public health and its principal determinants.
- ❖ Intense public, parliamentary, industrial and international concerns relate to agricultural, food and environmental problems as demonstrated by the BSE and dioxin crises and the beef hormone disputes of the last few months.
- ❖ The public's confidence in both governmental and scientific analyses and actions has declined because of a perceived bias towards political and industrial rather than consumer interests.
- ❖ Industrial groups, keen to produce novel biotechnological or other products, are exasperated by the complex and protracted system for clearing their products.
- ❖ Few Europeans understand or accept the present system of accountability in Europe where national Ministers, the Commission and European Parliament all seem to be involved, but where responsibility for specific issues or crisis management is hard to discern. This disjointed responsibility accentuates consumers' concern when major scares and problems develop which may affect their health.
- ❖ Current EU scientific analyses, policy-making and safety auditing are currently perceived to be isolated from any effective public or parliamentary scrutiny. This may have contributed to the public's disenchantment with European affairs

On the basis of these concerns and the expected enlargement of the European Union, the four options proposed by the Commission in its mandate were examined with help from a number of individuals and external bodies (Appendix 2). In addition a Hearing was held for Commission officials from all the related DGs and Agencies. The four options were a directorate within a current or new Directorate General, an independent Commission service, an inter-institutional office or an independent agency. Each of these mechanisms, as currently established by the EU Commission, has both advantages and disadvantages and other options are possible. The proposal presented in this report is initially confined to the mandate which essentially concerns the process of risk assessment, as part of the provision of scientific advice. The mandate includes public health issues which in non-Member States, e.g. the US, are primarily the responsibility of special centres such as the Centre for Disease Control (CDC) in Atlanta. Unfortunately there is no comparable organisation in Europe. Organisations such as the CDC has a crucial influence in ensuring that the activities of industrially sensitive issues such as those handled by the FDA are geared to public health concerns. Some of the benefits and drawbacks relating to the development of a system analogous to the U.S. Food and Drug Administration (FDA) are also set out.

In principle there should be a system for providing scientific advice which is independent, transparent, of excellent scientific quality and capable of being readily understood by non-experts, by Parliament, Member States and industry, as well as by the Commission. There is also the need to have the capacity to respond rapidly and effectively to issues of public, industrial and political concern. This will require novel arrangements. It is concluded that current scientific advice relates to many areas in addition to those of food safety and that these other public health issues are in health terms a greater burden on society than the effects of poor food safety which has dominated thinking so far. It is noted that currently the assessment of drugs is conducted by a European Agency for the Evaluation of Medicinal Products (EMA), based in London. The present proposal is that the new institution should deal with all other public health, environmental and food issues. A Brussels based organisation is considered essential to allow very rapid interaction with the Commission, the European Parliament and Member States. This is particularly important during the crises relating to food and health which can be expected to recur. The proposed system should have many of the features of the present inter-institutional system, i.e. OLAF, in order to cope with the scale of the problem, the need for urgent action and the desirability of a proper interplay with the major EU and Member State political and public bodies as well as the public and industry.

The overall structure of the proposed new organisation is shown in Figure 1. There needs to be good Member State interaction detailed conjoint work with international organisations and a scientific and administrative capacity to support the scientific work and to develop a series of effective units..

Figure 1: The proposed structure of the new EU institution



To signify the different nature of this organisation, it might be called an Authority rather than an Agency. It would have some parallels with the US Food and Drug Administration, but be seen to be more independent of political and industrial interests. It would link closely with the Commission. The title European Food and Public Health Authority (EFPHA) would signify the parallels but substitute public health concerns for the drug assessment and drug surveillance work which is dealt with by analysis and needs to include groups and mechanisms for ensuring:

- ◆ An effective system for monitoring European Public Health. This will require a totally new approach at a European level with some EU nations developing surveillance systems for health for the first time. In addition there will be a need for the audit of national surveillance and control processes. Surveillance systems using comparable techniques will be needed to assess trends in public health and problems relating to the food chain. The Environmental Agency will also provide

input. The appropriate techniques for this surveillance should be evaluated by the EFPHA.

- ◆ Policy analysis and options for policy developments for ensuring public health to all Member States. This will link the risk managers within the Commission.
- ◆ A legal unit for evaluating the implications of scientific opinions relating to regulatory and legislation proposals. Regulations and laws will continue to require processing by the Commission, reference to Parliament and co-decision making with National Ministers.
- ◆ A research analysis and research policy group: there is a need for the Commission to develop a coherent programme of research of relevance to public health and food safety, e.g. as in the US FDA system
- ◆ A communications unit to operate directly for the EFPHA.
- ◆ A role in crisis management. The Authority has to be involved in crisis management. The institution's function is not assumed to extend to regulatory and control responsibilities as well as those dealing primarily with scientific advice. The practices of policy making, research, management and the auditing of measures relating to public health, the food chain and the environment are often currently dealt with separately by a number of European and Member State organisations. The scientific committees at present provide risk assessments which contribute to risk management decision making. Issues of political or industrial concern are also put to the committees. The current risk assessment process, however, has negligible input from those dealing with issues of risk management, on practical options for change or on the validity and effectiveness of control measures. So the committees are handicapped in providing a realistic and valid analysis of the true risks currently faced by the European consumer. It is clear that the public wish to know the true risks of different measures. Confining a new organisation to providing advice which is divorced from the realities of what consumers have to confront will lead to further disenchantment with the European system for assuring public health and is therefore unwise.

These components would allow the EFPHA to relate openly to the European public but also interact with the European Parliament and with Member State organisations as well as with the Commission.

The Authority would need to have substantial scientific support as in the US FDA and new mechanisms for engaging with other major international organisations, e.g. the

OECD, OIE, WHO and FAO. On controversial issues, members of these other organisations should be invited to take part in the committees assessing risk.

The Authority should be run by a Board of 9 people chosen for their independence and breadth of vision. Member State, Commission and Parliamentary should be involved in the appointment processes. Consumer, public health, environmental and industrial groups should be consulted.

Funding for the Authority should be mostly from public sources and be determined by the Commission and Parliament but with part of the funds coming from charges made for work done, e.g. in scrutinising novel foods and processes. Experience with BSE has demonstrated that major issues of intense public concern cannot be left to the market place but clearance of new pesticides, additives, novel foods, cosmetics, GMOs, consumer utensils etc. could properly be considered as involving an appropriate fee. The system could be developed taking account of the EMEA's experience whilst recognising that the charges would need to make allowances for the industries involved.

1. BACKGROUND

The authors were asked in May 1999 to undertake an analysis of how the European Union might improve on the recent organisational changes in the provision of scientific advice which the EU introduced in response to the BSE crisis. The Mandate is set out in Appendix 1.

The European Parliament had become concerned in 1996 that the European Commission was not taking the threat of BSE seriously enough following the UK announcement of a probable link between BSE in cattle and v.CJD in humans. Their accusation was that the policy-making, auditing and formal safety controls governing the food chain were not being primarily conducted in the public's interest. In an EU context, many Parliamentarians expressed concern that the compromises involved in achieving consensus decisions in Standing Committees also involved the Committee being linked directly to the EU Directorates concerned primarily with industrial and internal market issues and the needs of the agricultural industries.

The provision of scientific advice and the development of standards in the EU were originally substantially geared to smoothing out the discrepant national regulations which in practice were becoming barriers to trade. Since the 1992 Edinburgh Summit there has been an emphasis on subsidiarity whereby national bodies were brought back into the process of analysis and with a Council of Ministers demand to limit the Commission's role only to resolving disputes or discrepancies between national systems of regulation. Given the additional need for rapid industrial clearance of new products or processes, a set of new EU procedures were developed to ensure that the initial clearance of a product by one Member State did not lead to long delays while other Member States considered the original clearance. The Commission then became involved with its own scientific review when objections arose. In relation to some food processing legislation, however, the legal EU texts still required the mandatory consultation of the Scientific Committee for Food before Community approval and did not require initial risk assessment by Member States.

The locations of the scientific committees within the Commission's industrial and agricultural DGs were seen by consumers, other public health interests and European Parliamentarians concerned by the BSE crisis as indicative of the dominance of industrial interests and a neglect of consumers' safety and well-being. In response to this Parliamentary challenge, the Commission in 1997 dissolved the principal advisory Scientific Committees and transferred staff from a variety of directorates to expand the Directorate General (DG XXIV) responsible for representing and safeguarding

Consumer interests. The committees responsible for the evaluation of medicines and the protection of workers were not included. In practice the Directorate General (DGXXIV) had, until then, been concerned mainly with the economic interests of consumers. This reorganisation was therefore seen to reflect a fundamental change in thinking for the Commission. The transfer of the committees to DGXXIV was considered therefore a crucial move in symbolising the shift in the Commission's position. The Commission also displayed its renewed commitment to excellence, independence and transparency in the procedures it developed for recruiting experts. Experts' particular financial interests had to be specified, there was a renewed emphasis procedurally on independence and a new approach to transparency. The new DGXXIV development involved an open competition in June – September 1997 for new advisory committees, supported by a scientific secretariat with responsibilities to ensure that industrial or political pressures did not impinge on the Committees' deliberations.

During the course of our deliberations major changes have occurred with the advent of a new President and Commissioners. There has been a restructuring of some Directorate Generalates and this has reinforced the new role for DGXXIV. The small section of DGV dealing with public health issues and health promotion, the component of DGVI concerned with animal and plant health, veterinary matters relating to public health, animal feed and issues relating to infringements in these specific fields have been incorporated into DGXXIV which is now termed DG SANCO. Furthermore, the new responsible Commissioner has a more focused role than his predecessor. Table 1.1 sets out the current disposition of responsibilities.

The mandate for this work is narrow in scope since it, in effect, specifies the risk assessment process as the principal issue to be addressed. This report accords with this mandate but adds a dimension of thinking to address some of the bigger issues now at stake. A strategic approach is taken, recognising that the development of new arrangements must be seen as part of a coherent system in an expanding EU where the European public needs to be reassured by explicit processes and practices which demonstrate that their health and well-being are being safeguarded at a time of extremely rapid societal and industrial change.

In this analysis other issues are included appropriate for the next 10-20 years as the Union expands and takes on a wide range of responsibilities commensurate with the increasing international role of the European Union.

Table 1.1

Map of the different Community authorities relating to Health and Consumer Health Protection issues with a designation of their status after the October 1999 reorganisation of responsibilities.

<u>Risk Assessment</u>	<u>Risk Management</u>
<p>DG SANCO Scientific Committees: all consumer health issues (see mandates in Appendix 3)</p> <p>EMEA - authorisation of pharmaceutical products (in the field of human medicine and veterinary medicine)</p> <p>DG EMPLOYMENT AND SOCIAL AFFAIRS Scientific committee Protection of the health of workers</p>	<p>DG HEALTH AND CONSUMER PROTECTION</p> <ul style="list-style-type: none"> - Rapid alert system - Management of the general directive on the safety of consumer products - Inspection (FVO - Food and Veterinary Office) <p>(from October)</p> <ul style="list-style-type: none"> - Responsible for veterinary legislation, (animal health and public health), hygiene of products of animal origin, animal feed legislation, pesticides (authorisation of pesticides and MRL), - Responsible with DG Trade for the management of external relations related to SPS (Sanitary and Phytosanitary Agreement) - Responsible for Public Health legislation (e.g. tobacco, in the future blood products) and Health Promotion <p>DG ENTREPRISES</p> <ul style="list-style-type: none"> - Food legislation: (additives, material in contact flavours, contaminants (except pesticides), technological aids, dietary products, general hygiene directive, Novel food, irradiation) - Cosmetics - Medical devices - Part of chemical products (shared with DG ENV) - Pharmaceutical products - -Responsible with DG Trade for the implementation of the TBT (Technical Barriers to Trade) agreement (GMOs, labelling etc.) <p>-</p> <p>DG AGRICULTURE -Wine legislation</p> <p>DG ENVIRONMENT GMOs (release in the environment)</p> <ul style="list-style-type: none"> - Chemicals (authorisation of new substances and re-evaluation of old substances) - Radio nuclear protection - Air and water quality <p>-</p> <p>DG EMPLOYEMENT AND SOCIAL AFFAIRS</p> <ul style="list-style-type: none"> - Legislation for the protection of workers
<p><u>Potential technical support</u> (scientific studies) analysis of products</p> <p>JRC ± REFERENCE LABORATORIES + DG RESEARCH</p>	

2. CURRENT UNRESOLVED ISSUES IN GAINING PUBLIC, PARLIAMENTARY AND INDUSTRIAL CONFIDENCE IN THE EUROPEAN HANDLING OF PUBLIC HEALTH ISSUES.

In the light of special hearings for Commission officials, consumer organisations, industry and following the European Parliaments preliminary analysis of the problems of coping with food crisis, it is clear that there are a number of unresolved issues. Perhaps inevitably there are intrinsic differences in the approach of the public, of industry and of the managers of risk. Part of the problem is therefore how to take account of these different sectors' perspectives and needs whilst being clear that any new system must operate primarily in the public interest.

All three sectors agree that they seek to have scientific analyses and advice which are independent of sectoral or political influence, of excellent quality and with transparent procedures.

All sectors also wish the system to be effective and able to deliver comprehensive opinions within a reasonable time. Nevertheless, the interpretation of some principles by the public, industry, the Commission and by Parliamentarians can be very different. The perspectives of the different sectors are now set out.

2.1. Public confidence

The public's attitude to public health issues naturally depends on the information and analyses presented to them by the media and by those opinion leaders whom they have come to trust on the basis of their own experience. EU surveys show that the public has the greatest faith in consumer representatives and the media with political parties, government agencies and the Commission being least trusted. The public's attitude is naturally also geared to their own concerns and to the perceived impact of governmental processes on their lives. It is now well recognised what features of policy making induce the greatest concern for the public. The more distant and obscure the decision-making process and the more uncertain but life-threatening the consequences of decisions made elsewhere, the greater the anxiety; when decisions also seem to be either made or heavily influenced by industrial or political forces with little concern for the public's welfare, then the greater the public's anger. The maximum response seems to relate to food issues which from time immemorial have been - in all cultures - recognised as a matter of life and death. If scientific advice is to be organised so that public confidence in European judgements and actions improves, then account needs to be taken not only of the public's general approach to new developments but also

whether health education or simply the provision of information is particularly valuable.

When a group of Western Europeans with varied backgrounds and encompassing the full range of intelligence is given the opportunity to evaluate, with meticulous expert help, the nature of scientific decision-making over issues such as the use of genetically modified organisms, or the risks of BSE, the outcome is, perhaps surprisingly, to increase not to decrease their anxiety. The citizen groups come to realise that their individual welfare is dependent on decisions made on the basis of so much uncertainty. Thus the traditional governmental and scientific approach which presumes that ignorance is the real problem in matters relating to environmental and health hazards and that public "education" is the key to solving the problem is wrong. It is now increasingly recognised that the public, through the analyses conducted by the media, need also to be reassured that there is an excellent, independent and transparent system of scientific analysis of the highest standard. Additional systems need to be in place to show the links with policy-making, risk management, control and audit processes which are capable of rapid and effective action. All of these components need to be conducted by groups or individuals who are able, trustworthy and manifestly operating in the interests primarily of the public with transparent structural arrangements demonstrating their effective interaction.

Despite the transfer of the scientific advisory system to DG SANCO and its removal from direct industrial pressures, the present structure makes, on this basis, only a modest contribution to public confidence. It is claimed that there is still no real mechanism for either the public, opinion leaders or the media to find out rapidly how the EU system works, whether it is operating in the public interest, who responds to the analyses of risk, whether the response automatically induces risk reduction processes, who controls these processes and what reassurances there are that any delay or failure is highlighted and remedied. The population naturally judges matters on the basis of its experience of crises and how these are handled. It is also particularly interested in the link between the recognition of a problem, its evaluation and its rapid resolution. Thus the conventional scientific, official and political distinctions between risk assessment, risk management, with appropriate audit and control systems and the process of risk communication are irrelevant in the public's mind. The distinctions which are crucial to effective working (see below) are often seen by the media and public as counterproductive particularly if it means that different groups can pass the blame from one to another.

It is evident that each constituent of the EU's chain of scientific evaluation, management and communication provides a highly professional and appropriate input. There are also entirely proper answers to each of the challenges made by the consumer groups but the overall impression is that the drawbacks of the present system are such that public confidence will not grow unless there are structural changes in the way these issues of intense public concern are handled.

On the basis of these concerns it is considered that the current system within DG SANCO is useful because it allows debate and the evolution of scientific analyses. Nevertheless, the system itself needs further reform to bring it into the public domain, i.e. to enhance transparency. It also needs to include stakeholder involvement, to become accountable, i.e. democratically responsive to people's concerns and to allow a clear communication system which also vividly displays how the scientific assessment system links with both the effective management of crises and the steady rigorous and rational pursuit of higher health and environmental standards in the public interest. There is also a need to target the outcomes of scientific analyses and policy decisions to appropriate societal groups. The public needs to see that there is consistency in legislative process and a proportion in risk/benefit decision-making. All these factors are missing at present as far as the public is concerned. Thus currently there is no public involvement with the committees' work, no real parliamentary scrutiny or linkage of any substance and a communication scheme which usually simply puts the minutes and scientifically written reports on the internet without explanation or interpretation. As far as even a relatively sophisticated member of the public is concerned, there is no evidence on why particular mandates are provided to the committees, no information on what will happen to the reports, no explanation of how these reports are dealt with in the Commission, what leads the Commission to propose different or modified proposals to those produced by Scientific Committees, what constitutes a Standing Committee, why they have such influence. and how this links to Parliamentary Scrutiny. On any reasonable grounds the European citizen will conclude that there is a democratic deficit in handling citizens' concerns and that the current system is an excellent scheme for ensuring that no single group takes responsibility and is accountable to the people. The present proposals take these issues into account.

2.2. Parliamentary involvement

Three factors reflect the great importance now being placed on consumer interests, health and the environment within the EU. First is the clear recognition in

the Maastricht and Amsterdam treaties that health issues deserve a higher priority at EU level. Secondly is the decision by the last Parliament, for the first time in its history, to threaten the Commissioners' positions on the grounds of their handling of the BSE crisis. Third is the recent and, to the media, surprising decision of the new majority EU parties brought to power following the June 1999 elections, to select preferentially the chairmanship of the environment, public health and consumer policy committee rather than chairmanship of other committees dealing with the traditional areas of the EU's power. This reflects Parliamentary recognition that this area is now of very great significance for both Parliament and the Commission.

There has been parliamentary committee debate about the extent to which the European Parliament should scrutinise or be involved in ratifying opinions such as the recent SSC analyses of BSE in relation to the British Date Based Export Scheme. Originally MEPs demanded to be involved in the process of scientific evaluation but this was not taken further other than by their holding two public hearings with the Commission on issues relating to BSE. No special communication channels seem to have been opened between the independent scientific committees and the European Parliament so scientific committees are unaware of specific Parliamentary concerns or requests. There is also, at present, no strategy for any conjoint involvement of parliamentarians in the processes of EU crisis management. Thus there seems to be no clear focus of EU Parliamentary involvement when specific proposals are put by the Commission on consumer, health and environmental issues to a scientific committee. How to improve Parliamentary interaction has therefore been one of the considerations in this report.

2.3. Industrial confidence.

Industrial interaction at an EU level – perceived by many as lobbying – is a valuable input to the Commission and certainly sensitises officials to the potential impact of decision-making. When the scientific advisory committees were based in DGIII and DG VI, the officials serving the committees had numerous demands for meetings with industry and were often provided with industry's position papers before and after the scientific meetings. Only some of these papers were made available to committee members, presumably because officials were protecting the committees from undue industrial pressure.

This raises an important issue of how to achieve the right balance between independence and transparency and the sometimes extremely valuable technical input that industrial groups can provide to the risk analyses and the implications of these assessments in practice. A mechanism for gaining the benefits of industrial interaction without prejudicing the independence of the committees has therefore been a major issue in the preparation of this report.

Analyses of company attitudes suggest that the technologically innovative are particularly anxious to have a rapid scheme for assessing novel products which need approval. Industrial pressure and the needs of Member State governments and the Commission to reveal themselves as welcoming innovation led, for example, to the current system for assessing novel foods or novel food processes whereby 90 days are allowed for the first evaluation of a novel product with subsequent assessments by other Member States having to be dealt with within 60 days. Such rules have led to a complete change in management and assessment strategies within some Member States but there is still pressure from industrial and innovative scientific groups to abolish the need for a third full evaluation by the EU itself. Effort is also being put into a demand that the EU no longer has the right to "stop the clock" during the risk evaluation if a Member State objects to the original analysis of a novel product by the principal Member States involved. The "unnecessary" duplication of evaluation procedures is also cited as a distinctive disadvantage of European evaluation schemes compared with the single and supposedly rapid procedure held, for example, in the US by the Food and Drug Administration (FDA). In practice recent evidence shows that the FDA take a substantial time to consider many new proposals but the FDA process is seen to be much simpler. For these reasons large multinational companies tend to favour the development of a major overarching mechanism for obtaining scientific scrutiny and agreement on new products. Several industrial groups have also indicated that they now feel somewhat detached from the scientific evaluation process. Indeed they consider themselves as often having the most expert understanding of scientific issues and the implications of different policy options.

The large multinational companies perceive substantial advantages in the development by the EU of a single set of standards with which industry needs to comply throughout the EU. With appropriate EU standards, large companies can put substantial resources as a single company or on a conjoint basis into maintaining a presence in Brussels so that they are aware of new EU developments and can highlight potential problems.

The attitude in smaller companies is very different. Small businesses, however, find it difficult to sustain financial and clear purposeful support from their constituent groups for interaction with the Commission or with the European Parliament. In some Member States, many companies in the food business with large turnovers of 50-100 million ECUs have only a very few technical staff. Most food manufacturing involves a very large number of small companies: about 80% of food companies in Europe are so small that they rarely have staff who have the time or motivation to understand EU rules and regulations or the basis for these in the scientific advice produced by expert committees. This implies that any new scheme which is proposed should consider mechanisms for communicating effectively to small companies as well as to the public in readily understood language.

3. ESTABLISHING A SET OF PRINCIPLES FOR ANY NEW ORGANISATION RELATING TO SCIENTIFIC ADVICE.

Many of the principles relating to scientific advice are universally accepted whereas others have become evident during the course of our analyses and hearings: they can be summarised as follows:

3.1. Scientific advice should be:

- excellent in quality
- independent of industrial and political interests, and extreme public lobby groups.
- transparent in the manner of its development
- realistic in terms of specifying the actual risks and benefits in practical circumstances
- effective in terms of the coherence of the proposals and the time taken to come to conclusions
- understandable by the Commission, Parliament and Member States but also by industry and the public.

The following principles should also apply:

- A location in Brussels to ensure detailed interaction with legislative, regulatory, audit, policy, management and other groups within many Directorates of the Commission.
- A powerful involvement with public interest groups.
- Direct accountability to elected representatives in the European Parliament.
- The need for the new body to be sustained by public funds since crises such as those relating to BSE, beef hormones, dioxin, Coca Cola and GMO problems are not manageable if the resources are dependent on industrial funding.
- The capacity for playing a major part in crisis management when these actions are traditionally seen as the responsibility of the Commission as well as Member States.

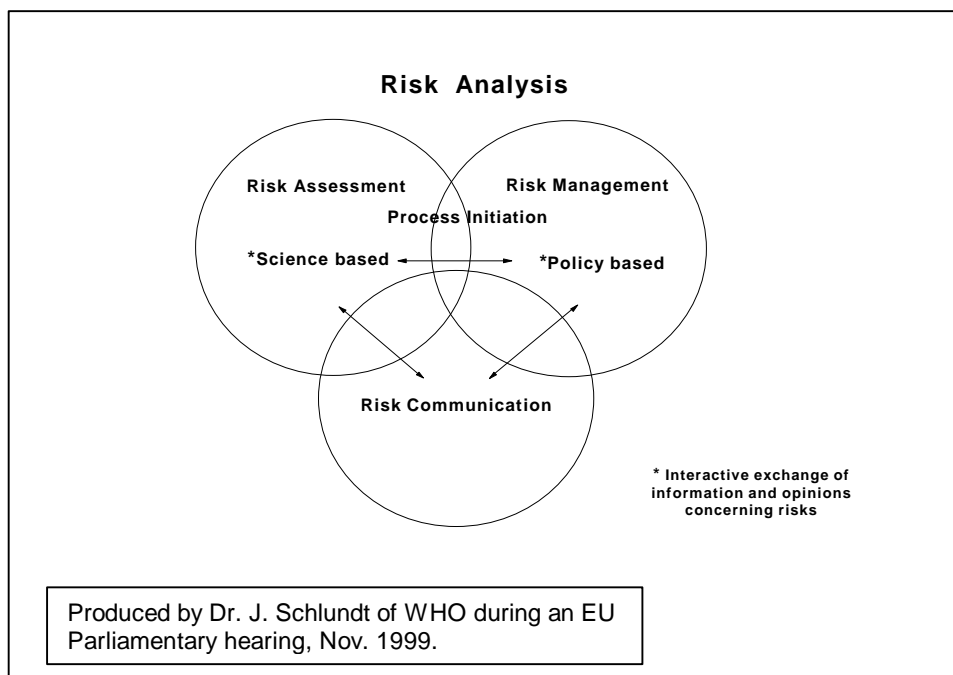
- Maintenance of close and effective working relationships with Member States' scientific advisory systems and the Commission, including those dealing with risk management issues (legislation and controls)
- A communication facility which can be linked rapidly to the Commission and its new system for the media whilst preserving the option for independence.

3.2. The relationship of scientific advice to risk analysis

The overall processes of risk assessment, risk management and risk communication are included in the term risk analysis as shown in Figure 3.1. The separate identification of the three is extremely valuable. Our mandate relates to risk assessment but as illustrated in Fig. 3.1, the three components have to be fundamentally interactive. Risk analysis has been specified as those activities needed to protect human health and minimise the incidence of disease through a process of determining realistic risk levels for the hazards involved and basing policies on the application of results from these analyses.

In considering how to improve the value and effectiveness of scientific advice these interactions have also been considered as have their relationship with any control measures needed in public health, environmental health issues and food safety. The value of the four suggested options and of international systems will be assessed before setting out the proposal for a more effective evaluation of issues of public health importance in Europe.

Figure 3.1



4. STRUCTURAL OPTIONS FOR CHANGE IN RELATION TO THE MANDATE

4.1. A scientific analysis system within a Directorate General

This option has been enhanced by decisions made by Mr. Prodi in July 1999 on the reorganisation of the Commission. Clearly with additional units of relevance to health and consumer protection being assigned to DG SANCO, there is now a sense that the safety and well-being of the Union's population is being given a higher priority. This rearrangement is welcome and if a reconstituted system for scientific advice continued within a Directorate General there is no reason to assign the health and consumer protection groups to another Directorate General

The new system for scientific advice which has developed in the last 2 years has much to commend it but the question is whether the scientific assessment scheme should remain within a Directorate General. There are advantages in that the scientific process can be funded, supported and organised through routine Commission mechanisms. The present system in effect, however, lacks any formally organised political or public involvement and its presence within a single DG means that the scientific committees do not have the ability to demand of other Directorate Generals immediate access to data and monitoring systems controlled by these other Directorate Generals. Within the Commission each DG is seen as very distinct and although the EU has been in existence for only a comparatively short time, it has already become rather rigid in structure, in its operational lines of command and in its rules relating to process within the Commission. There are routine interactions between DGs within the Commission but the Commission processes are seen by outsiders as being highly secretive. Recent scientific analyses reveal that multi-sectoral issues are involved in the analyses of actual risk as distinct from theoretical risk so the processes within a single DG automatically limit the expert scientists' analyses appropriate to tackling risk assessment on a proper basis although the Scientific Secretariat may well be aware of the broader issues. Although the new Commissioners have signified their desire to both reform and open up the Commission, the development of a modern, democratic, open system within a DG, which is seen to be relevant to the people of Europe, will be very difficult.

The presence of a scientific assessment system within DG SANCO is therefore seen as the best option should one have to retain the system within the Commission structure, but dramatic changes would be needed in membership, transparency, process and support. At present, the membership of committees is

still rather narrow in its expertise. Transparency, although greater than previous arrangements is still minimal compared with systems operating elsewhere. The processing of scientific opinion would also need to be transformed and the support system is currently very inadequate for the challenges which lie ahead (see below). The ability to take cross-Commission initiatives would also need to be developed. The lack of relationship to the European Parliament, or to elements of EU's risk management, auditing and communication organisations within the Commission – all these issues lead to the conclusion that it is unwise to continue to deal with issues of such immense public concern simply by devising an improved system within DG SANCO. This option is therefore rejected.

For the next three options being considered, some of the principal issues and how they relate to the options are set out in Table 4.1.

Table 4.1

A comparison of some possible issues relating to the three principal options

Independent/autonomous Commission Service or Directorate (in terms of not being a component of a Directorate General)	Interinstitutional office analogous to OLAF	An Agency analogous to EMEA
<p>- provides administrative support for the management of the scientific Committees composed of independent members.</p> <p>Excellence of members : rules of selection: current rules can be implemented (or improved)</p> <p>Transparency : current rules of transparency (publication of the opinions on internet) can apply or be improved if need be.</p> <p>Independence (rules on conflicts of interest) : current rules can apply (or be improved if needed)</p> <p>Staff : scientific, administrative support is provided by the Commission (Commission permanent civil servants, temporary civil servants; "expert national détaché"(trained civil servants coming from members States for a 3 years period). Private contracts are possible for a specific tasks such as literature researches and special reports.</p> <p>Budget : set up along current Commission procedures, i.e.</p>	<p>- provides administrative support for the management of the scientific Committees composed of independent members</p> <p>Excellence of members : rules of selection: current rules can be implemented (or improved)</p> <p>Transparency : current rules of transparency (publication of the opinions on internet) can apply or be improved if need be.</p> <p>Independence (rules on conflicts of interest) : current rules can apply (or improved if possible)</p> <p>Staff : scientific, administrative support is provided by the Commission (Commission permanent civil servants, temporary civil servants; "expert national détaché"(trained civil servants coming from members States for a 3 years period). A specific "budget" annex lists the post allocated to the office. Private contracts are possible for a specific tasks such as literature researches and special reports.</p> <p>Budget : budget entered in a special budget heading within the</p>	<p>- provides administrative support for the management of the scientific Committees composed of independent members</p> <p>Excellence of members : rules of selection : current rules can be implemented (or improved)</p> <p>Transparency : current rules of transparency (publication of the opinions on internet) can apply or be improved if need be.</p> <p>Independence (rules on conflicts of interest) : current rules can apply (or improved if possible)</p> <p>Staff : Commission rules for staff but more flexibility (in current practice : permanent Commission civil servants for statutory tasks : director, head of unit, financial auditor; temporary staff and local staff for the others tasks. Private contracts are possible for a specific tasks such as literature researches and special reports.</p> <p>Budget : independent budget, can be sustained by fees (fee for</p>

Independent/autonomous Commission Service or Directorate (in terms of not being a component of a Directorate General)	Interinstitutional office analogous to OLAF	An Agency analogous to EMEA
<p>specified within a Directorate General during the routine formulation of budgets</p> <p>Scope for interaction with risk managers (Commission services in charge of drafting legislation):</p> <p>Will depend :</p> <ul style="list-style-type: none"> - on the guarantees given to ensure that the SC are consulted - on the scope of competence of the independent service or directorate (scientific advice + recommendations/follow- up of scientific opinions, monitoring of risks) - on the way in which the demarcation risk assessment/risk management is defined - on the development of a good collaborative relationship with the risk managers <p>Scope for interaction with European Parliament and Council</p> <p>Relationship can be set up between parliament and council representatives and the independent service or structure but this would not normally be formally structured.</p> <p>Scope for interaction with stakeholders</p> <p>Specific hearings of stakeholders by the SC or their WG may be set up. Communication policy can be established.</p>	<p>Commission.</p> <p>Application of fees (fee for commercial application of an authorisation..) may be possible.</p> <p>Scope for interaction with risk managers (Commission services in charge of drafting legislation):</p> <p>Will depend :</p> <ul style="list-style-type: none"> - on the guarantees given to ensure that the SC are consulted - on the scope of competence of the independent office (scientific advice + recommendations/follow-up of scientific opinions, monitoring of risks). - on the way in which the demarcation risk assessment/risk management is defined - on the development of a good collaboration relationship with the risk managers <p>Scope for interaction with European Parliament and Council</p> <p>Well structured relationship can be set up between parliament and council representatives and the office. The Director (Commission official) is appointed by the Commission after consultation with Council and Parliament. A supervisory Committee is appointed by common accord of European parliament, the Council and the Commission.</p> <p>Scope for interaction with stakeholders</p> <p>Specific hearings of stakeholders by the SC or their WG may be set up. Communication policy can be established. The supervisory committee is composed of independent outside persons (which could include stakeholders)</p>	<p>commercial application of an authorisation..) and subsidies from the European Community. The agency prepares its own budget independently.</p> <p>Scope for interaction with risk managers (Commission services in charge of drafting legislation):</p> <p>Will depend :</p> <ul style="list-style-type: none"> - on the guarantees given to ensure that the SC are consulted - on the scope of competence of the independent service or directorate (scientific advice + recommendations/follow- up of scientific opinions, monitoring of risks) - on the way in which the demarcation risk assessment/risk management is defined - on the development of a good collaborative relationship with the risk managers <p>Scope for interaction with European Parliament and Council</p> <p>Well structured relationship can be set up between Parliament and Council representatives and the agency Administrative board is constituted in general by a majority of representatives of Member States (30 in EMEA) Parliament (2 in EMEA) and Commission (2 in EMEA). Specific composition rules can be set up in the legal text creating the agency. The executive Director (Commission official) is appointed by the board on the basis of a proposal of the Commission.</p> <p>Scope for interaction with stakeholders</p> <p>Specific hearings of stakeholders by the SC or their WG may be set up. Communication policy can be established. The administrative board may be composed of some representatives of the stakeholders but it is not the current practice in setting up the agencies.</p>

Independent/autonomous Commission Service or Directorate (in terms of not being a component of a Directorate General)	Interinstitutional office analogous to OLAF	An Agency analogous to EMEA
<p>Geographical location (operational needs : meeting infrastructure for around 420 meetings/year, daily meetings with legislative departments or more in case of crisis)</p> <p>Brussels is in principle the location for a Commission service</p>	<p>Geographical location (operational needs : meeting infrastructure for around 420 meetings/year, daily meetings with legislative departments or more in case of crisis)</p> <p>Brussels is in principle the location for an office</p>	<p>Geographical location (operational needs : meeting infrastructure for around 420 meetings/year, daily meetings with legislative departments or more in case of crisis)</p> <p>In the current practice, to create a balance between Member States, the different agencies have been located in each of the MS. Actually, Four Member States do not currently have an Agency. No legal rules demand the decentralisation of an Agency to a Member State rather than Brussels.</p>
<hr/> <p>GENERAL</p>	<hr/> <p>GENERAL</p>	<hr/> <p>GENERAL</p>
<p>Administrative/political independence of the structure An independent commission service or directorate is under the political responsibility of a Commissioner. The Parliament plays a supervision role (budget, appointment and censorship of the Commission) .</p>	<p>Administrative/political independence of the structure An independent interinstitutional office is under the political responsibility of a Commissioner (in the case of OLAF: the President). The Parliament plays a supervision role (budget, appointment and censorship of the Commission) Furthermore, in the case of OLAF, the Director shall neither seek or receive instructions from any government or institution, body or agency in the performance of his duties with regard to the opening and carrying out of investigations or to the drafting of reports following such investigations. He shall report regularly to the EP, Council, the Commission and the Court of Auditors on the findings of the investigations. The Supervisory Committee shall reinforce the office's independence by regular monitoring of the investigative function. The supervisory committee shall be composed of five independent outside persons. They shall neither seek nor take any instructions from any government or any institution, body, office or agency.</p>	<p>Administrative/political independence of the structure An agency has its own legal personality. Therefore it is an independent structure. The Executive Director is only under the supervision of the Administrative board composed in general of a majority of representatives of the Member States. Financial control is performed within the structure. There is no supervision by Parliament.</p>
		<p>Important legal points</p>

Independent/autonomous Commission Service or Directorate (in terms of not being a component of a Directorate General)	Interinstitutional office analogous to OLAF	An Agency analogous to EMEA
<p>Important legal points An independent commission service or directorate follows the same legal rules and is entitled to the same powers and guarantees as any other Commission services. No legal text, apart from a Commission's decision, is needed to create this independent service or directorate.</p>	<p>Important legal points An interinstitutional office follows the same legal rules and is entitled to the same powers and guarantees as any other Commission services. But a specific legal text is needed to create an interinstitutional office in order to ensure its independence and to set up the involvement of the three institutions (Parliament, Council and Commission)</p>	<p>An agency can only be set up on a legal basis that requires the unanimity of the Member States. An agency can never be in charge of the legal tasks of the Commission (to monitor the implementation of community law, to propose legislation, to adopt executive measures)</p>

4.2. A Commission Service

In this option, the principal difference from the current procedures is that the committees and their support teams would be transferred to an independent entity but continue to be the responsibility of the Commissioner in charge of Health and Consumer Protection. The Service would operate outside the Directorate General system and have the ability to act and be seen to act perhaps more independently than is traditionally the case within a Directorate general. The relative simplicity involved in establishing this mechanism is set out in Table 4.1 which compares a service with the next two options for change.

This commission service clearly would need, as noted above, to develop very different modes of work from those currently in place but by relating to a single Commissioner one is inevitably involved in the understandable interplay between different axes of power within the Commission and Commissioner system. One of the principal concerns for the public is the evident sidelining of issues of public concern when short-term political demands seem to require it or when the financial implications are thought – as in the original BSE affair in the UK or, currently, in the rest of the EU – to be too great to be justified on the basis of the supposed risks. This then means that one would need to develop a totally different Commission service system with different communication, public relations, parliamentary and other schemes from those seen in current Commission service systems. There are presently seen as very dependent on the support of the particular responsible Commissioner. The food, veterinary, phytosanitary environmental and public

health issues are of such great concern that such Commission based processes may be seen as only a very modest improvement on the current system. Furthermore, it has two distinct additional disadvantages. First it will be seen by the public as operating within only one component of the triangular system of power within Europe, i.e. Commission, Member States and Parliament. The public, therefore, will not see it as operating in a transparent open manner on their behalf because it would not have any direct relationship to them. A more direct relationship would also be needed with the Food Standards or Safety Agencies and other institutions in Member States. The Parliament and media could amplify these concerns, particularly when controversies arise during a food crisis (see later). Nevertheless, as indicated in Table 4.1, Parliament could play a supervisory role so this second option would be seen as more appropriate than the first. The service role within one Commissioner's system may also not allow the scientific structure and process to interact routinely and with the necessary power, independence and speed with other Commission Services and with Member States when the need arises.

There is a clear need to institute a new strategy in terms of scientific support, interaction with stakeholders and novel arrangements for new surveillance systems relating to public health and the other concerns. It is therefore likely that adequate recognition of these needs by Member States and Parliament would only emerge from a very explicit new mechanism of budgeting which would require special justification.

It is concluded that a Commission Service is not an ideal scheme for a scientific assessment system relating to such profound and immediate issues as those relating to public health. If, however, such a structure is developed then it is considered essential to retain the reporting of this service to the Commissioner responsible for health and consumer protection.

4.3. Establishing an Interinstitutional office

This type of structure is new and has been used to set up the European Anti-fraud office (OLAF). OLAF is an Inter-Institutional rather than a Commission body and specific legal texts ensure its independence and its own power to take initiatives. Its main function is the investigation against fraud, corruption in all the institutions, bodies, offices and agencies established by or on the basis of the EC and Euratom treaties. A Supervisory Committee is set up to reinforce OLAF's independence

and to enable a regular monitoring of its functions. The Supervisory Committee is made up of outside independent persons who are highly qualified and renowned in the office's fields of activity.

Following an open call for applications, the Director of the Office is appointed by the Commission, after consultations with the Parliament and Council.

The Director neither seeks nor receives instructions from any government or institution, body, office or agency in the performance of his duties. He can open and carry out any investigation or report in writing following such investigations. He reports regularly to the EP, the Council, the Commission and to the Court of Auditors on the findings of the investigations.

The Supervisory Committee reinforces the office's independence by regular monitoring the implementation of OLAF's investigative function. At the request of the Director or on its own initiative, the Supervisory Committee delivers opinions to the Director on the activities of OLAF but without interfering in any way with the conduct of specific investigations in progress.

The Supervisory Committee is composed of five independent outside persons who possess the qualifications required for appointment in their respective countries to senior posts relating to the office's areas of activity. They are appointed by the common accord of the European Parliament, the Council and the Commission. Their term of office is for 3 years and this term is renewable once. They have to agree formally to neither seek nor take instructions from any government or any institution, body, office or agency in the conduct of their duties.

The Supervisory Committee appoints its own chairman and adopts its own rules of procedure. Decisions are taken on the basis of a majority of its members and OLAF's Secretariat provides the support for the work of the Supervisory Committee.

The office has the responsibility not only to develop the necessary infrastructure for its task and for collecting and analysing information, but it also has a special training role for bodies with similar duties in Member States. It has direct access to its immediate investigative and management / intervention arms, i.e. the judiciary and police, and represents the Commission in the arena for which it has responsibility. The Director is responsible for generating a preliminary draft budget which goes to the Director-General for Budgets; the office's budget is separately identified in the annual general budget. As noted in Table 4.1, a close relationship is planned between the European Parliament and this office, but experience with

this structure is limited because the office was only established by a Commission decision on 28.04.1999.

Whilst recognising that there is as yet no experience of this scheme working effectively in practice, the Interinstitutional model has most of the features specified as desirable for issues of immense public concern in Europe. It is a distinct entity with its own public profile, it relates seemingly appropriately to the overall power structure in Europe, it has independent membership and has direct access as of right to immediate investigative and management/intervention arms. Its budget is also specified separately and it is planned to relate closely to the European Parliament.

It is concluded that this scheme has many of the features of an optimum system for dealing openly with issues of immense public concern and particularly when dealing with questions which potentially threaten political and industrial concerns. It is important, however, to recognise that the entity relating to fraud is essentially an analytical, rigorous organisation which displays openly the problems rather than intervening in the European management of industrial or public sector practices. Its role is therefore in a sense declamatory, the assumption being made that any fraud is by definition unforgivable and that public and parliamentary opinion will automatically accept the OLAF findings. The issues relating to environmental, veterinary, public health and other scientific issues are more complex – as shown by the surprising *volte face* of the media and many politicians in the UK when a beef-on-the-bone ban was introduced. Suddenly there was a complete turnaround from persisting with an absolutely prudent policy of reducing the risk from BSE to zero to a perception that the risk profile had changed and that it was legitimate to allow individuals to balance individual pleasure against personal risk. These problems and uncertainties are likely to escalate. In the environmental area, there are extremely complex issues with to some public groups taking somewhat extreme views. The confusion about what constitutes public health and suitable policies to improve public health in Europe have also barely begun to be considered by the EU. Uncertainties in other areas of scientific analysis, e.g. on the risks of xenotransplantation, also exist. There is therefore a real dilemma as to how best reflect complex analyses and judgements in public policy making. Therefore there could be a need to have a mechanism analogous to OLAF but where the outcome of the scientific analyses can properly be put into perspective by public enquiries conducted by the European Parliament with additional discussions and interactions with the Council. Again, an explicit transparent approach by a manifestly independent body would be of value.

A further difference from an OLAF type body relates to food, veterinary, environmental and other health crises where daily decisions may become necessary on the basis of very uncertain knowledge as in the recent dioxin and Coca Cola affairs. To handle these issues, there is a clear need to develop a different scheme from that currently considered appropriate for an OLAF type of organisation. This is dealt with below.

4.4. Establishing an Agency

As set out in Table 4.1, this entity in its standard mode is very different from that needed in the food and public health areas. An agency is a completely independent structure established by the unanimous agreement of Heads of Member States, with an Agency being based in a Member State. There are 11 agencies so some countries do not have an Agency as yet. One such Agency is the European Agency for the Evaluation of Medicinal Products (EMA). This Agency differs substantially from an Interinstitutional office because it is run by a Management Board comprised of two representatives of each Member State, with only two additional representatives for the Commission and a further two proposed by the European Parliament.

EMA has acquired a good reputation and has expanded in size to cope with the agreed need for the rapid as well as effective screening of new drugs. It has developed with the help of Member States and a network of over 2000 experts. The Management Board elects its own chairman and decisions are adopted by a majority of two-thirds of the Board thereby allowing suitable negotiations and compromises between Member States. The Commission originally nominates the Executive Director but he is then appointed by the Management Board to represent legally the Agency and be responsible for its daily management. Experts identified by Member States are elected to serve for 3 years; their term is repeatedly renewable. Member State nominees may be replaced by a deputy and, through conjoint action, ensure that the Agency's conclusions are satisfactory from their point of view. EMA uses a variety of techniques to ensure the development of coherent reports within an acceptable time scale.

The transparency of Agencies seems in general to have been limited. Thus, for example, EMA makes public the membership and the members' qualifications when serving on their two committees dealing with either human or veterinary medical products. The public also has access to the declarations of interest of the committee membership and there are also EMA meetings with stakeholders. The

EMEA, like other agencies, also produces public annual reports and a projected work scheme for the Commission, Member States and the European Parliament. Nevertheless there is very limited public health, media or parliamentary involvement. The EMEA system therefore does not have the ring of public transparency because only when the final conclusions emerge are they made public. In terms of transparency, the contrast with such open systems as the US FDA is therefore striking

EMEA's funding is relatively independent of the EU budget since the EU subsidy now amounts to less than a third of the income, the rest coming from fees not only for scrutinising any new veterinary or medicinal products (100K and 200K E respectively) but also for renewing approval and inspections. Any company involved also has to pay an annual fee of 60,000 E in the medical field and 30,000 E in the veterinary field. The charges are considered onerous by the veterinary drug industry. In undertaking its scientific evaluations, the EMEA again has to use experts specified by its Member States. Thus it may be fair to conclude that this particular Agency has detailed interactions with industry, is extremely aware of Member State interests but has only modest interactions with the Commission, the European Parliament and public interest groups.

EMEA's processes may be very appropriate for pharmacological assessments which traditionally relate to individual patient needs and which involve the balancing of sometimes substantial drug risks with considerable benefit for patients who may be extremely ill. This approach is, however, totally different in terms of public perception and in actual risk assessment from that of an agency involved in environmental, food and public health issues. Other Agencies were also examined. Agencies seem to be considered as relatively divorced from major decision-making within the Commission and have relatively slow moving processes leading to selective action of modest public concern.

It was concluded that the current Member State location of Agencies is inappropriate for the new Authority given the nature of its work and the need for extensive interaction, not only with visiting experts, but with centrally located risk managers as well as the Commission, Council and European Parliament. Many Agencies seem divorced from immediate, major and politically contentious

decision-making which will inevitably relate to many food, public health and environmental issues. The proposed Authority should therefore be located in Brussels.

The conclusion that an Agency system, as currently organised within the EU, is not the appropriate structure was reinforced by the finding that Commission officials automatically make assumptions about the nature of an Agency which are totally at variance with what is currently needed in relation to food, public health and environment in Europe. The Agency concept was therefore rejected in favour of some of the aspects of the Interinstitutional model (see below).

5. STRUCTURAL ARRANGEMENTS DEVELOPED BY OTHER LARGE ORGANISATIONS FOR DEALING WITH CONSUMER PROTECTION AND PUBLIC HEALTH.

Three organisational systems deserve to be considered: the UN system, mechanisms such as OECD and national mechanisms.

5.1. The UN System

The huge UN system has had to develop a series of mechanisms to cope with scientific evaluations. Those in consumer protection and public health terms relate primarily to WHO and FAO which are also conjointly responsible for the CODEX Alimentarius Commission (CAC) first established in 1961/62. WHO itself is concerned with every aspect of public health and consumer protection in relation to health whereas FAO has a major interest in promoting effective agriculture, food production and processing in an appropriate environmental context.

Both FAO and WHO depend on a fairly standard set of procedures in developing their scientific analyses and policies. First, both organisations make substantial use of experts selected by the scientific Secretariats of the UN agency. Experts produce reports which may then be extensively edited, expanded or modified by the recruitment of further experts on paid contracts. These reports, which are not UN policy statements, are then published. A second system may then be developed, e.g. by WHO which convenes an Expert Technical Committee to report on a topic of particular importance. Often working groups are established first and expert reports submitted (at little or no cost to WHO because of its financial straits) before a single meeting of the final expert committee is held with carefully selected regional delegates. These delegates are proposed by all WHO regions in the world and have a special concern for general consumer protection and public health interests. A few selected experts are also designated as either temporary UN Secretariat staff or as extra members of the committee which has to produce its report within the 4-8 days allocated. The report is then submitted to the Executive Board for agreement before being sent by WHO as an official policy document to all Member States of WHO.

The Codex system is responsible for international harmonisation of food standards. The members of Codex are the national governments. Different intergovernmental Codex sectoral committees (food additives and contaminants, hygiene, veterinary drug residues, dietary products) prepare the international

standards and these standards are adopted by the Codex Commission where all the governments' members of FAO or WHO are represented.

The initial Codex proposals for international food standards are based on the scientific advice of two scientific committees. These scientific Committees are joint FAO/WHO committees: one is responsible for safety assessments of food additives, contaminants and veterinary drugs residues (JECFA) and the other one is responsible for the safety assessments of Pesticides (JMPR). They are independent committees which are not considered intrinsic components of the CODEX system but advisory bodies with CODEX taking the final decision for managing the risk assessed by these committees. Members appointed to these committees are independent experts in their own right.

Since the Sanitary and Phytosanitary Agreement (WTO Agreement) provides that "Measures, which conform to international standards, shall be deemed to be in accordance with the provision of the SPS Agreement and necessary to protect human health", there is a need to ensure that the current arrangements within CODEX and its advisory scientific committee system ensure an independent and transparent risk assessment process.

There is an increasing tendency for FAO and WHO to rely on external funding for holding Technical Expert Consultations. This inevitably means that there is a risk of external influence. This is a problem which is now being tackled to rectify any suggestions of undue influence. The importance of ensuring transparency of effort in the scientific advisory system is also clearly recognised by other well-established institutions, e.g. the US FDA. Consumer analyses of CODEX have recently highlighted the dominance of industrial – and particularly N. American and European – interests. Consumer interest groups are now claiming therefore that the standards specified are those conducive to free trade and the benefits of European and N. American exporters. WHO CODEX staff are also publicly on record decrying the limited attendance of Third World health ministries and the dominance of Western industrial interests.

FAO and WHO are in fact aware that the credibility of the risk analysis process in JECFA and JMPR depends upon the independence and competency of the experts providing scientific advice. They recently recommended to Member States that "FAO and WHO be encouraged, with the help of Member states, to expand the range of experts who serve on scientific committees and to consider tightening their conflict of interest requirements" (FAO/WHO conference on international Food trade. Melbourne, Australia 11-15 October 1999).

The current perceptions of CODEX's mode of operation are of particular concern given the current differences in EU and US approaches to consumer protection. The current Commission and N. American trade disputes often relate to health so these are being referred to the WTO and subsequently to CODEX for arbitration. The Commission should recognise that Europe will need to take account of the current arrangements within CODEX and its advisory committee system if any new EU scientific advisory system is to be effective in terms of WTO disputes.

5.2. Organisation for Economic Co-operation and Development (OECD)

The OECD is an organisation that provides governments a setting in which to discuss, develop and perfect economic and social policy. Their exchanges may lead to agreements to act in a formal way, but more often, their discussion makes for better informed work within their own governments on the spectrum of public policy and clarifies the impact of national policies on the international community.

The OECD is a club of 29 developed countries, which produce two thirds of the world's goods and services. Essentially, membership is limited only by a country's commitment to a market economy, a pluralistic democracy and a respect for human rights.

Exchanges between OECD governments' flow from information and analysis provided by a Secretariat in Paris. Parts of the OECD Secretariat (1850 staff) collect data, monitor trends, analyse and forecast economic developments, while others research social changes or evolving patterns in trade, environment, agriculture, technology, taxation and more.

The Secretariat is directed by a Secretary-General, assisted by four deputies Secretaries-General. The Secretary-General also chairs the Council, providing the crucial link between national delegations and the Secretariat.

Member countries meet and exchange information in Committees. The overriding committee is the Council, which has the decision-making power. The decisions taken in this forum are not binding for the member countries.

There are about 200 committees, working groups and expert groups.

The OECD main activities are related to Economics, Statistics, Environment, Development, Public Management, Trade, Enterprises, Financial and Fiscal Matters, Science, Technology and Industry, Social Policy, Agriculture, Regions, Cities and the Countryside, Energy and Working together with non-members.

However the Directorate for Science, Technology and Industry conducts analyses of safety related to biotechnology and the Directorate for Environment issues guidelines for risk assessments of chemicals.

Increasingly the need for multidisciplinary analyses is evident to OECD and systems of working on technical issues include the use of recognised experts in member countries. Technical reviews from experts are managed by the Secretariat who themselves adapt and update reports in the light of further expert analyses. Controversial topics may precipitate a supervisory panel of all member country representatives to call an Expert Meeting. The new system is, as proposed later for the EU, pro-active with structured inputs from all member countries and with greater transparency than hitherto. Programmes are also becoming broader with individual committees issuing a series of reports each year. Analyses of different programmes have led Committees to conclude that they are too slow and their priority setting is insufficiently defined. Yet OECD's interactive process with national networks of experts ensures that realistic analyses are made and these eventually lead to a consensus. To speed the process, lead countries and *ad-hoc* groups may be identified, the feasibility of projects is being determined first and ranking systems for priority setting have been devised. The Secretariat may simply manage the procedures for consensus building or have full management responsibility when stakeholders, e.g. industry or particular member countries are seen to potentially prejudice the independence of the scientific analyses. There seems, however, to be little emphasis on public involvement in these OECD processes.

5.3. The Office International des Epizooties (OIE)

This is a world organisation for dealing with issues of animal health which was created in 1924. It is sited in Paris, France with a mission to inform governments of the occurrence and course of animal diseases throughout the world and how best to control these diseases. It also co-ordinates the international surveillance and control of these diseases and harmonises regulations for the trade in both animals and animal products. It meets at least annually in an International Committee which is supported by an Administrative Commission with regional organisations in all regions of the world and a series of specialist bodies which deal with different diseases, health codes and standards. OIE also has collaborating centres, reference laboratories and working groups dealing with different topics of particular importance such as biotechnology. The organisation is seen as a mechanism for facilitating international trade on the basis of agreements

made by negotiation between representatives of Member States. Necessarily, therefore, regulations relating to international trade are seen to be the outcome of compromises between the scientific analyses developed by working parties and the practical and political needs of Member States. There is little or no evidence of public scrutiny in either the development of the scientific analyses or in the process of compromise by the pre-eminent International Committee.

5.4. The United States Food and Drug Administration

This is a very large and centralised public health agency which combines a capacity to undertake risk assessment, risk management controls and inspection throughout the US, as well as risk communication. It is an institution under the responsibility of the Secretary of Health within the US Department of Health. It has over 9,000 employees and monitors the manufacture, import, transport, storage and sale of a huge range of products throughout the U.S. It can be sued for its judgements and practice and has the ability to institute legal proceedings. It has a complement of about 2,100 scientists working in about 40 laboratories throughout the country. In relation to drugs and novel foods and products, it operates a system which allows the Agency to determine what can be marketed and in what form. It therefore has immense power, a very large staff and a broad range of activities.

It is evident that the three components have helped to ensure the public's appreciation of FDA work. First it develops what are seen to be exhaustive and rigorous analyses of the scientific risks to the public. Secondly, it undertakes its work with a remarkable degree of openness and legally binding transparency which is unmatched in the EU. Thirdly, the FDA sees itself as operating entirely in the interests of the public with the combined tasks of risk evaluation, management and communication within the single entity. This apparent integration of the three components within a single agency is seen by many senior officials as crucial to maintaining the prestige it has gained. The public knows exactly which body is responsible for ensuring that the public's welfare is safeguarded. This image is enhanced by the remarkable response time to a crisis. Thus clear responsibility for coping with a crisis resides with designated senior officials in the FDA and with others in the US Department of Agriculture and Centres for Disease Control. They can meet within an hour and have explicit responsibility for handling issues which may rapidly involve the Commissioner of the FDA, his senior, the Secretary of State for Health and then the President himself. The FDA has the legal capacity to shut down a facility anywhere in the US, recall a product line and take legal

sanctions against a company. In practice it operates closely with each state's officials and with the state's own core of expertise. The State's control covers dealing with the inspection and the validation of proper procedures. The majority of work is therefore state run but the FDA has overarching control. In practice the FDA has separate groups dealing with risk assessment, risk management and risk communication and recognises the value of having different staff clearly designated for these three areas. Their interaction is, however, considered crucial to ensuring that appropriate perspectives and effective actions are taken. Senior officials of the FDA consider that their power and willingness to act to protect the public is one of the crucial features of reassurance which has led to its high standing.

In the FDA perhaps 90% of the scientific work is done in-house. It is claimed that there is such transparency that every meeting and memorandum relating to the process of analysis and approval is open to public scrutiny. Only about 10% of the FDA's scientific analyses are referred to external committees so the distribution of work is very different from that currently undertaken by the EU. Nevertheless, in both modes of working, the level of scientific support within the FDA is often at least an order of magnitude greater than in the current EU system.

The exhaustive nature of many of the US analyses helps to swing opinion should there be disagreements with other bodies. Given current conflicts of opinion on several scientific issues between the EU and the US experience supports the value of having the sustained presence of high quality specialist scientists as officials associated with the scientific committees.

There have, over the last five years, been a series of reports which suggest that the FDA has been subjected to very intense pressure to sanction the sale of particular new foods or drugs despite the disquiet of scientists advising the FDA. Such improper influences are difficult to define and the FDA seems to consider its policy of remarkable transparency as a major safeguard. Nevertheless the FDA's procedures, which involve officials and industrialists agreeing beforehand the type and range of studies needed to clear a drug, food or other product, mean that the FDA officials could feel obliged to pass the product once the test is completed. In many European countries further options and opinions may emerge during the testing procedure which change the balance of evidence. By not agreeing protocols of assurance beforehand, the EU Member State system, therefore, has greater freedom to develop its precautionary approach during the course of further industrial testing.

The FDA system is clearly different from that in Europe where the number of Brussels officials currently involved in scientific assessment is minute compared with the FDA. To produce a comparable organisation in Europe would therefore be a major undertaking. It would require that a number of current organisations, e.g. the JRC for research, the FVO for the control of the food and veterinary sectors and other components of the Commission's legal and regulatory arm would come within the remit of the Authority as well as an appreciable part of the research budget. This is a separate issue from that dealt with in this report, but whether or not a conjunction of these agencies and powers is undertaken, there will be a need to develop a clearer and more transparent system for the interaction of the different components of risk assessment, risk management and risk communication.

5.5. Member State procedures

Within the Member States of the EU there is a variety of schemes for assessing risk but as in the Commission's system there is an increasing emphasis on the three cardinal principles of excellence, transparency and independence. Thus, for example, Denmark, France, Ireland and the United Kingdom have recently reorganised their advisory and reporting systems to improve the public's awareness and acceptance of the processes of risk assessment and structures of risk management as well as the control and auditing of the arrangements. Some Member States already have well-established independent food agencies, e.g. Sweden, and another Member State, Finland, has made unusual arrangements by having developed a renowned national institute of public health. It is clear that some agencies are very separated from the governmental processes whereas others, e.g. in Denmark, are embedded within a government departmental system. Some new agencies, e.g. that in France, have to be consulted before the government makes a decision but is confined to providing advice, whereas others, e.g. that emerging in the UK, is required to control and ensure the effectiveness of general food hygiene rules and animal health inspections whilst operating at an EU level as the negotiating component of UK interests.

Submissions by Member States revealed very different systems for assessing scientific advice with some states having a single committee dealing with a topic, e.g. food, whereas other states had much more complex structures.

Given the variety of options being developed, which are well-known to the Commission, Member States and European Parliament, the analyses for this report

have been concentrated on assessing and visiting the longer established international and external bodies such as CODEX, OIE and the United States Food and Drug Administration (FDA).

6. A PROPOSAL TO ESTABLISH A EUROPEAN FOOD AND PUBLIC HEALTH AUTHORITY

At the second parliamentary enquiry into BSE in December 1998 some Commissioners and European Parliamentarians came out in favour of a Food Standards or Safety Agency for Europe. Given this background and recent events, it would seem that there is a body of opinion supporting the establishment of a more robust organisational entity to cope with the challenges and problems set out earlier. The mandate for the present analysis is, however, confined to the scientific assessment of risk so this is dealt with first; the broader picture and issues which the Commission and Parliament need to consider come later. The views expressed here are dominated by the three agreed priorities of ensuring excellence, independence and transparency in any new mechanisation of scientific assessment.

A new entity is proposed which has many parallels with the third option, i.e. an inter-institutional office. A Brussels-based organisation is needed which might be called the European Food and Public Health Authority (EFPHA). The need to incorporate "food" into the title is obvious and, given the Amsterdam Treaty with its new emphasis on public health, there is major benefit in re-emphasising the public health priority of the new organisation. It is also evident that environmental issues will need to be included but to incorporate this into the title makes for a cumbersome name. Having food Public health and environmental issues as linked entities is appropriate since all three require unusual multidimensional and multi-sectoral approaches if consumers are to gain maximum benefit. The interaction between these three sectors is also extremely important.

The term Authority is chosen because it is distinctive and immediately specifies a different entity from the Agency concept which is so familiar to Commission officials and Member State policy-makers. It has also, in English, the ring of excellence and the ability to respond which may be helpful given the recent crises. Its effectiveness, however, depends fundamentally on its structure, relationships, remit and operating capacity which is set out below.

6.1. Remit

There are two dimensions to the issue of remit. First the range of issues to be tackled and secondly the extent to which a new organisation confines itself to providing scientific assessments.

It is proposed that the fields covered by the current 9 committees established in 1997 be retained since it has become clear that each of these fields can be of

intense public concern and often requires complex multidimensional analyses. Table 6.1 lists the current committees and Appendix 3 gives their mandates. Experience over the last two years re-emphasises the need to consider the whole food chain, public health in a new dimension and a wide range of environmental issues.

Table 6.1

Scientific Committees currently involved in the DG SANCO system of advice.

1. Food
 2. Animal Nutrition
 3. Animal Health and Animal Welfare
 4. Veterinary Measures relating to public health
 5. Plants
 6. Cosmetic Products, and Non-food Products intended for Consumers
 7. Medicinal Products and Medical Devices
 8. Toxicity, Ecotoxicity and the Environment.
 9. Overall Scientific Steering Committee dealing with multidisciplinary issues, e.g. BSE.
-

6.1.1. Food

It would be surprising if there were not unanimity on the need to include the array of complex issues relating to food in the Authority's remit with general acceptance of the importance of considering the food chain in an integrated manner, i.e. from production to consumption. The need to deal with issues ranging from the challenges of the expanding global food trade, the complexities of novel infective components and increasing technological opportunities will also present ever increasing demands in the future. There is therefore benefit in having a multidisciplinary steering committee for food with an emphasis which is not dominated by classical toxicology and where a series of sectoral committees will be needed to deal with the wide range of issues and to interact with other groups dealing with environmental and public health problems. These aspects are well known and will not be detailed.

6.1.2. Public Health

With the transformation of the Commission's role in public health a high profile needs to be given to this important area which has necessarily been a minor

consideration until the recent Member States agreement that it should now come within the competence of the Commission's activities.

Public health has many dimensions which in a European context require analyses in relation to the health impact of actions by other sectors. Thus the spectrum of issues relating to tobacco, recently highlighted, for example, by the new WHO Director General with proposals for the specific funding of tobacco farmers to allow them to transform their holdings to other uses, include the need to consider the importance of passive smoking, of possible measures based on a scientific understanding of the difficulties of helping reduce the use of cigarettes by teenage girls and the validity of any steps taken to reduce the nicotine, tar or other components of tobacco. There are many other questions. To have scientific analysis on a European basis is important because currently many policy makers simply consider that the answer to tobacco problems is to "educate" the individual consumer not to start smoking. This naïve approach is evident in many other dimensions of public health, e.g. those relating to inappropriate diets in pregnancy; the substantial problems of low birth weight babies; the continuing challenge of iodine deficiency within the EU; the widespread anaemia in children and adult woman; the major issues relating to the health of Asians and other immigrant communities within the EU; the challenge of coping with escalating rates of adult chronic diseases and the huge and growing impact of the poor health of Europe's elderly. In societal terms the health impact of societal deprivation, social exclusion and poverty is now becoming a major European issue which requires much more objective scientific analyses than are currently available. Equally important is the profound significance of the remarkable decline in physical activity induced by a transformation in society with town planning and traffic policies of some Member States having been geared predominantly to the private motor car. City planning, building regulations, school and workplace policies have largely neglected the importance of physical activity; current levels of sedentariness in children and adults have alarming long-term health implications which have as yet not been considered. Similarly dietary factors relating to major public health problems have not been considered by the EU's scientific committees before and the analyses are made more difficult by the paucity of coherent comparable data on diet, activity and the health profile of EU citizens. This field of public health surveillance should be added to the now evident need for a monitoring system for acute food poisoning. Currently few Member States have an effective system. An appropriate system developed by Member States in conjunction with the EU would then allow a series of appropriate public health analyses to be developed. Such a

system would be comparable to the Centre for Disease Control in the US. There is therefore a major need to have a Surveillance Unit or Centre in the new Authority.

6.1.3. Environmental issues

The recently established European Environmental Agency has concentrated on the important field of data collection and many of the scientific issues relating to the environment are dealt with within the existing structures of DG SANCO. Thus water and air quality, environmental toxicology, issues relating to the potential health impact of high tensions power lines and the environmental aspects of GMOs - these are all considered. Given the numerous health implications of so many of these issues, it is proposed that the environmental issues continue to be addressed within the same Authority as the public health and food chain assessments. The interactive processes with the Environmental Agency and between committees will need to be established.

6.1.4. Relating scientific risk assessment to risk management.

Currently the Scientific Secretariat provides the interface between the independent scientific advisory process and the risk manager. This is a subtle process that is not restricted to the process of preparing questions and transmitting opinions. The essential dialogue between risk management and risk assessment continues during the Committee meetings. The secretariat plays a key role in ensuring that the dialogue is appropriate, effective and productive. It is essential that the scientific secretaries understand both the science and the implications of the advice for the legislator and policy maker in order to ensure articulation between these two components of the risk analysis process. Similar requirements exist for the interface between risk assessment and risk communication. This interfacing function is now an integral part of the risk analysis process given the Commission's stated aim of a functional separation of risk assessment and risk management. It is, however, a matter of experience that this pure separation is often hard to realise in practice. Again, the Scientific Secretariat has an important role in guiding the process so as to minimise, if not exclude, the involvement of the Committees in risk management.

Practical experience also shows that to be effective, this interface depends on a close working relationship between the risk assessor and risk manager from the beginning of the process when the questions are defined, to the final stage when the advice is translated into management proposals. This requires frequent and direct contact with officials in the many customer DGs at all levels. It is therefore

essential that the advisory process is fully integrated into the risk analysis process which demands that it is physically located with the central administration which it serves in Brussels.

In addition to the Commission services, the Secretariat must also be accessible to the other stakeholders: petitioners (a large proportion of the Committee's client base), Member State officials, other submitters of information and to special interest groups that wish to make their views known. Again, this requires the physical location of any new structure to be central but the range of interactions needs to become more transparent as in the FDA system.

7. ADMINISTRATIVE STRUCTURE

This structure should be developed to support an independent and transparent risk assessment process. The structure is depicted in Figure 7.1 which sets out the Authority as having an independent Board, analogous in type to the OLAF system. However, it is suggested that it has a membership of 9 with 3 figures of major international repute appointed by the Presidents of the Commission, of the European Parliament and the Council of Ministers. A further four members should be appointed from individuals proposed by the principal stakeholders, i.e. two from the consumer, environmental and public interest groups and two from the industrial sector. It is important, however, that these individuals, approved by Parliament, the Commission and Council of Ministers conduct themselves as general board members and not selectively as formal representatives of constituent stakeholders. This will help to overcome complaints, for example, by one industrial group that their "representatives" have not been chosen in preference to other representatives proposed by farmers, agricultural businesses, co-operatives, wholesalers, distributors, food manufacturers, retailers, pharmaceutical groups or others. Finally, two further members should be appointed by the Scientific Community through the network of the principal scientific organisations within Member States. It is suggested that the Authority's Board elects its own chairman from amongst its members, instructs the Director of the Authority, reports to the three institutions, i.e. the Commission, Parliament and Council, and ensures the Authority's Communication Unit is operating in line with the Board's policy. The Board should be responsible for the work of the Authority and should also specify that documents from scientific committees are set out appropriately. It should not, however, have the right to veto the publication of a report once the scientific committee has considered and responded to any general points made by the Board. The activities of the Board should also be transparent as in the US system with freedom of information. This will be further reassurance that they do not as a Board interfere with the Scientific Committees' assessments.

The Authority's Director would best be appointed for a five year term (renewable for a single further term). The Commission should be responsible for the appointment but only after having the agreement of the European Parliament and Council of Ministers. The Director is responsible for the activities of the Authority, with executive powers determined by the Board. The Director should therefore be considered as a high status EU official with powers over every component of the

Authority including the Communication Unit but would have no right to edit, refuse or keep secret the deliberations of the Scientific Committees.

Figure 7.1

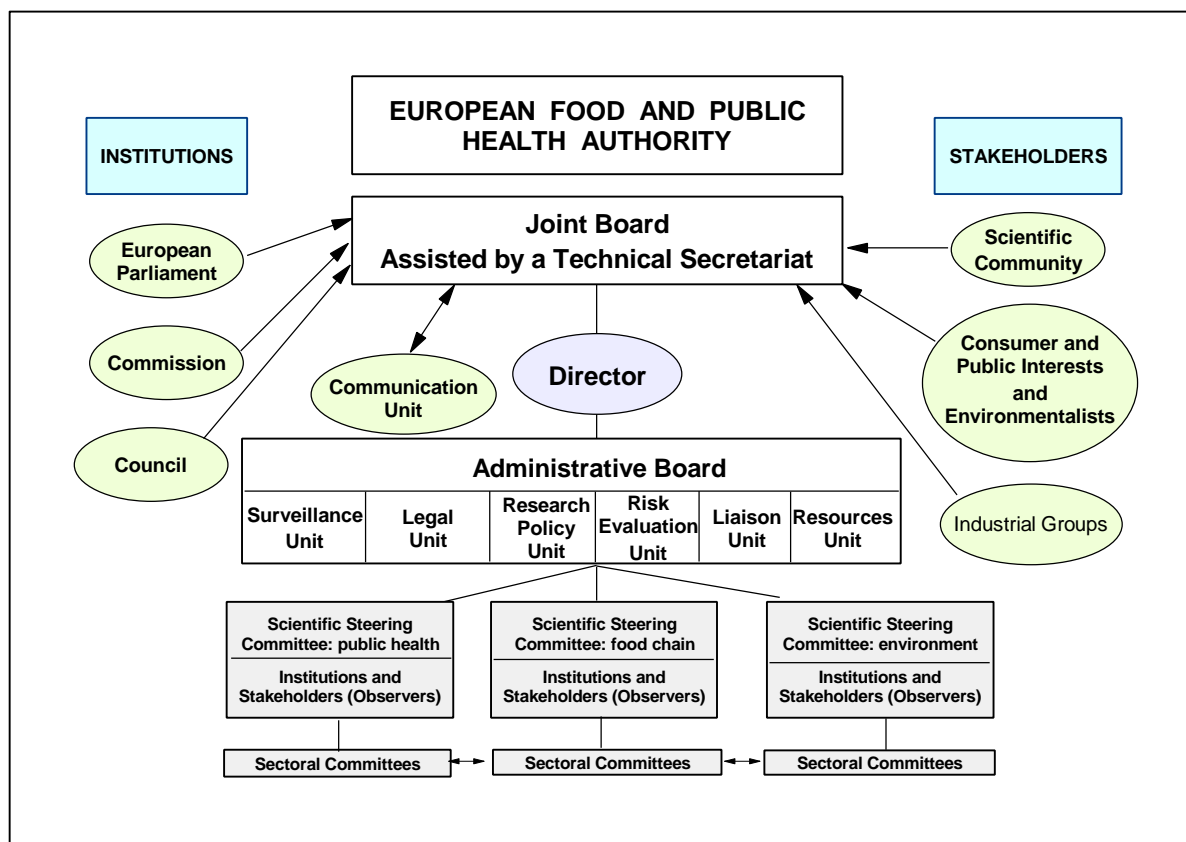


Figure 7.1 illustrates the various components needed within the Authority even if it is simply to serve as a major resource of scientific advice in relation to policy analysis. Seven components are proposed but in addition there is the primary need for a more substantial Secretariat.

7.1. Scientific Secretariat

A fundamental decision needs to be made concerning the extent of the involvement of the Secretariat in the development of the opinions. In the current system, the Secretariat involvement is low but variable, the external experts doing the major part of the work of assembling documents and reviewing dossiers prior to developing the final opinion. At the other extreme are systems used in some Member States where the Secretariat does the preparatory work (data assembly, initial working documents, drafting of opinions etc.) and the external experts take responsibility for the final conclusions. The choice has implications for the independence (or the perceived independence) of scientific opinions. In the

present “hands-off” approach, the burden is on the experts and therefore depends on their willingness to assist the Commission. The size of the Secretariat is modest in the current system but this is unsatisfactory.

Practical considerations rule out an “unlimited” full time Secretariat. However, experience of the present system suggests that it has the potential to provide an effective scientific infrastructure that could accelerate the handling of dossiers and reduce the burden on the experts if properly resourced.

Currently, resources do not allow the Secretariat time to study and become fully involved in the details of the many individual issues and dossiers. This limits the managerial effectiveness of the Secretariats and means that they cannot always play a full and satisfying role in the work of the Committee. This may ultimately lead to frustration and the loss of competent officials who can readily find other posts in the Commission.

Options for improvement within the likely budgetary constraints of the Commission include:

- a substantially increase the number of scientific personnel;
- making better use of temporary expertise e.g. national experts serving as temporary officials for up to 3 year periods;
- making better use of the budget to fund preparatory work (as working documents assembled with pertinent information by paid rapporteurs or literature reviews; this would require the proper funding of rapporteurs with an agreed commitment to manage the project on an in agreed time-scale. This is an “EMEA approach”;
- hiring of professional scientific writers to draft documents which remain under the full responsibility of the committees;

It is concluded that there is a need for an appropriately sized secretariat for coping with the complexity and range of issues for the scientific analysis. This need has so far been underestimated by the EU. Analyses of Member State and international systems suggest that each major committee needs at least 3 highly qualified, knowledgeable scientists routinely involved in writing scientific opinions, a full-time administrator with full secretarial support, as well as the back-up of those required for handling all the financial support issues. In most national arrangements it is the secretariat which produces the drafts and redrafts of position papers and not the individual expert scientists. Furthermore, analyses undertaken by the US Food and Drug Administration show that they have a far greater staff

involvement at every level of scientific analysis than that currently operating in the EU.

There is a need for the responsibilities and duties of the Scientific Secretaries to be defined and codified so that their functions in the Committees are clearly understood by all those concerned (Member States, experts and other Commission officials)

Responsibilities include:

- adherence to the mandate, time-scale, principles of risk assessment, independence.
- ensuring the clarity of the opinion, consistency of supporting argumentation and the conclusions, consistency with previous or related opinions even in other committees.
- reasonable awareness of the underlying legislation or regulatory environment where the advice is required and is going to be used
- keeping up to date with developments in the area where the committee is developing the advice: attendance of conferences, workshops, regulatory meetings

They need the authority to intervene when:

- Questions are delayed through organisational problems e.g. rapporteur unable to deliver on agreed time-scale, participants fail to deliver agreed contributions
- Members fail to contribute effectively
- Important scientific issues are not addressed fully in the draft opinions
- The Secretariat has an important role in the elaboration of the mandates of the questions. The Secretariat needs to have recognised authority for ensuring that questions are appropriately expressed having regard to the mandates of the Committees, conflicting policy objectives of Commission departments, the principles of risk assessment, practicality and any risk assessment policy determined by the Commission. better use of existing National resources

The other components of the administrative structure are as follows:

7.1.1. A Communications Unit

This unit is seen as a major component of the new Authority with a direct and specific responsibility for engaging with the media, Commission and Parliament. It would need to develop, therefore, a completely different portfolio of presentations from those in the scientific opinions as currently set out on the Internet. The scientific committees documents would still be essential public documents but there is a need to engage the principal stakeholders in society and the triangular power base of decision-making within the EU with a more understandable synthesis of the work of the committees and its implications. Thus the significance and weight of evidence emerging from the advisory committees can be set in a proper perspective. This Communications Unit should also be involved in crisis management (see section 10).

7.1.2. Surveillance Unit

Currently the surveillance and audit functions of the EU are divorced from scientific analyses which currently have to presuppose that all risk management and control systems operate perfectly. Whilst a proper distinction needs to be made between scientific risk assessment, risk management and the auditing of the effectiveness of management schemes the current lack of awareness by scientific committees of the outcome of audited control systems means, as discussed earlier, that the public and external policy makers are not given a realistic assessment of risk by the scientific committees. This audit function should be allied to a surveillance facility. It is at present striking that in DG SANCO individual experts are somehow expected as part of their contribution to be able to collate information from the EU's Member States as part of any initial assessment of a range of issues. The scientists often fail to obtain the information in time.

There now needs to be a system for the collation of quality assured data from Member States, many of whom do not have agencies or government departments able to provide the data in comparable form within the time required. Nevertheless, valuable data exist in both the private and public domains. There therefore needs to be a resource and a Secretariat within the new Authority to allow these data to be collected more effectively and on a systematic basis. The experience of scientific co-operation on the food committee and the OECD experience suggests that Member States could also be involved more effectively by take responsibility for the EU wide collation of data in a standard format.

Note has already been made of the need for a new approach to health surveillance in Europe analogous to that conducted by the CDC in Atlanta. Such a facility should properly be linked with this unit which has responsibility for the proactive collation of data relevant to the work of the Scientific Committees.

7.1.3. A Legal/Regulatory Unit

This would serve as a link to policy making: a large number of scientific issues arise when lawyers translate complex scientific reports into appropriate regulations. Their task would be helped if a unit within the EFPHA contributed to this process and allowed the scientific advisers to recognise legal needs. It is recognised that this facility already exists within the Commission service, but at least part of this facility needs to be transferred into the Authority. Their role is to ensure that the multiplicity of legal groups within the Commission are clear about the nature of the scientific advice and its implications for legal developments and at the same time to inform the Authority of the outcome of the Commission's response to the scientific analyses.

7.1.4. Research Policy Unit

DG for Research has responded to some of the committee's analyses of BSE issues, initiated new research and indeed reorganised funding from the Framework V programme to highlight issues of public concern in Europe. These developments are to be commended. Nevertheless, there is the need to develop a formal system whereby the outcome of all the analyses and judgements of the scientific committees include in the future a specific set of recommendations for tackling the wide range of uncertainties revealed by the committees' deliberations. These should then be fed to a research policy unit within the new Authority with the unit having responsibility for ensuring not only direct links to the JRC, but also with DG for research such that the research needs can be prioritised and an overt specification of what can and cannot be done is then made public as part of the new Authority's public communication portfolio. This Research Policy Unit may also have to undertake a substantial amount of background collation, enquiries and analyses in its own right. Many would then classify the unit as having its own research portfolio as well as developing a scheme for EU research priorities. It is also recognised that if one took an FDA approach to these issues then the JRC would become a component part of the new Authority and DG Research might well be asked to specify the proportion of its budget being devoted to reactive policy

related research as well as to strategic research of relevance to the work of the committees.

Whether or not the Commission moves to a more coherent integration of the different components of risk analysis within a single Authority will emerge in due course but from a research point of view it is evident that the United States' FDA considers itself as having benefited from recognising four components to its research needs:

- a) In-house research in terms of improving technical testing or developing practical research programmes with a 2-3 year time horizon - as in the EU's JRC;
- b) Designating publicly the need for specific research topics to be conducted with funds allocated by the organisation to external groups.
- c) Negotiations with the US Department of Agriculture and other agencies to agree research priorities. The Agricultural and other departments then take initiatives involving more strategic / basic research with results of value emerging in perhaps 5-8 years' time.
- d) Recognition that the States within the US have particular interests, e.g. in the issues relating to fruit growing in Florida and California. These States have their own budgets which the FDA seeks not to duplicate.

From this experience it is clear that the research policy unit in the new Authority could play a novel role by interacting with Member States so that it becomes clear that particular aspects of research are a strength of special research institutions or Member States. These can then be designated as making a major contribution to EU developments.

7.1.5. Risk Evaluation Unit

Such a unit already exists and is directly attached to the Director General's office. This reflects the priority concern of the Commission to protect consumer health, particularly with regard to food safety.

The need to establish a structure dealing with the highly sensitive issue of risk evaluation was identified in the Communication of the Commission on Consumer Health and Food Safety of 30 April 1997. The need for a network of external experts in a broad variety of specialised areas has been identified with the aim of making scientific advice quickly available in emergencies.

A Risk Evaluation Unit can play a major forward looking role in identifying potential and emerging health risks; in so doing it contributes to a proactive, rather than reactive, approach in dealing with issues related to consumer health.

The Scientific Committees carry out the routine risk-assessments in their area of competence such as food, animal feed, cosmetics etc. The Risk Evaluation Unit, however, can react rapidly to immediate problems in order to provide decision-makers with prompt advice on specific questions. This is the case whenever safeguard-clauses are provided for in order to limit the risks of food-borne disease from imported products. Recently the present Risk Evaluation Unit contributed to assessing the risks arising from the cholera epidemic in Africa and avian influenza in Hong Kong.

This Risk Evaluation Unit also works in close collaboration with the Scientific Committees on matters of particular concern or major political interest. In 1997, the composition of the Euro coins needed to be finally agreed, but consumers had expressed concern about the nickel content of the alloy to be used for the 1 and 2 Euro coins, since in certain circumstances nickel can give rise to allergies. The Risk Evaluation Unit was able rapidly to mobilise the necessary resources to carry out laboratory tests on samples of coins.

This strengthened the position of the Scientific Committee for Toxicity, Ecotoxicity and the Environment to assess the risk of nickel allergy in consumers handling the coins, and ultimately led to the public being reassured. In other cases, the Unit has been able to perform extensive documentary research in support of the Scientific Committees.

The EU has banned the import of meat from hormone-treated animals. Under a recent ruling by the World Trade Organisation (WTO), the EU is now obliged to provide scientific justification for this ban. This is an example where both the scientific advisory system and a risk evaluation unit could be responsible for the co-ordination of risk assessment on hormones which is being carried out as a follow-up to the WTO ruling.

Within a new Authority such a unit would not only link with the Surveillance Unit, but would be directly involved with a crisis management team and then feed back to the Scientific Committees the challenges emerging from the crisis.

7.1.6. *Liaison Unit*

One of the principal challenges in the enlarging of the EU will be how best to ensure that Member States and their designated scientific institutions are involved

effectively in the Authority. This is of major importance and the time involved should not be underestimated. This function is therefore designated as a liaison unit.

7.1.7. A Resource Unit

There will be the need for a designated unit to cope with the implications of the present proposals and the demand for such extensive interactions in the expanding EU. Strong administrative support will be needed to fulfil the new tasks relating to the management of contracts, staffing, information networks, documents, equipment, website and general communication etc. There will also be the need to support the expert and scientific secretariat with literature search facilities and expertise, library, archiving and rapid retrieval of dossiers and documents. Also required is the collation of new data emerging from the much needed surveillance system in the expanding EU. Much better equipped meeting rooms are already needed with administrative support, electronic information exchange, exposure assessment unit and web-page management etc.

7.2. Stakeholder involvement

Not only should stakeholders be involved in the Board but they should also be able to attend meetings of the Scientific Committee members as observers. Whereas industrial interests will be able to attend, paying for their own costs, it is essential that the EU ensure that public interest groups are also able to contribute at least to the same extent. Therefore when the principal committees meet, the EU should agree to pay for the attendance of consumer, environmental and other public interest groups when their attendance would otherwise be prejudiced. How to select a representative of appropriate groups will require the development of a formal system. In addition to their involvement, scientific committees or at least their chairs with 1 or 2 expert members, should in the future take part in systematically ensuring that the stakeholders are fully in the picture before a mandate is agreed, i.e. before a problem is tackled and again when an opinion is being reached. Different forms of hearing and debriefing procedures should be tried to see which prove most effective. The need, however, for these meetings to improve the transparency of the process should not be in doubt.

A system of observers is proposed where, as in the current scientific selection process, the individual stakeholder would be proposed for selection. The selection process would identify the person with the most appropriate background for service on the committee. Again, therefore, the chosen would be there on an

individual basis and not as a representative of a particular sector. This system has already worked well in some Member States and is expanding. The Commission should learn from this experience.

8. THE ORGANISATION OF THE SCIENTIFIC COMMITTEES

8.1. Mandates

The competencies of the scientific advisory committees should clearly encompass those currently involving DG SANCO and be extended as indicated above to cope with the new portfolio of DG SANCO's responsibilities. The mandates of the steering committees need to be broad and explicitly allow the committees to indicate a new analysis which they perceive to be of emerging concern. This approach, unlike that seen in several national systems, has already proven beneficial in the new working format for the current Scientific Steering Committee . The ability to initiate enquiries should therefore be a consistent feature of all three major multidisciplinary scientific steering committees in the future.

A further principle needed is one where the scientific committees help formulate the mandate for their specific work. Mandates have on occasion been proposed – in practice at the request of other Directorate Generals – which not only set the confines of the agenda but in practice prejudice the outcome of the analysis. This will be avoided if one of the tasks of the committee is to discuss and develop the mandate for their task in conjunction with the Commission and after involving stakeholders as already specified.

Thus the new approach needed to risk assessment in public health analyses (see Section 6.1.2) means that great benefit can emerge from ensuring that in each dimension of analysis a coherent system is developed which attempts to be consistent so that the Communications Unit can develop a new approach to the different sections to which it relates.

8.2. Options for initiating scientific review

The experience of the last two years illustrates the benefit of scientific committees having the option of initiating a review on a topic which they consider to be of emerging importance. It is important to continue to support the policy whereby a scientific committees has the right to review an area. Clearly the committees need to be able to respond to requests from the different DGs of the Commission but the proposed new arrangements will create a new opportunity for the European Parliament to be provided with additional analyses and policy options. A need for further work may also arise as a result of discussions by the Council of Ministers.

Given a potential multiplicity of requests, the EFPHA Board might need to develop systems for both prioritising requests and considering how best to cope with complex questions which include political or other components which go well beyond the mandates of the collective range of scientific committee responsibilities. The Board should be the final arbiter of how to respond to these novel demands.

8.3. Number, composition and structure of scientific committees

With the exception of the Scientific Steering Committee, the current committee structures continue to reflect the legislative structures that the Committees were originally established to serve. Whilst continuing to providing a sound basis for ensuring that the advice is relevant to the corresponding legislative and policy sector, a structure based on technical rationales can also be envisaged. e.g. by scientific discipline (toxicology, molecular genetics, microbiology and hygiene..) or even by broad generic area (e.g. public health and environment).

Whilst admitting the attraction of ensuring scientific coherence, such arrangements run the risk of creating bottle necks and delays because a very large number of questions would need to be examined by a series of Committees and, there would still remain the requirement to meld the individual parts into a single coherent opinion. Such "multi-committee" approaches would also conflict with certain formalised procedures as typified by the Novel Foods regulation that requires consultation of a specific committee. Generally, the present system has proven its ability to serve the needs of its primary customers (the legislating and policy making DGs). Any new system should be at least as effective as the present one.

As illustrated in Fig. 7.1, three general overarching steering committees are proposed, i.e. those dealing with the food chain, environmental and public health issues. Within this committee structure, there will be a full complement of committees which deal with particular areas of responsibility. On the basis of current experience there may be more than a 100 opinions/analyses continuing to be produced by these groups each year. To ensure that these reports are set out clearly, are also compatible with each other as well as contributing effectively to policy-making is a remarkable challenge for the Scientific Secretariat as well as for the overarching Steering Committees.

Given the major restructuring of committees in the last 2 years, it is concluded that for the present there should be no further major changes with the following two exceptions:

- a) The major task of the current Scientific Steering Committee relates to BSE and other TSEs. This is inevitable given the dimensions of the public health crisis of the last 3 years. Nevertheless, this activity might logically be considered within the context of a communicable disease committee which also copes with such emerging problems as E. coli 0157 and other similar food borne diseases which have major implications for environmental, agricultural and food processing concerns.
- b) The principal public health problems of Europe need to be handled by a strategic committee with a clear perception of public health. Given its intersectoral nature, this would have a format and perhaps operating style analogous to that now used in the Scientific Steering Committee. This proposal is based on the assumption that no new institution for this specific purpose is likely to be developed.

The overall portfolio of committee mandates is wide and in consumer protection and health terms is likely to broaden. Thus the new Authority's remit means that its interests and analyses will impact on several DGs' work.

The one area which requires particular consideration relates to public health which, following the Amsterdam Treaty, now acquires a new prominence in European affairs. Several Member States have a strong tradition in public health analyses and actions, e.g. Scandinavia, whereas others have a poor understanding of these issues. With the EU's enlargement, there needs to be a new emphasis on public health because there is a very large number of structural factors which have a major impact on consumer health and well-being, e.g. water, sanitation, housing, industry, transport, local planning and other environmental policies which have received too little attention in relation to health. In this preliminary report the issue is simply highlighted and should be developed in greater depth by a public health committee.

8.4. Selection of experts and the Secretariat

8.4.1. Selection of experts

The new arrangements whereby experts are recruited as candidates for the principal committees by responding to a public invitation is an important step forward in ensuring that the process is transparent and that individual experts have the chance of being considered. It is proposed that there should be a public call

for proposals and consultation from Member States, the European Parliament and stakeholders.

There are six areas in the current system which could be improved:

- ❖ To enhance transparency and to ensure that stakeholders are able to contribute to the overall development of the portfolio of expertise, representatives from the Stakeholder groups listed in Section 7 should be invited to comment on the development of the portfolios of expertise for each committee's mandate. They could also be considered as observers of the appointment system.
- ❖ World class European scientists are unlikely to put themselves forward given the intense demands on their time and the likelihood that they would be unaware of the current method of advertising. The experience of the US FDA may be relevant since they overcame the difficulty by contracting experts for specific tasks or agreeing, for example, a day/week contract for a year at a *pro rata* cost of \$60-100,000 per year with higher fees for exceptional scientists with unrivalled knowledge or experience.
- ❖ A proportion of scientists with excellent academic records prove unable to operate in an interactive environment where eventual consensus is desirable rather than the demonstration of individual pre-eminence. This implies the need to include external enquiry of potential candidates and a new system of appointment with a one year temporary appointment prior to the provision of a full contract for attendance at meetings. An option for a probation system where inappropriate scientists can be removed earlier is an alternative preliminary scheme. Care needs to be taken, however, in ensuring the continued presence of scientists with different views. A new transparency in procedure will help to safeguard these scientists. Alternatively, potentially suitable scientists can be invited to join a working group, thereby allowing a preliminary evaluation of his/her contribution.
- ❖ Some appointed scientists, once recruited, in practice rarely attend meetings and/or rarely undertake personal responsibility for contributing with additional input to the committees. The ability to remove such appointed experts would be covered by a probation system but again needs to be transparent.
- ❖ The balance of expertise within the principal committees has sometimes proved to be inappropriate; that suggests the need for a clearer specification of the range of expertise needed when handling a committee's mandate. The

breadth of expertise would also be helped by having stakeholder suggestions but the specification of what exactly is required from an expert committee is a task which needs very clear thinking and specification as recently highlighted by the Office of Science and Technology in the UK.

- ❖ The present appointment process involves recruiting the whole committee for a 3 year period. It would be preferable to develop a system of rotating but renewable appointments so that the corporate understanding of the committee can be retained with the option for both adjusting expertise and introducing fresh thinking at yearly intervals.

These proposals for change imply the need for a more flexible recruitment system with the development of a standardised annual procedure which becomes a simple routine organised by the Secretariat but supervised by the EFPHA's Board. The need of specific procedures to ensure that the criteria for excellence, independence and transparency are fulfilled will still exist.

As indicated above, external experts should now be drawn from anywhere in the world if the expert identified in, for example, Japan, Australasia or North America has a unique and important contribution to make to the Authority's analyses. The difficulty in recruiting world class experts to the often tedious process of scientific analysis and its policy implications is amplified if experts live outside Europe. A mechanism is therefore needed to involve selected experts. One option is to provide them with a contract to produce a preliminary report. The issues which then need to be addressed could then be explicitly developed by the relevant EFPHA committee and its Secretariat to limit the time and travelling demands on the expert.

8.4.2. Links with other relevant institutions and groups.

The experience of the last two years has clearly demonstrated the value of interacting with other international institutions and groups involved in a particular field of endeavour. The policy for scientific interaction at a scientific working group level should therefore be reinforced in the future. Where there are particular concerns there is benefit in ensuring that those groups with the greatest expertise or established views are recognised and that they are allowed to provide information and potentially a representative for a special hearing of their concern. Care needs to be taken to ensure that the external groups are not allowed to hijack or pre-empt proceedings but in general the more open and interactive the process the better.

8.4.3. Geographical balance of scientific expertise

The current system of appointment developed with the heavy involvement of Commission officials from several DGs. It was clear that some officials were particularly anxious to promote scientists with whom they had worked well whereas others were anxious to reduce the dominance of scientists from 2-3 Member States where there seems to be particular expertise. After the first phase of selection and another round where some scientists had been chosen for 2-3 committees, the Commission had the responsibility for finalising the choice of expert. The geographical distribution of the chosen scientists was then considered.

From a scientific point of view, it is easy to specify that the ideal selection system is one which selects the best expertise irrespective of their national origin. Clearly, however, the practicalities of handling contentious issues of intense political concern are helped if there is a good geographical spread of scientists on committees. With the enlargement of the EU this will become a more contentious issue. It is suggested that, to handle this problem, the new Authority, as part of a new relationship with Member States Agencies, sets out to encourage best practice in handling scientific expertise and in effect becomes a training facility for those Member States with little experience in handling policy issues relating to food standards, public health and environmental concerns. In this way the Authority draws on and enhances the best practice of some Member States and nurtures the development of the type of expertise which some major countries within the EU find hard to identify within their country despite having outstanding laboratory scientists and doctors.

8.4.4. Selection of Secretariat

In Section 7.1 it is proposed that the scientific secretariat is enlarged to provide the degree of support currently enjoyed by similar national expert committees. The scientific secretariat needs ideally a scientific background in the general area covered by an EFPHA committee, the ability to draft documents at speed, good management skills and good communication skills. To find such highly qualified individuals is not easy but three sources should be considered: a) Commission staff; b) short-term, e.g. for 3 year or so secondments from National Ministries and c) new temporary as well permanent recruits from Universities and other academic centres within the EU. The value of secondments to the EFPHA for both the EU and the Member States should be recognised: special efforts should be made to provide experience of the EFPHA

for staff from the smaller nations, e.g. those <10 million. Particular emphasis should also now be placed on recruiting temporary staff from nations expected to become part of the expanded EU within the next five years. Other nations expected to come close to membership within the next 10 years should also be targeted so that there can be an appropriate interaction between the Commission and Member State scientific staff on a long-term basis.

Although the construction of a multi-layered bureaucracy brings organisational problems, there is a clear need for an additional forum that brings together all the stakeholders: scientists, legislators, EP, member states, consumers, industry etc. The UK's Food Advisory Committee (FAC) may provide inspiration for such a forum. It should be distinct from the science based risk assessment work of the "scientific council". The French Conseil National de l'Alimentation is another example of stakeholder involvement.

8.5. The process of scientific evaluation taking account of Member State and international interests.

A series of approaches to scientific evaluation has been evolving as different committees respond to the need to combine exceptionally detailed analyses of complex problems in fields where scientific progress may be rapid with an integrated multidimensional perspective based on having to present conclusions and policy options on the basis of great uncertainty and limited scientific understanding. These include the complex issues relating to BSE, issues relating to GMOs and the basis for the development of antibiotic resistance. In 2 of these areas up to 3 different layers of analysis have emerged:-

- a) Focused and often basic analyses of a problem undertaken by a group of specially convened experts from one or two disciplines. Sometimes this involves the commissioning of a report by a single expert or European institute.
- b) The combination of a group of reports or inputs from a variety of disciplines into a single overview which often displays the very large number of unanswered questions which emerge particularly when attempting to link work from different fields. This evaluation thus emerges as a background document or working group paper.
- c) A final integrated opinion from a supervisory general committee made up of scientists from many disciplines who have to recognise the many dimensions of the problem and weight the analyses to provide a balanced

set of judgements and recommendations. This opinion is usually presented as a separate opinion but published in conjunction with the working background paper. This approach should be retained in the new system. It also provides opportunities for widespread geographical input and for scientists to learn the skills of risk assessment.

8.5.1. Member State interests

Experience has shown that there is great benefit in having different national perspectives, particularly when considering risk assessments and the policy implications which can have a very different impact on the very different environmental, social and cultural contexts of Member States. However, two principal issues have emerged:

- a) There is not enough interaction with the expertise and analyses available within national governments of Member States. A new system needs to be devised to facilitate the rapid exchange of views. This exchange needs to be recognised as mutually beneficial: the EFPHA's scientific committees can take account of regional or national issues as well as of additional expertise. The Member States also benefit because their expertise as well as any unusual national issue will have contributed to the integrated view and often reveal a new agricultural, environmental or policy dimension previously unrecognised by the EU committee. This need is likely to increase markedly with the impending EU expansion of the EU into Central Europe.
- b) Some Member States' industrialists and scientists perceive that there is substantial duplication of effort with some Member States having exceptional expertise in a particular area. This recognition in part underlies some of the current EU policies on subsidiarity as displayed, for example, in the procedures for assessing novel foods or GMOs where a national or international company can submit their application to any Member State of their choosing. The Member State's opinion then becomes the EU opinion if no other national objections are raised.

In practice, many issues are emerging as contentious, e.g. novel foods, functional foods, GMOs, the response to BSE and Member States may object to the opinions generated. This then requires the Commission to request an adjudication by its own committee. It has been argued that this system is exceptionally cumbersome,

leading to a long delay before the Commission's proposals are put to the Standing Committees of Member States' officials for approval.

Clearly, as the EU expands, it is increasingly unlikely that all Member States, particularly small countries with limited scientific personnel, will have the depth of expertise necessary to undertake a thorough and wideranging review which incorporates an understanding of all the issues at stake across the whole EU. This inevitably leads to the likelihood that large Member States with a substantial depth and breadth of scientific expertise will be increasingly used in any devolved system for handling risk analyses. The EFPHA's committees are also likely to prove of increasing importance.

Rather than seeing these developments as competitive alternatives, it is suggested that there should be greater interaction of Member State advisory groups with the EFPHA system. Three improvements are proposed:

- ◆ A routine request at the start of any evaluation for Member States to provide whatever input they consider would be useful for EFPHA scientific analyses.
- ◆ The nomination by EFPHA committees of particular expert groups or advisory bodies within Member States to undertake specific studies.
- ◆ The involvement of specific government scientists with particular expertise from Member States in EFPHA expert groups whenever possible. This should not be seen as a proposal to develop a political balance by having all Member States represented – the choice should be based on a few individuals with particular experience.

8.5.2. *International interests.*

It is becoming clear that the Commission's scientific committees work and the impact of their reports are more effective if there is international involvement. This is particularly true when issues arise which have major implications for specific countries. Thus this year's analyses of the geographical BSE risks in different countries has benefited greatly from non-EU involvement. Not only is there additional scientific input, but when the non-EU experts come from governmental positions, their involvement in complex analyses and decision-making has allowed them to have a much better insight into the basis for the EU's scientific analysis. It is therefore suggested that the EU take a much more pro-active approach to the involvement of international experts and scientists from government departments, particularly when a country is likely to have a

major interest in the outcome of the analyses. This is already underway in the current system where, for example, 4 American scientists were members of the working group on hormones". This procedure should be encouraged.

It is also now becoming clear that the Commission's scientific committees and those involved in the analyses conducted by the US Food and Drug Administration are taking very different perspectives, e.g. when considering GMOs, the animal and human risks from the use of bovine somatotrophin and the risks of hormone use in beef rearing. This is leading to major trade disputes and charges from both EU and American scientists and policy-makers that the other's analyses are determined by industrial or political interests. Certainly US opinion has not yet recognised the last 2 years' changes in EU arrangements for scientific procedures and analyses. The recent proposals in US-Commission negotiations* to have conjoint analyses with both EU and US scientists is therefore welcome.

Emerging from these developments is the need for the EFPHA to develop a very pro-active set of procedures which anticipate potential difficulties in coping with different international perspectives on the food chain, environmental and public health issues. So far only benefit has come from involving stakeholders in these deliberations but care is needed to safeguard the independence of scientific analyses.

8.6. Transparency of scientific analyses and their outcome.

There is a need to continue to develop a transparent approach to the EU's scientific analyses. The stakeholders as well as the European Parliament need to recognise that the committees of DG SANCO have been shielded from industrial and political pressures. So there is benefit if this policy decision is clearly set out by DG SANCO in its presentation of the new system. The transparency of the process could be increased however. There is merit in allowing the stakeholders the opportunity to highlight issues of concern before a committee is fully embarked on its analysis. Furthermore, there would be benefit in having a designated qualified representative of stakeholder group serving as an observer on the main committees. It would seem important to have single, specified observers designated with no substitution option and with the recognition that preliminary discussions in committee are likely to continue

* Bonn declaration

to be considered confidentially. This allows committee members to range freely over a large range of options without having particular proposals ascribed to them. Stakeholders could become involved in proceedings but this would need careful monitoring and control by the committee chairs. The earlier request by EU parliamentary committees to be allowed to take part in these principal committees might best be handled by having the Parliamentary committee designate one of its expert secretariat staff to serve in this capacity. The exhaustive analyses and redrafting of reports – which has sometimes required up to 30 drafts or more in recent experience – is not an environment conducive to the busy parliamentarian or those who simply seek a particular outcome to the scientific analysis and wish to come only for the final approval process.

Currently the outcome of committee meetings and the reports are placed as rapidly as possible on the internet. This should continue but the practice of putting a draft of the report out for consultation is, in general, a good idea and should be done more frequently than at present. Furthermore, the proposal to have a communications unit incorporated into the new authority will provide a more effective opportunity for communicating with the public. The stakeholder representative in the committees should also have the responsibility for alerting their constituent bodies to developments and new analyses once these are agreed by the committees.

Particular attention will need to be given to the European Parliament which has in the last 2 years held two major sessions in Brussels involving >500 people in public meetings dealing with the handling of BSE and its aftermath. It is expected that future parliamentary committee will hold regular meetings into consumer protection and public health so the proposed new Authority would need to develop mechanisms to ensure that Chairman, selected experts and the scientific Secretariat become accustomed to handling these opportunities to explain their work.

8.7. Remuneration and maintaining the best European advice

Top quality scientific advice is a 'marketable service' obeying to some extent the rules of the market, i.e. if the Commission wants top notch scientists to be vying to become members of its scientific committees it needs to pay them at least at par with other 'customers'.

Current procedures for reimbursing experts expenses has changed recently but, as widely recognised, the procedures continue to handicap the Commission's

attempts to involve the best experts. In several countries national experts are coming to see the helping of the Commission as a low priority because their standing in academia and their local institution increasingly depends on the capacity of scientific leaders to win major contracts through competitive tenders. Their personal contracts and remuneration are increasingly being determined by their track record as scientists who conduct effective research and produce very high quality papers in the best journals. The pressure on scientists and universities to maintain a cadre of junior and support staff has increased very substantially in the last 5 years so a request from the Commission for immediate and perhaps prolonged help is seen not only as cavalier, but insensitive to the realities of modern academia. It is therefore likely that it will prove increasingly difficult to recruit top flight scientists to undertake the Commission's work.

In terms of reimbursement, there are several further developments whereby the Commission could improve its reputation but these are not dealt with here because the major issue is how to cope with the new circumstances of scientists being forced to consider themselves operating in a consultancy mode.

There are three options which should be tried. First the EU could reserve the major scientists and his/her group for specific contracts to produce substantive reports of importance for scientific committee. These contracts can then be seen to limit the time involved in Brussels and be in keeping with modern research practice. Secondly the Commission could undertake to pay the scientists' institution the equivalent of his salary and personal overheads for the time contributed to the Commission's business. This is the practice in some organisations and needs careful handling by administrative staff who are used to negotiating this type of contract. This then allows the scientist to recruit a junior member of staff to promote his research while in Brussels. Thirdly, an option could be considered for selectively recruiting for a year or more a senior member of a scientist's team to serve as a special expert to a particular committee involved in reviewing an area. This third option may prove harder to enact because of the disruption of the scientist's life by a temporary transfer to Brussels.

9. CRISIS MANAGEMENT

The EU needs to develop further its approach to crisis management. A unit or group is needed to enhance the importance of the recently developed risk evaluation unit. Experience in Member States and the US demonstrates the need for professional training on how to manage and be seen to manage crises. The proposal to incorporate a risk evaluation unit into the Authority is made on the basis of its role being that of a rapid response unit which in effect has to be completely aware of the detailed work already undertaken by scientific committees. Immediate and effective interaction by a crisis management unit is an essential part of the current needs with designated trained personnel, excellent communication channels to the Parliament and Member States and the ability to respond calmly, and where possible, proactively in difficult circumstances.

10. CONCLUSIONS

These analyses stem from a recognition that the Commission has made major advances in the organisation of scientific advice in the last 2 years, but that the continuing challenges are wideranging and likely to increase as the Community expands. The proposals have deliberately taken on board the current range of scientific advice and the dimension of public health as a new responsibility. The present report has not considered the option of a completely new public health entity in its own right because experience has shown the crucial links with food and environmental issues. Nevertheless, public health is largely unexplored by the Community as such so the proposals for three Steering Committees is based on the need for an initiative in public health with the development of public health surveillance system for Europe. It is recognised that these developments must be seen to be part of an evolutionary process. The proposals are set out in the expectation that their implementation would greatly enhance the credibility of the Commission, allow a framework to be developed for coping with EU enlargement and, it is hoped, bring clear benefits to the citizens of Europe.

APPENDIX 1: THE MANDATE

Since April 1997 clear guarantees have been given to citizens that the scientific opinions, upon which Community legislation on food safety and consumers' health protection are based, meet criteria of excellence, independence and transparency. All the interested parties (Member States, Parliament, consumers and industry) largely approved these principles. Moreover, it has been recognised that the present system of scientific advice and in particular the role of the SSC represents an important improvement compared to the situation before the BSE crisis.

Nevertheless, a review of the working methods of the scientific committees has been asked for by the EP. In addition, the organisational arrangements have been the subject of reflections as to whether an independent agency type structure could lead to further improvements in scientific advice at the EC level. In any case, the present committee composition will have to be renewed before October 2000.

It is therefore necessary and appropriate to prepare the ground for possible improvements in the EC system of scientific advice. This should be done in the light of

- experience with the functioning of the scientific committees since autumn 1997
- the new organisational set-up of scientific advice developed recently in some Member States, in particular the UK and France, in international organisations, e.g. JECFA, and, more generally, Member State systems of scientific advice
- the growing international importance of consumer health related issues
- the need for consistent, internationally acceptable risk assessment methodologies.

Basic material on these aspects will be provided by the Commission services.

The **first task** of the experts is to reflect on the purposes of the EC scientific advice system. Normally, scientific advice will be used as input for risk management decisions that directly affect consumers and industry. Consequently, at least a triangle of interests will be served by scientific advice:

- - it should meet the needs of the authorities responsible for risk management, i.e. in particular the Commission, the EP and the Member States
- - it should be geared to the objective of consumer health protection and as such confidence-building for European Consumers
- - it should take account of the interests of industry for efficient and reliable procedures.

It is clear from this that no system of scientific advice could ever claim to be "optimal" in view of these three often divergent basic interests. The experts are therefore asked to analyse the different purposes of scientific advice and their potential lines of conflict, in order to provide a framework against which changes in the generation and organisation of scientific advice can be judged.

As a second task, the generation of scientific advice should be examined and options and recommendations for improvement developed. Quality standards should be identified for all stages in the generation of scientific advice:

- - the mandates for the scientific Committees or their equivalent
- - the criteria for selecting/recruiting the persons generating scientific advice (incl. the secretariats)
- - the origin of the demand for scientific advice in particular the role of the scientific committees in initiating reviews of policy sensitive issues
- - the scientific methodologies applied for risk assessment

- - the modes and sources of generating advice: basic material, draft opinion, finalisation of opinion, peer review
- - openness and transparency of the process and its results.

In the light of the options and recommendations for improving the generation of scientific advice, **the third task** consists in presenting options and recommendations for the organisation of scientific advice. A number of issues should be examined in this context:

- - the number, composition and structure of scientific committees and remuneration of their members
- - the relationship between committee members, expert group members and the committee secretariats
- - the linkages between scientific advice and scientific research, in particular the research financed by the EC budget (JRC, DG XII etc)
- - the potential for synergies between national scientific advice systems and the Community one
- - the need for a structured information policy related to the generation of scientific advice towards journalists, consumers, industry, Member States etc.
- - the desirability to charge fees, e.g. for product authorisations and its potential impact on the independence of scientific advice.

Finally, the crucial issue of the most appropriate place for scientific advice should be addressed, in particular with reference to the necessary degree of independence and to the relationship to the Community institutions. Different options have already been advanced: as now, a directorate in a DG (but which one would be the most appropriate), an independent Commission service, an interinstitutional office, an independent agency. The advantages and drawbacks of these options should be examined and a recommendation should be made.

APPENDIX 2

THE ASSOCIATIONS AND INDIVIDUALS ATTENDING A SPECIAL OPEN DAY HEARING ON THE FUTURE OF SCIENTIFIC ADVICE ON 4TH AND 5TH NOVEMBER, 1999 AND THOSE SUBMITTING SUBSEQUENT WRITTEN REPORTS

Adamson BSMG/communication

AESPG (Association of the European self-medication industry)

Agra Europe:

Akin Gump Strauss Hauer:

Alpharma:

APAG - Groupement européen des produits oléochimiques et associés:

APCO EUROPE

BASF:

BEUC (Bureau Européen des Unions de consommateurs)

Berlin Business Representation

BKSH:

British Retail Consortium

CEFIC (European Chemical Council):

CELCAA/COCERAL

CIAA (Confédération des industries agricoles et alimentaires)

CIFOG - Comité interprofessionnel des palmipèdes à foie gras

CLCV (Confédération du cadre de vie/Association française de consommateurs)

COLIPA (European Cosmetics and Toiletry and Cosmetics Association):

Consumer's association

COPA (Committee of Agricultural Organisations in the EU/Comité des organisations professionnelles agricoles de l'UE)

COGECA (General Committee of Agricultural Cooperation in the EEC/Comité général de la Coopération agricole de la CEE)

CEJA (European Council of Young Farmers/Conseil européen des jeunes agriculteurs)

DBV

Dow Europe:

ECPA (European Crop Association):

EFFA (European flavour and fragrance Association)

EHPM (European health product manufacturers):

ELC (Federation of European Food Additives and Food Enzymes Industries)

ERNA (European Responsible Nutrition Alliance):

EU Food Law:

Eurocommerce

Eurocoop

Eurometaux

Eurogroup for Animal welfare:

European coalition to end animal experiment:

European health Alliance:

European policy Centre

FEDESA (European federation of Animal Health)

FEFAC (Fédération européenne des fabricants d'aliments composés):

FEFANA (Fédération européenne des fabricants d'adjuvants pour la Nutrition Animale)

FRANCE SOIR

Giordano Andrea

Grant Bernie

Greenpeace European Unit:

Hill and Knowlton

Hoffmann- Laroche:

IDACE (Association of the food industries for particular nutritional uses of the European Union):

Kimberly Clark

Meat and Livestock Commission

Novartis

Office of Catalonia

Patronat Catala pro Europea :

Polish Mission to the EU

Representation permanente danoise:

Roche Vitamins Europe

STOA (Scientific and Technological Options Assessment Bureau of Parliament DG IV):

UCBV/CLITRAVI :

UNEGA (European animal fat Processors Association)

**LIST OF STAKEHOLDER GROUPS PROVIDING WRITTEN CONTRIBUTIONS AFTER ATTENDING
THE PUBLIC HEARINGS**

- Alharma
- BASF
- BEUC
- British Retail Consortium (BRC)
- CIAA Views on a European Food Safety Authority
- CIFOG
- Comité Européen de Liaison des Commerces Alimentaires (CELCAA)
- COPA-COGECA: Contribution and Press Release
- European Crop Protection Association (ECPA)
- German Farmers' Union

APPENDIX 3

Scientific Committee on Food

Field of Competence

Scientific and technical questions concerning consumer health and food safety associated with the consumption of food products and in particular questions relating to toxicology and hygiene in the entire food production chain, nutrition, and applications of agrifood technologies, as well as those relating to materials coming into contact with foodstuffs, such as packaging.

Scientific Committee on Animal Nutrition

Field of Competence

Scientific and technical questions concerning animal nutrition, its effect on animal health, on the quality and health of products of animal origin, and concerning the technologies applied to animal nutrition.

Scientific Committee on Animal Health and Animal Welfare

Sub-committee on Animal Health

Field of Competence

Scientific and technical questions concerning all aspects of animal health, hygiene, animal diseases and therapies, including zoonoses of non-food origin and zootechnics.

Sub-committee on Animal Welfare

Field of Competence

Scientific and technical questions concerning the protection of animals, notably in regard to animal husbandry, herd management, transport, slaughter and experimentation.

Scientific Committee on Veterinary Measures relating to Public Health

Field of Competence

Scientific and technical questions concerning consumer health and food safety, and relating to zoonotic, toxicological, veterinary and notably hygiene measures applicable to the production, processing, and supply of food of animal origin.

Scientific Committee on Plants

Field of Competence

Scientific and technical questions relating to plants intended for human or animal consumption, production or processing of non-food products as regards characteristics liable to affect human or animal health or the environment, including the use of pesticides.

Scientific Committee for Cosmetic Products, and Non-food Products intended for Consumers

Field of Competence

Scientific and technical questions concerning consumer health relating to cosmetic products and non-food products intended for the consumer especially substances used in the preparation of these products, their composition, use as well as their types of packaging.

Scientific Committee on Medicinal Products and Medical Devices

Field of Competence

Scientific and technical questions relating to Community legislation concerning medicaments for human and veterinary use, without prejudice to the specific competences given to the Committee for Proprietary Medicinal Products and the Committee on Veterinary Medicinal Products¹ in the context of the evaluation of medicaments. Scientific and technical questions relating to Community legislation concerning medical materials and equipment.

Scientific Committee for Toxicity, Ecotoxicity and the Environment Field of Competence

Scientific and technical questions relating to examinations of the toxicity and ecotoxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment

¹ Committees established in the European Agency for the Evaluation of Medicinal Products