Science and Governance: describing and typifying the scientific advice structure in the policy making process – a multi-national study

An ESTO Project Report

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Executive summary

Background
As policy issues facing governments increasingly involve a scientific or technological component, so the need for decision-makers to seek scientific advice has grown. A variety of avenues exist through which such advice can be sought. Individuals may be consulted or committees employed to examine the relevant issues. Committees may consist of scientific or other experts, legislators, or a mixture of people with different backgrounds. Bodies may be established ad-hoc to examine a particular problem or may be long-standing, perhaps statutory bodies, with a broader remit. Whatever form they take, advisory bodies are tasked with aiding policy decisions through the provision of robust and reliable advice. However, recent environmental and public health scares have highlighted some of the difficulties faced by both those providing advice and those who rely upon it, and have prompted discussion of how the provision of advice to policy-makers might be improved. An essential starting point in thinking about improvements is to develop a better understanding of current advisory processes. To that end, this study was commissioned by IPTS, through the ESTO network, to identify and typify the advisory structures in the science related policy and regulatory decisions making systems in several states.

About the Study
The study encompassed the UK, France, Italy, Germany, and Sweden. It also considered the case of the US, and the situation at EU level. The first task was to produce a general overview of the advisory systems in each of the countries studied. The second task involved a more detailed study of the advisory processes involved in each of these countries for two issues in which scientific advice has formed a major input into policy considerations: the possible cloning of embryonic stem cells for use in research; and the health effects of electromagnetic fields (EMFs). These two issues differ in interesting ways. The stem cell issue is a relatively new policy issue that is emotive, high profile and has a clear ethical dimension. The health effects of EMFs have been a matter of public concern for some time now, though the issue has a lower profile than the stem cell debate, and seems more dependent on technical arguments.

General Findings
The study confirms that a wide variety of advisory structures may be employed to support the policy-making process. Advisors operate at all levels of the political system, and the advisory process can be initiated in a number of ways. So, for instance, advice may be sought by the head of government, ministers or civil servants, or the legislature. Alternatively advice to policy-makers may be initiated by a standing advisory body. The need for advisors to be seen as independent from interested stakeholders is increasingly important and, whilst advisors are rarely excluded outright on the basis of their interests, it is usually the case that they are expected to declare any interests they may have at the outset.

More generally the openness of the advisory system is increasingly recognised as an important contributory factor to the robustness of advice. The expectation that advisory bodies will publish information, from final reports to the minutes of meetings, is growing. The most obvious moves in this direction appear to be in the
UK and France where recent scandals have raised the profile of scientific advice, though the trend may be more obvious in these countries because their advisory systems have been less open in the past.

The degree of dialogue between decision-makers and advisors and the involvement of the latter in the policy process varies. The distinction between risk assessment, where advisors assess the scientific evidence but have no role in defining policy options, and risk management, is not easy to maintain - even in France, where the two functions are formally separated. The ‘impact’ of scientific advice on public policy is clearly heavily dependent on the particular issue, and it is important to remember that ‘science’ is only one aspect of any policy decision: economic, ideological or ethical dimensions can often play a more prominent role.

Case Study 1 – The use of embryonic stem cells in research
The key issue in the case of embryonic stem cell research is whether the potential medical benefits that might arise from such work outweigh the moral and ethical concerns surrounding both embryo research and the cloning of human tissues. Given the nature of the issue, it is not surprising that policy makers have recognised that scientific expertise should form only one input into the advisory and policy process. In Sweden, Germany and France, bodies involving elected officials have played important roles in the process, whilst in all countries, advice has been sought from experts on ethics and law. The process has often spread beyond the advisory body itself, whether by holding hearings through which further expert evidence could be collected or (as in the UK and Germany) by making consultation documents available on the internet.

In some cases, advisory bodies have been established specifically to address the use of embryonic stem cells (for instance, the UK and Italy), whilst in others, the process has involved bodies with a broader remit. The degree of transparency with which the process has operated again differed between advisory bodies. In all cases, final reports have been made available on the internet e.g. the UK and Italy, whilst a greater degree of transparency in the actual process has been seen in Germany and, in particular, Sweden.

In all countries, the advisory bodies have been involved in risk management, providing recommendations on possible approaches to the regulation of stem cell research. While the process is still ongoing in a number of the countries studied, advice in the UK has already resulted in an approval for extensions in the allowed uses of embryos in research.

The impact of national advisory bodies has not been limited solely to the countries concerned. Policy debates have not been conducted simultaneously in every country, and an important aspect of the advisory process is an examination of the state of the issue in other countries. This can include the use of reports by overseas advisory bodies as inputs into the process of reviewing the scientific evidence on a particular issue.
Case study 2 – the health effects of non-ionising EM radiation

While the health effects of high frequency, ionising electromagnetic (EM) radiation are clear, the question of whether exposure to lower frequency, non-ionising EM radiation could have adverse health effects has been disputed for over ten years. The initial focus of this debate was on the extremely low frequency (ELF) EM fields emitted from power lines. However in recent years there has been a growing concern over the possible effects of the higher frequency non-ionising radiation emitted by mobile telephones. With regards to the effects of power lines, standing advisory bodies with broad remits have played an important role. Emergent concerns over mobile phones have resulted in more use of ad-hoc bodies concerned specifically with this issue.

The international context proved to be particularly important in this case with the International Commission on Non-Ionising Radiation Protection (ICNIRP) providing influential guidance. As with the stem cell case, the degree of transparency has varied from publishing the final advice through to holding public meetings and publishing minutes. While in a number of cases the role of the advisory body has been to review the scientific evidence and provide a risk assessment, the boundary between risk assessment and risk management has often become blurred, raising the question of whether they can realistically be separated, or whether it is better to acknowledge the fact that advisory bodies will necessarily be involved in making judgements about the wider policy context, including outcomes.

In the EMF case advisory processes are largely ongoing. However different advisory bodies have produced different recommended exposure levels. These differences can be seen not only between but within countries (in Italy, two different advisory bodies made conflicting recommendations).

A typology of advisory bodies

These case studies suggest a number of different dimensions within which advisory bodies might be classified. These include: the way in which advice is initiated; the status and permanence of the advisory body; the scope for action that the advisory body has; the role of the body (risk assessment or risk management); the breadth of remit of the body; the degree of consultation the body engages in; whether the body reviews existing research or commissions new work; the degree of openness and transparency with which the body operates; and the make-up of the body. The utility of such a classification schema was explored by using the above dimensions to classify the main advisory bodies used in the stem cell and EMF cases. This exercise highlighted a number of points, such as the links between the status/permanence of an advisory body and its remit – with ad-hoc bodies having more focused remits – and some notable differences between countries where transparency is concerned.

However it is clear that further work would be needed to refine this classification system. For example, it is our contention that the ‘role’ category as it stands has little value, as all advisory bodies seem to be involved in risk management to some degree. Another difficult issue is the unit of analysis: in many cases statutory or standing advisory bodies may set up more ad-hoc sub-bodies to examine the issue in question. Clearly choice of unit of analysis will have implications for other dimensions in the classification framework.
There are more fundamental problems with attempting to reduce the diverse and complex reality of scientific advice provision into a rigid classification scheme. In particular, the need to confront the issue-specific nature of advice to policy makers represents a profound challenge to any attempts to develop a more comprehensive classification system. Additional problems are presented by the need to consider the negotiations between advisors and decision makers – for example in selecting advisors, in setting remits, in producing the final advice – that are inherent in all advisory processes. The international context of scientific advice and the question of what impacts advice may have present further complications. Given all these difficulties, the use of a classification scheme such as the one explored in this study can at best form one component of a broader investigation of scientific advice processes.

Conclusions - Science and Governance
While most countries have seen some movement in the direction of better governance in the area of scientific advice, there is clearly still some way to go in every dimension, from the selection of advisors to the publication of final reports. It is clear from the study that there is no best practice for seeking scientific advice. However, the European Commission could play an important role in promoting good practice through the identification and transfer of ideas of good governance in relation to scientific advice.

In the time frame of the project, it has not been possible to comprehensively cover all the pertinent issues in sufficient detail. However, it is hoped that the development of a classification system and, as importantly, the discussion of its limitations, will provide a useful input into debates surrounding the use of scientific advice.

Acknowledgements
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1 Introduction

1.1 Scientific advice and policy

Policy issues facing governments have become increasingly complex and it has been argued that “science and technology today have an impact on most core government functions” (Keough, 2000, p.1). Within this environment, the role of ‘expert’ scientists, who provide technical advice to government, has grown in importance. Such experts may be individuals, or members of formal committees or informal groups, and may provide continuous or *ad-hoc* advice. They may be part of the policy-making organisation, semi-autonomous or wholly independent of it. The different types of advisory structures are important, as the nature and source of the information may be a significant factor in whether scientific advice is taken up in the policy-making process.

At the same time, policy is not made by individuals, but develops through negotiation between a variety of actors that may include elected politicians, civil servants, scientific and other experts, pressure groups and business interests. These actors might be thought of as comprising ‘policy networks’ or ‘communities’ (e.g. Rhodes, 1997; Jordan and Richardson, 1987), which may be shaped not only by political culture and institutional structure, but also by the norms of professional groups (e.g. of scientists). Hence, different policy communities may display different policy styles. For example, Renn (1995) identifies four styles of scientific advice in the policy arena that differ in the extent to which they are open or closed, inclusive or adversarial.

Scientific experts are expected to provide ‘robust’, ‘reliable’ and ‘impartial’ advice. However, recent environmental and public health scares have highlighted some difficulties faced both by those providing the advice and those who rely upon it. Conflicting scientific claims have meant that answers to scientific questions are largely qualified and uncertain. In many cases, the questions that experts are being asked cannot be clearly answered due to the complexity of the systems being examined – questions termed ‘trans-science’ by Weinberg (1972). Jasanoff (1987) argues that due to the scrutiny that it receives, “the authority of science is seriously jeopardised when scientists are called upon to participate in policy making” (p.197). Work in the sociology of science has highlighted the uncertain and contestable nature of all science (e.g. Collins, 1985) and involvement in the policy process is seen to exacerbate these problems. Indeed, the contestability of scientific claims has led some authors to argue that science can play little role in policy-making (e.g. Collingridge and Reeve, 1986). Funtowicz and Ravetz (1993) are more positive, arguing that in cases where both system uncertainties and decision stakes are high, science can still be influential. However, they feel that scientific discussion needs to be extended to a wider peer community, incorporating more participants who have an involvement with the issue – they term this ‘post-normal’ science. Such issues are increasingly recognised within governments, and recent initiatives, for example, the proliferation in the UK of guidelines to Government Departments on the use of scientific advice, have aimed to open up to public scrutiny and professional analysis the mechanisms
through which scientific advice is elicited (e.g. Office of Science and Technology, 1997).

1.2 The European dimension

Funtowicz et al (2000) have identified a number of reasons why a debate on the relationship between science and policy in the EU is timely:

1. Developments in science itself, particularly the life sciences, offer the potential of new products and services. Yet, the impacts of the changes that these innovations are likely to bring about are ill understood, and new ways are required to manage the inherent uncertainties.

2. The attention devoted to science by governments is increasing, at least in part due to an increased need for scientific input into policy and legislation.

3. The evolution in European institutions over the last decade means that a debate at the European level is appropriate.

4. This evolution of EU institutions is continuing at an increasing pace, on account of the enlargement of the Union to include pre-accession states, as well as an expansion in the Union’s scope, to include Justice and Home Affairs and the development of a Common Foreign and Security Policy.

5. An increased understanding of the complexity of the natural world has led to a realisation that scientific certainty in a number of important areas will not be achieved in the near future. Under these conditions, some sort of ‘precautionary principle’ needs to be explicitly invoked.

6. Crises, such as that surrounding BSE-nvCJD, have led to a loss of public trust in scientific expertise and advice. This has led to governments attempting reforms of their scientific advisory structures.

Taken together, these issues have led the Commission to call for the development of a common system of scientific and technical reference for EU policy implementation, in the context of the recent European Research Area (ERA) initiative (CEC, 2000). The ERA proposals call for an alignment of methods, the harmonising of results and a greater comparison of results across the Union. In this context, this project is an early attempt to scope existing arrangements in Member States and the Union, on which we will say more below.

1.3 Project approach

As Funtowicz et al (2000) conclude in their review of science and governance issues in the EU, “the system is complex, unique and changing quickly. Therefore, further analysis is needed (of how the system is working at present, what its shortcomings are, what the needs of policy are and what constitutes good scientific practice) both within the Member States and at the European level”. In order to respond to this, a research project was recently launched by IPTS and the ESTO network, in collaboration with another institute of the Joint Research Centre, ISIS, to identify and typify the advisory structures in the science-related policy and regulatory decision making systems at work in several states. By analysing and comparing those structures among different countries, the intention was to better understand the complexity of the relations between Science and Governance. The scope of the project covered the UK,
France, Germany, Sweden, Italy, the EU, and the US. These were studied by research institutions of the ESTO Network (PREST/University of Manchester, OST, VDI, Nutek and Fondazione Rosselli), IPTS and the EC Delegation in Washington DC.

There was a two-stage approach to the project. Firstly, the project teams produced an overview of scientific advice structures in their respective countries, all of which were then incorporated into a general overview (see chapter 2). With such variety of existing advisory structures (ad hoc or permanent committees, agencies, technical support bodies, research centres, regulating authorities, norms and standard setting organizations, intergovernmental organizations…) only a brief overview could be achieved. This was done by focusing on a number of points, in particular the recipient of the advice (e.g. executive or legislative) and the purpose of the advice. Important characteristics of these structures, like independence, operational transparency, the actual impact of their advice and how it is incorporated into policy, were identified and used as bases for the comparison. Issues such as independence and transparency are becoming essential to the system, which is also expected to have clear protocols or guidelines.

For the second stage, two issues were identified for closer scrutiny across the five Member States:
1. The use of embryonic stem cells for research
2. The possible health effects of electromagnetic fields

These two cases represent quite different examples of where decision-makers have sought scientific advice. The stem cell issue has arisen more recently than the EMF example and the level of debate has been higher. The EMF case has been ongoing for a number of years and only occasionally has the issue become of public importance (although concerns over the health effects of mobile phones have been high profile of late). The two issues also differ in the nature of the problem. While the EMF case is largely concerned with technical arguments, the stem cell issue is characterised by wider debates, including ethics and law, of which science is but one part. In addition, while the EMF issue is concerned with the risks from an established, beneficial technology, the stem cell case deals with potential benefits and risks.

The particular advice structures that were prominent with regards to these issues have been identified and their operation and interaction with decision-makers and wider publics examined. Where possible, the incorporation into policy of any advice provided and its ultimate impacts have been discussed. All of these issues have been examined through a combination of reviews of available documents and interviews with relevant actors in the policy sphere. Collating all of this data, a structural-functionalist typology for advisory bodies has been constructed and subsequently tested for its suitability as a framework for comparing different bodies.

1.4 Structure of the report

Following on from this introductory chapter, a general overview of advice structures in the EU, the US, and five Member States is presented in chapter 2. The stem cell case is discussed in chapter 3 and the EMF case in chapter 4. Using the information
gathered from these chapters, Chapter 5 sees the development of a classification framework (typology) for advisory bodies. This framework is then used to classify the main advisory bodies discussed in chapters 3 and 4. The issues raised by this exercise are discussed and the limitations of such a framework are explored. Chapter 6 contains brief conclusions concerning the classification framework and a discussion of wider issues concerning scientific advice, such as the science-governance relationship and an emerging agenda for the EU. Finally the individual country studies, containing country overviews and both the stem cell and EMF cases are to be found in the annexes.
2 General overview of advice structures

2.1 Types of advice structures

2.1.1 High-level policy-making

At the highest level, there may be, as in the UK and US, an individual who is responsible for advising the head of Government on scientific issues. However, advice structures go beyond the control of both the Chief Scientific Advisor in the UK and the President’s Scientific Adviser in the US (and the respective groups that they head - the Office of Science and Technology, and the Office of Science and Technology Policy). In the US, as in the UK, a single high-level scientific panel (for the US, PCAST, which meets in public, and in the UK, CST, which does not, but which now publishes agenda, minutes and reports) can have an input into strategic policy-making. Both PCAST and CST are (mainly) chaired by the government’s Chief Scientific Advisor and consist of distinguished scientists drawn from academia and industry. However, at least in the UK, advisory committees set up by government departments to deal with specific issues are also involved in policy-making (often in dialogue with officials) as well as in regulatory risk assessment. Indeed in most countries covered in this study, the role of ministries or departments and their advisory structures is very important. However in the US, the major input for scientific advice into the Executive Office of the President (the President’s department) comes from an ‘inner circle’ of councils that are established through executive orders of the President, whilst members of the US Cabinet tend to rely on information produced within departments and agencies. At the EU level, committees such as the Comite Scientifique et Technique (CREST) and the Research Group of the Committee of Permanent Representatives (COREPER) provide input into high level policy making. Dominated by high-level government scientists, CREST advises the Commission on the development of European research policy and represents the official views of the Member States. The Research Group of COREPER represents a more informal channel of influence, negotiating the Council’s and Member States positions with regards to Framework Programmes.

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1 The Prime Minister nominally chairs the CST, although the Chief Scientific Advisor tends to chair the Committee in practice.
2 In both the US and the UK, the Chief Scientific Advisor is a distinguished non-government scientist appointed to this high-level government service position for a temporary period (in the UK perhaps 5 years, in the US perhaps for the duration of the Presidency) before returning to industry and academia.
3 For example, in the lead up to the Kyoto Conference on climate change, President Clinton established a Climate Change Task Force, made up of 25 experts from academia, industry and administration, that was to work with existing councils and provide advice to the President.
4 While not fitting into the ‘country’ structure of this discussion, it is important that scientific advice at EU level does receive coverage. Committees that represent the views of Member States are covered here, while committees that feed into the Commission are discussed in the following section.
2.1.2 Advisory structures for Government Departments

Unlike other countries, much of the scientific advisory structure in France is now enshrined in law. The result of this is that expertise, and the job of providing advice, has been externalised from ministries to dedicated agencies covering issues like the safety of food or health products. Currently the actions of these agencies are coordinated by the national committee on health security (CNSS). These agencies bear some resemblance to executive Non Departmental Public Bodies (NDPBs) in the UK. Like the French agencies, these are statutory bodies with their own staff, who can be involved in research and supplying advice to Government. As with some of the French agencies (e.g. AFSSA), Executive NDPBs also (as the name suggests) have an executive function, implementing legislation on behalf of the Government. In Sweden too, there are a number of national boards and agencies whose main purpose is to implement Government policies, which are developed in small, policy-focused ministries. These boards/agencies employ a number of researchers and the small Government ministries tend to be reliant on them for advice on scientific issues. One difference between the Swedish case and the UK is that in the UK the Executive NDPBs comprise only a small part of the system that provides advice to the executive.

In the UK, France and Italy the relevant ministries or departments tend to be advised by a number of scientific committees. Science policy in the UK is fairly devolved, and it is left to individual departments to decide both where and how they spend money on research and when and how they should seek external scientific advice. There is also no statute to say what an advisory committee should look like, though there are now at least guidelines on ‘good practice’. The political system in Germany ensures that ministries are relatively autonomous. Scientific advice is incorporated into highly specific issue networks involving the ministries, committees of the Parliament and other relevant interest groups. As with the UK, in Italy the advisory structure is devolved and there are no general principles regarding access to scientific knowledge, and as with the UK, the result is that structures differ between ministries. Ministries that deal with technical matters have their own permanent scientific committee composed of experts who are nominated by the Ministry. These committees provide

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5 CNSS acts as the link between the political level and the assessment level. The Ministry of Health is in charge of transmission to the prime ministry.
6 E.g. English Nature, the Environment Agency
7 E.g. The Swedish Gene Technology Advisory Board, established in 1994 with the task of following international and national developments in gene technology, cover ethical matters and promote a safe and ethical use of gene technology. The members of the Board included, judges, members of parliament, and researchers nominated by different research councils.
8 As a result there are differences between the various departments. For example, in the case of the Department of Environment, Transport and the Regions (DETR) decisions on accessing advice are further devolved to different programmes within the Department. In contrast the Ministry of Agriculture, Fisheries and Food (MAFF) has more central control within the department.
9 There is also a move in UK towards more broad, strategic advisory structures. For example, the Human Genetics Commission (HGC) was recently established. The role of the HGC is to advise the UK Government on how new developments in human genetics will impact on people and on health care. It is to give strategic advice on the ‘big picture’ of human genetics, with particular focus on social and ethical issues. The Foods Standards Agency (FSA) will have similar responsibilities for GM foods, and the Agriculture and Environment Biotechnology Commission (AEBBC) will have responsibility for all other areas of biotechnology.
10 E.g. the Health Ministry has more formal structures for accessing scientific advice that the Environment Ministry.
advice on regulatory activities and can also be asked to give advice on any relevant questions that reach the political agenda. In practice, when a specific problem arises, an ad-hoc committee is often set up to deal with it. In France, in addition to the agencies described earlier, there are other scientific committees that provide an input to Ministries.

To support its role in drafting proposals for legislation the European Commission employs a range of advisory committees. For example, in order to provide advice on the ‘key action’ of the Fifth Framework Programme, the Commission formed 17 advisory groups. Another policy area that is well served by advisory committees is that of consumer protection, in general, and consumer health in particular. Recent changes mean that there are now 8 thematic scientific committees operating in this area, with their work being overseen by a Scientific Steering Committee.

Research organisations constitute another important source of advice. While these may sometimes come under the jurisdiction of government ministries, they tend to operate independently. Policy makers may use the results of particular research programmes, or they may commission a specific piece of work. Advice on scientific issues can also come from other types of organisations, such as research funders like the UK research councils, national academies, and non-governmental organisations.

2.1.3 Advice to the Legislature

Looking at scientific advice to the legislature, there is much diversity between countries. In part, this may be explained by variations in the power of the legislature as compared with the executive. In the US, members of Congress and of its various committees are supported by numerous, well-funded and expert staff. In addition Congressional hearings call upon expertise from the US and abroad. In Sweden there are multiple opportunities for scientific (and other) advice to input into the step-by-step process by which legislation is produced. In contrast, in the UK there is no automatic public consultation period during the legislative process, though the broad outline of proposed legislation is often published as a consultation paper prior to a Bill being drafted. Once Bills are introduced into Parliament there is little further room for input of expert advice (though advice may have been input in the drafting stage – virtually all Bills being drafted by Government Departments). Thus the main role for scientific advice in UK parliamentary processes is in informing the oversight of the executive by parliamentary select committees. These committees hold inquiries into specific issues, have the right to call witnesses and can appoint a specialist advisor to assist them with a particular inquiry. In Italy too the permanent parliamentary commissions call upon scientific experts to provide them with advice. There may be

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11 And may, in Italy for example, constitute the most important source of advice for government.
12 Whenever an issue is thought to merit sufficient attention, a committee is formed in order to consider the topic. The committee is free to call experts and arrange hearings. Eventually the committee will produce a report. This is followed by a wide consultation process, allowing inputs from experts and interested parties to influence the development of a Bill by civil servants (who may have access to relevant scientific expertise within their own departments, or within associated government boards or agencies). Once introduced into Parliament the Bill is dealt with by a standing committee which again can call upon expert advice if necessary.
more general sources of scientific advice to legislators. Though the well-funded and highly-regarded US Office of Technology Assessment has been disbanded, the UK has a more modest Parliamentary Office of Science and Technology (POST), which is charged with providing balanced and objective analysis of science and technology-based issues of relevance to Parliament. In order to do this they carry out studies and publish reports. Similarly, a relatively small-scale body, the Science and Technology Options Assessment (STOA) unit, supports the European Parliament. The French Parliament has its own science and technology assessment office (OPECST), made up of members of both the National Assembly and the Senate. Matters can be referred to OPECST by the board of either assembly or by a special or permanent committee. OPECST acts as an intermediary between Parliament and the world of research and, through the collection of information, by carrying out assessments, and by launching study programmes, it informs Parliament about scientific issues in order to aid decision making. OPECST has a permanent scientific committee to aid its work that reflects the diversity of scientific and technological disciplines, comprising fifteen leading figures selected for their competence.

2.2 Purposes of advice

New French legislation on the protection of human health (passed on 1 July 1998) distinguishes risk assessment, which it sees as a task for scientific expertise, from risk management, which is felt to be the responsibility of policy-makers armed with scientific advice. A further role for scientific expertise in government is to monitor the development of risks, a function which in France is again separated from risk assessment and risk management activities. In contrast, UK advisory committees may be involved in the risk monitoring, assessment and management processes, but there are no generic statutory divisions between these responsibilities (except perhaps in the case of policy for and regulation of health and safety in public and work places, where the Health and Safety Commission is responsible for the former, whilst the Health and Safety Executive is responsible for the latter). In the US the use of scientific advice in regulatory processes is quite formalised – as in the French case US agencies are responsible for taking regulatory decisions (which they have to be able to justify, and defend against legal challenge) based on advice from advisory committees.

2.3 Independence of advice

There are two aspects to the issue of independence of scientific advice. The first of these is whether advice structures are independent of the governmental body that they are advising. Secondly, there is the question of whether the advisors themselves are acting in the public interest or whether other interests may influence their actions. It can be argued that there is no such thing as ‘independent’ advice as everyone has particular interests that influence their actions.

With regard to the first dimension, the level of independence varies from country to country and case to case, but much advice comes from officials within government, either using their own expertise or through their contacts. Further to this, many advisory structures, while nominally independent, are overseen by government departments that often select the advisors.
The second dimension, the issue of the advisors’ independence from industrial interests, is dealt with differently in different countries, reflecting the way in which their research systems operate. The two extremes are probably the US and France. In the US many of the experts who sit on committees have financial links with industry, while in France public scientists are obliged to declare publicly any link (financial or family) with industry and, at the very least, are excluded from any discussion where there may be a conflict of interest. In the UK the position taken is a pragmatic one: committee members have to declare any interests and they may be asked to not take part in any discussions if there is a conflict. They are not automatically excluded because it is felt that doing so would risk excluding some of the best possible sources of advice.

Perhaps a third element can be considered here when thinking about the EU – independence from Member States. Attempts to address this issue have been made. Considering again the changes to committees on consumer health, since 1997, the Member States no longer propose members for these scientific committees. In place of this, a call for expression of interest is made, and after evaluation of applicants, the Scientific Steering Committee is selected. This committee then provides guidance to the Commission on the selection of experts for the other committees.

2.4 Transparency

The degree of transparency in the advisory process varies both between countries and within countries, depending on the source of the advice. Congressional hearings and other advisory committee meetings in the US are open to the public, as are certain meetings of advisory committees in the UK, the latter being a recent development and part of a broader trend towards more open government (but also due in part to post-BSE developments). Meetings of the EC committees covering consumer health are closed to the public, however agendas, minutes and opinions must be promptly made public. In France all the advice of the food and drug safety agencies is published on the World Wide Web – which in many countries plays an important role in allowing a level of access to the workings of such committees which would not have been possible before its advent, whatever the policy towards openness. The advantage of the very formal Swedish system for gathering advice before a Bill is put to Parliament is that it helps ensure a degree of openness and transparency. In most countries surveyed transparency is increasingly recognised as an important means of improving confidence in the advisory process. The most recent UK guidelines on scientific advice suggest that all evidence upon which advice is based should be published, and there is an increasing tendency for UK advisory committees to publish on the Web annual reports and minutes or summaries of meetings.

Despite these efforts there are aspects of the advisory process that remain murky. For example, the selection of committee members in Sweden is a relatively closed process in which ministers make the appointments. This is similar in many countries and, it is now recognised in the UK that the selection process could be more open, and small
steps are being taken towards this end. Where processes are informal, transparency may be more difficult to maintain. However, if everything is very prescribed then it may lead to an inflexibility to quickly deal with particular issues.

2.5 Incorporation of advice into policy

Advice is incorporated into policy in a number of ways, with different degrees of formality. With its formal separation between risk assessment and risk management, the French system requires experts to provide advice on a scientific issue, but in theory it is left to the policy makers to decide what action needs to be taken. In this ideal case, lines of accountability are clear – it is down to the policy makers to interpret and act on, or if they can give good reason, not act on the advice that they have been given. However, policy makers may not clearly understand the implications of the advice, or may interpret it in a different way to that intended.

Some of these problems might be overcome if policy makers engaged in more of a dialogue with scientific advisors. Despite what was said previously, this can be seen in France where both the food and drug safety agencies are consulted on the preparation of legislative and regulatory texts. The Swedish case, as already noted, involves a long consultation process, allowing for scientific input at various stages. It is also recognised that in some cases scientific advisors are asked to make policy recommendations based on their expert opinion. A less open dialogue process can occur between scientific advisors and civil servants. Such dialogue is important in Germany where the consensual character of policy making means that much effort is made to try and balance opinions through consulting with multilateral sources of (scientific) expertise. In the UK a dialogue between advisors and officials can lead to further questions being raised, allowing for the scientific input to evolve as an issue changes. Given their understanding of the issue at hand, and based on the advice that they have formulated, the advisors may be asked to recommend some possible policy actions. In France, despite the attempts to separate the assessment and management functions, agencies are not prevented from producing policy recommendations within their fields of expertise. While such a process may allow a clearer understanding of the issues and their implications, it has the disadvantage of being less transparent and of muddying the lines of accountability.

Particularly problematic are those occasions where there is recognised uncertainty in the science. The UK guidelines express the view that uncertainty needs to be explicitly recognised in the advice given to policy makers. The obligation to deal with that uncertainty then lies with those policy makers. The problem here remains that policy makers tend to want an answer one way or the other and may still expect their advisors to supply this.

13 The ‘Guidelines’ discuss the selection process, whilst the new Food Standards Agency (FSA) recently advertised for applicants to join several advisory committees – again part of a broader trend towards more open appointments in UK non-departmental bodies.
2.6 Impacts of advice

The impact of scientific advice is likely to vary from issue to issue. Where the scientific aspect of a policy decision is the major component then it may be easy to identify where certain advice has had a large impact. However, in most cases science is just one part of a complex political problem and the impacts of advice will inevitably be diffuse and hard to trace. The political system and the shape of advice structures might be expected to have some influence on the likelihood of advice having impacts on policy - where there is an open discussion, allowing for conflicting views to be expressed, it may be the case that advice has less impact than in circumstances where carefully-selected advisors offer confidential advice to a particular ministry. It may be that ministries are more concerned with promoting their own agenda than acting on the best scientific evidence. Scientific uncertainty coupled with other political considerations may mean that advice cannot be acted on. Ideological issues may also conflict with scientific advice, or regulated industries may lobby hard against a particular policy position, whatever the scientific advice. In other cases it may be that scientific advice is used to provide ex-post justification for policy, rather than as a real input into the policy formulation process.

A final issue that needs consideration is the way in which the impact of scientific advice on policy varies over time. In the US during a brief period of the 1970s there was much public support for the use of science in regulatory policy. Subsequently a more anti-regulation stance has been the norm. In France after the contaminated blood scandal, and in the UK after BSE, it could be argued that scientific advice has assumed a more prominent and influential place in the policy making process.
3 Stem Cell Case-study

The following will give a brief overview of the advice structures that have been employed to inform policy regarding the use of embryonic stem cells for therapeutic cloning in the UK, Germany, Italy, Sweden, France and the US. This will begin with a short description of the reasons behind the proposed use of stem cell. Following this legislative background to recent debates will be described before the advice structures that were used, the operation of these structures, the interaction between the advisory structures and decision makers, and the incorporation of advice into policy are all explored.

3.1 Introduction

Although research on stem cells is at an early stage, the potential medical benefits have caused great excitement. The possible therapeutic applications that have been listed include, amongst others:

- The repair of damaged organs;
- The treatment of severe diseases such as Parkinson’s, hepatitis, diabetes and leukaemia;
- The treatment of burns and complex fractures;
- The use of stem cells to correct genetic diseases such as cystic fibrosis and Huntingtons’ disease; and
- The use of blood stem cells to treat blood disorders.

The possibilities of stem cells derive from the fact that they have the capacity to renew themselves and can develop into more specialised cells. The flexibility of the stem cells to develop into other cells depends on their source. After fertilisation an egg is totipotent, having the ability to turn into all cell types needed for embryonic development. However, after only three rounds of cell division, the cells differentiate into those that will form the placenta and those that will form the embryo – the embryonic stem cells. These cells are pluripotent and can develop into all cell types except placental cells (hence they cannot form an embryo). They can be isolated from the blastocyst, a ball of 50-100 cells that forms around five days after fertilisation and contains around 20 pluripotent stem cells. Multipotent stem cells are already partially differentiated, e.g. as blood stem cells or neural stem cells, and may have a more limited ability to develop into different cell types. These cells can be obtained from foetuses and from adults, where stem cells make up a diminishing proportion of adult cells. Although they may be more limited, research has suggested that it may be possible to reprogramme multipotent stem cells of one type into another.

A breakthrough in stem cell research came in 1998 when two teams of scientists reported that they had managed to isolate and then culture stem cells from human embryos and from foetal reproductive tissue. This raises the possibility of stem cell transplants, where the transplanted cells would have the capacity to turn into the cell

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14 The chapter is based on more detailed country studies that are not included here due to space constraints. As such it can only provide a flavour of the debates and actions in each country. (This is also the case in chapter 4).
type that was required. As the cells would be able to renew themselves they could continue to deliver their therapeutic effect long-term. However, a possible problem with the transplant of stem cells could be rejection. One solution to this is the idea of somatic cell nuclear transfer (SCNT) or therapeutic cloning. The nucleus of a donor egg is removed (enucleation) and then replaced with an adult somatic (non-sex) cell from the patient. The egg would then be allowed to develop into the blastocyst stage and could be used as a source of stem cells compatible with the patient and avoiding the risk of rejection.

However, all these benefits are currently strictly hypothetical and scientists are a long way off being able to realise them. Although it may be possible that adult stem cells could be reprogrammed, reducing the need for embryonic stem cells, at the present time, research on the embryonic cells is seen by many as necessary. This research involving embryos and the idea of therapeutic cloning raises a number of ethical issues. Of course a further consideration is that these potential benefits may not be attainable at all due to some difficulties with employing stem cells. The only way that many of these questions can be answered is through further research, hence the question facing governments is whether the possible benefits of these types of stem cell research outweigh the ethical considerations and whether further research should be sanctioned.

3.2 Background

An important consideration in examining the recent debates over the use of stem cells has been whether there is existing legislation that already governs this area. The situation has differed between the countries studied and this section will detail the legislative background for each of the countries concerned.

3.2.1 Legislation on embryo research

Debates on the use of embryos for research led to the introduction of legislation in the UK, Germany, Sweden, France and the US. While the UK and Sweden permit certain uses of embryos for research, the German and French legislation is more restrictive. In the US the approach is a mixture of restrictive and liberal as legislation only bans the use of federal money for embryo research, not the research itself. Italy meanwhile has no legislation in this area.

In the UK, The Human Fertilisation and Embryology Act 1990 permitted research on human embryos but only for research with particular aims. The Act also established the Human Fertilisation and Embryology Authority (HFEA), the first statutory body of its type in the world. Any research on embryos had to be licensed by the Authority and these licenses would only be granted when the HFEA was convinced that the use of embryos was essential to the research, that embryos would not be kept after 14 days, and that consent had been given for the embryos use. An important aspect of the
Act was that it did allow for other research purposes to be added to the original list through 'affirmative Regulations'.

In Sweden the *In Vitro* Fertilisation Act 1988 permitted some research on human embryos, although as with the UK any research must be performed within fourteen days of fertilisation, and the consent has to be given for the embryos use. Research to genetically modify an embryo is strictly prohibited, as is the implantation of a research embryo *in utero*. While not mentioning stem cells explicitly the recent Environment Code, which came into force on January 1 1999, does have some implications for this type of research as it provides some controls on gene technology activities.

The two ‘bio-ethic’ laws, introduced in 1994, govern the position in France. They cover the use of elements and products from the human body and medically assisted procreation and prenatal diagnosis. The laws specifically prohibit research on embryos and in particular cloning and the creation of embryos purely for research. Still, a specific commission may, in exceptional circumstances, allow some medical study to be carried out on an embryo, provided the couple has given explicit written agreement and as long as the embryo will not be disturbed in any way. However, the law does not explicitly forbid research on cells extracted from aborted foetuses. These laws were meant to be reconsidered every five years in order to take account any changes in the area. Although this should have taken place in 1999 it is now planned for 2001. The interpretation of these laws is problematic, with some people arguing that certain researchers have taken too liberal an interpretation, claiming that anything that is not specifically prohibited is allowed.

In Germany the Embryo Protection Act 1990 is a far more restrictive piece of legislation. The Act prohibits all in vitro experiments with an embryo that do not pursue the preservation of the embryo. The extraction of cells from embryos for research purposes is prohibited by the Act, even if the embryo's development is not disturbed. Anyone found breaching the provisions of the law faces up to five years imprisonment. While the creation of embryonic stem cells by the transfer of human somatic cell nuclei into a human enucleated egg falls under the prohibition on cloning humans, embryonic stem cells can be imported, with some restrictions, from countries that do allow their use in research.

As mentioned previously, in the US there has been legislation for the last five years that bans the use of federal money for research on human embryos. Meanwhile there are no regulations whatsoever on research activities undertaken by private organisations supported by grants from non-public sources. Attempts to redress this imbalance, allowing limited research in the public sphere, have been hindered by opposition in Congress. In August 2000 the National Institute of Health did approve guidelines that would allow for the use of human stem cells in federally funded research, although these only allow for the use of existing pluripotent stem cells, not for the extraction of these cells from embryos or foetuses. These guidelines are currently being challenged in Congress.

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15 That is regulations that have to be debated in the House of Parliament before they can come into force.
16 The Embryonenschutzgesetz (ESchG).
Unlike the other countries Italy does not have any legislation in this area. There are ordinances issued by the then Minister of Health, Rosi Bindi, in 1997 that have subsequently been renewed ten times. Initially these prohibited any experimentation that would directly or indirectly lead to animal or human cloning. Changes have allowed for the cloning of animals for the production of life saving medicines, or to prevent species extinction. It seems that the purpose of these ordinances was to allow time for the Italian Parliament to consider the topic, however, this has not yet happened. The problem with the ordinances is that without the formal approval of Parliament they do not have much regulatory power. Indeed, this problem has been highlighted by the cloning of a calf, and the establishment of the world’s first bank for cerebral stem cells in Milan.

The role of the EU in this area has been relatively limited as under the EU Treaty Member States retain full prerogative to legislate on ethical matters. However, that is not to say that the stem cell issue has not been debated in the EC and European Parliament.

In light of this background, recent debates surrounding the issue of cloning embryonic stem cells will be considered.

3.3 The advice structures that were used

3.3.1 Type of structures used

The advice structures that have been used to inform decision-makers on the issue of stem cell research have varied both within and between countries, with use being made of both permanent and more ad-hoc bodies (see table 1), and with advice being given to government ministries and parliaments. The nature of the ad-hoc bodies varies between those that were set up specifically to deal with issues related to stem cell research (e.g. such as in the UK, and Italy) and those bodies that had a slightly wider remit that encompassed this area (e.g. Sweden and Germany).

The main advisory bodies in the UK have been set up through the Department of Health, and while their reports are widely available, their main function is to advise the Government. Similarly, the Commission in Italy was established by the Health Ministry and the Advisory Council on Ethics in Germany advises the Health Ministry. In US, an established advisory body, the National Bioethics Advisory Commission (NBAC), presented its recommendations on the issue to the Government upon request. The CCNE is a high level advisory body that informs the French Government and the President of the Republic. The Conseil d’Etat, whose main function is as a ‘supreme court’ for public law, has recently extended its role to produce reports on issues that concern the Government and that have a public law element. In this case they were asked to look at the issue by the Prime Minister. Hence, while not strictly a source of scientific advice, they have contributed to the debate on the bio-ethics laws in France. Other bodies, including OPECST, the Advisory Boards in Sweden, and the Enquete Commission in Germany, have been set by the respective countries Parliament (or Federal Assembly) and provide advice beyond the executive. Within
the EU two advisory bodies have been most prominent with the Group of Advisors on Ethical Issues in Biotechnology (GAEIB) being replaced in 1998 by the European Group on Ethics in Science and New Technologies (EGE). Hearings held in the US Congress are an established method of seeking advice.

### Table 3.1 – Formal advisory bodies in the stem cell case

<table>
<thead>
<tr>
<th>Permanent</th>
<th>Ad-hoc</th>
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<tbody>
<tr>
<td><strong>France</strong></td>
<td>• the Conseil d’Etat (CE)</td>
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<tr>
<td></td>
<td>• the Office Parlementaire pour l’Evaluation des Choix Scientifiques et Technologiques (OPECST)</td>
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<tr>
<td></td>
<td>• the Comité Consultatif National d’Ethique (CCNE)</td>
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<tr>
<td><strong>UK</strong></td>
<td>• the Human Genetics and Advisory Board (HGAC) and the Human Fertilisation and Embryology Authority (HFEA)</td>
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<td></td>
<td>• the Chief Medical Officer’s Expert Group</td>
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<tr>
<td><strong>Sweden</strong></td>
<td>• the Medical Ethical Advisory Board</td>
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<tr>
<td></td>
<td>• the Swedish Gene Technology Advisory Board</td>
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<td></td>
<td>• the Parliamentary Committee on Biotechnology</td>
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<tr>
<td><strong>Germany</strong></td>
<td>• the Advisory Council on Ethics of the Federal Health Ministry</td>
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<tr>
<td></td>
<td>• The German Research Union (DFG) and the Research Council</td>
</tr>
<tr>
<td></td>
<td>• the Federal Assembly’s Enquete Commission on “law and ethics of modern medicine”</td>
</tr>
<tr>
<td><strong>US</strong></td>
<td>• NBAC (National Bioethics Advisory Commission)</td>
</tr>
<tr>
<td></td>
<td>• Congressional hearings</td>
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<tr>
<td><strong>Italy</strong></td>
<td>• the National Committee on Bioethics (CNB)</td>
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<td></td>
<td>• Commission on the use of stem cells</td>
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<tr>
<td><strong>EU</strong></td>
<td>• Group of Advisors on Ethical Issues in Biotechnology (currently replaced by the EGE)</td>
</tr>
<tr>
<td></td>
<td>• European Group on Ethics in Science and New Technologies (EGE)</td>
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In addition to these formal sources of advice, the case studies have shown that informal advice has an important part to play. In Germany the discussion on stem cell research has been characterised by a continuing exchange of information between science and politics. In order to increase their understanding, the German Research Committee (DFG) initiated working groups in the area involving external experts, while the Federal Ministry for Education and Research (BMBF) sought advice from the research community. In addition, various symposia, attended by ethics experts, scientists, and politicians have been organised. The American Association for the Advancement of Science (AAAS), along with the Institute for Civil Society have produced an influential report in this area. Meanwhile, in the UK the Royal Society has produced two reports, and MPs have received briefings from interested groups, both pro and anti embryo research. In France, groups such as the Academy of Medicine, the National Consultative Commission on Human Rights and the National Union of Family Associations have all made pronouncements related to stem cell research.

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17 These groups were tasked with advising EC, the European Parliament and the Council of Ministers
3.3.2 The selection of advisors

The selection of the advisors varies. Some of the advisory bodies are composed of members of parliaments (e.g. OPECST in France), some of a mixture of MPs and experts (e.g. the Enquete Commission in Germany or both the Medical Ethical and Gene Technology Advisory Boards in Sweden), others are composed solely of experts (e.g. the HGAC, HFEA and the CMO’s Expert Group18 in the UK, the Commission in Italy, and the EU advisory groups). The MPs on the bodies in France, Germany and Sweden are selected to reflect the make up of their Parliaments. The selection of experts for the formal bodies tends to be the responsibility of the ministries or of the different political parties. The transparency of the selection process is variable. Selection of experts is generally concerned with obtaining the right expertise to address the questions at hand. However, in some cases (e.g. Sweden) the selection is informal, the suitable experts just need to be identified, while in others (e.g. for the CMO’s Expert Group in the UK) there are formal rules governing selection.

Given the nature of the stem cell case, this expertise has necessarily been wider than just science, encompassing ethics, law and theology. However, the type of experts is obviously related to the remit of the advisory body. For example, the CE in France is responsible for checking the legal acceptability of new laws passed by the Parliament, hence its members require legal expertise and are appointed on this basis.

3.4 The operation of the advisory structures

3.4.1 The use of experts

The operation of the advisory structures is partly the result of their make-up. For example, given that it is made up of MPs it is unsurprising that the main investigative tool used by the OPECST is to hold interviews with various experts. The situation is similar for Congressional hearings in the US, which aim to bring together the most knowledgeable people from the US and abroad. Given its particular focus on legislation, for advice on other issues the CE relies largely on external experts. For other structures, the aim of having experts as part of the advisory bodies is obviously so that they can feed directly into the advice process. However, that is not to say that expertise is limited to that of the people on the different committees.

In Sweden, if the Advisory Boards feel that there is a shortfall in their expertise they will call in the necessary experts for consultation. In the UK this has gone further, with the advisory processes in this area being based on consultation exercises with scientists working in the area and others who have an interest in the issue. The role of the experts on the UK advisory bodies has been to use their expertise to interpret the information from these consultations and then draw their own conclusions. The Enquete Commission in Germany also engages in consultations with experts outside of the Commission itself. In these cases, consultation is not limited solely to experts’

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18 In addition to experts from outside of the Government, as the name suggests, the Government’s Chief Medical Officer chaired the Expert Group, which also contained the Government’s Chief Scientific Advisor.
in particular areas. The consultation documents in the UK were available on the internet for anyone to comment and the involvement of the public is also seen as important in the German case. Unlike the other bodies, for the Commission charged with examining the issue of human cloning and stem cell research in Italy, the expertise does appear to be limited to those in the Commission. The possibility of consulting experts’ external to the Commission did exist but was not done.

3.4.2 The role of the advisory bodies

Given the nature of the issue, it is perhaps unsurprising that the advisory bodies have not been engaged in commissioning new research. Rather their role has tended to focus on an examination of current state of research and its implications – both scientific and ethical.

The specificity of what the advisory bodies are asked to look at varies. Those bodies set up solely to examine the issue of stem cell research were given clear guidance as to what should be examined. The Commission in Italy was established with the specific task of answering two precise questions:

- the first regarding the actual possibility of using stem cells to contribute to the cure of degenerative diseases; and
- the second concerning which type of cells represent the best source of stem cells.

In light of these questions the Commission was also asked to consider the ethical issues that the issue raised. These are similar to the requirements of the CMO’s Expert Group in the UK, which was established to assess:

- developments in, and the potential benefits of, stem cell research and research involving cell nuclear replacement;
- the likely timescales of the research; other possible alternatives to research involving embryos;
- and any safety issues that may arise from this research.

They were also expected to consider any new ethical issues that may arise from the creation and use of embryos for the extraction of stem cells for research. Similarly, the NBAC in the US was charged with a specific task by President Clinton, namely to conduct a review of the issues associated with human stem cell research, balancing all ethical and medical considerations.

In France, the context for recent debates has been the planned revision of the 1994 bioethics laws and it is this that has shaped the approaches of the advisory bodies. Although it is an ad-hoc body, the Enquete Commission in Germany has a wider remit than the examination of stem cell research alone. The focus of the Commission is on reproductive medicine, clinical uses of modern medicine, and an analysis of the area of genome research (e.g. considering business aspects). The stem cell issue is considered mainly in the first two of these areas. The Swedish Advisory Boards are largely free to select the issues that they examine, reflecting the general independence from Government office that public authorities tend to have in Sweden.

At the EU level, the broad remit of the EGE is to draw up common rules to enable the internal market to operate in accordance with the ethical values of Europe. In addition, the EGE was given the objectives of promoting a multidisciplinary approach, providing clear and up to date advice and to promote dialogue within the EU.
One thing that is clear is that the stem cell case cannot be seen as an example of ‘scientific’ advice alone, ethical issues have been crucial throughout. This need for a multi-disciplinary approach to issues of this kind is exemplified by the objectives of the EGE. Even where more science-orientated bodies (e.g. DFG in Germany) have examined the issue, ethical considerations have been at the forefront. For the CMO’s Expert Group in the UK, while there was a desire to avoid similar ethical discussions to those surrounding the 1990 HFE Act, they could not avoid some reconsideration of these debates during the course of their deliberations.

3.4.3 The international context

Of course, none of these countries are debating these issues in isolation and advisory bodies have examined the international context. This is particularly important for the Italian case, where the debates that have been long ongoing in other countries are only now really beginning. One of the primary tasks of the Commission on the use of stem cells is to look at what has been done in other countries in order to provide a reference point for their conclusions. The importance of the international context is clear, as if some countries have more lax laws than others there is the possibility that research will just shift to these countries – this has to be weighed against the ethical issues.

3.4.4 Transparency of the advisory structures

It is clear from looking at the advisory structures in this area that there are different levels of transparency. Reports (to be) produced by the advisory bodies have been (or will be) publicly available. For example, the reports of the CMO expert Group in the UK, the Commission in Italy and the EGE are available on the internet. While this allows public scrutiny of the results of deliberations, in some cases transparency has been taken further. For the German Enquete Commission, transparency is seen as a key issue and it is more open to the public than similar commissions have tended to be in the past. Publications are placed on the internet and the public also have access to on-line conferences. Public debate on the issue is being encouraged. In Sweden a high level of transparency is the norm and this case is no exception – all information is publicly available. In France, the OPECST may organise some public debates on issues it is dealing with. The NBAC and AAAS in the US holds regular public debates and meetings and all Congressional hearing are open to the public.

3.5 Interaction between advisory structures and decision makers

3.5.1 Relationship between advisory bodies and decision makers

The level of interaction between the different advisory structures and decision makers varies. For some of the sources of advice discussed here there is no direct link. For example, the DFG in Germany chose to investigate the issues itself, the Government did not direct it to do so. The same is true of, for example, the Royal Society in the UK and the AAAS in the US.
In contrast, most of the advisory bodies were appointed by ministries or parliaments, or in the case of the NBAC, the US President, and given a specific remit (as was discussed previously) that to some degree, encompassed the issue of stem cell research. However, that is not to say that they did not operate independently. Indeed, all the appointed advisory bodies are seen as independent from the organisations that appointed them. Worth noting is that at the EU level, the EGE answers directly to the President of the EC and is the only body of its kind with such independent status.

3.5.2 The purpose of the advice

An important aspect that was discussed in the general overview of advice structures was the difference between advice on risk assessment and advice on risk management. For the stem cell case, all the advice has been concerned with risk management. Risk assessment is an important part of the process but the aim of the advisory bodies is to provide Government with recommendations for possible policy approaches to the regulation of stem cell research.

For example, the CMO’s Expert Group in the UK produced nine recommendations for the Government – some of which were related to the modification of the HFE Act 1990, some of which would require primary legislation, and some of which were concerned with allocation of funds for research. The report of the NBAC in the US also made a number of recommendations, suggesting that research on embryonic stem cells should, with certain restrictions, be eligible for federal funding. In France, the CE’s report on this issue suggests that reproductive human cloning should be explicitly forbidden, and that research activity on non-desired in vitro embryos should be allowed under very strict regulations. The report went as far as proposing some draft texts for the revised laws. In Sweden the unique position of the advisory bodies in relation to the ministries means that they are expected to examine policy options and play an important part in the policy-making process.

3.6. The incorporation of advice into policy

It is difficult at this stage to discuss the incorporation of the advice into policy in much detail, as, apart from in the UK and, with respect to the NBAC, the US, the advisory processes are still ongoing. For the UK, where the CMO’s Expert Group finished its deliberations earlier in the year, the impact of scientific advice is clear. While the Government did not follow the recommendations of the HGAC/HFEA report, choosing instead to establish the CMO’s Expert Group to further investigate the issue, the Expert Group’s recommendations have been accepted in full. Subsequently, the issue has been debated in Parliament and the Government has laid down changes to the regulations of the HFE Act 1990 to extend the number of uses for embryos in research. These regulations were debated in both of the Houses of Parliament and, after a free, unwhipped, vote have been approved. New legislation to cover other recommendations will also be debated in Parliament.

It is usual for the political parties in Parliament to instruct their members as to which way to vote in a debate. The result is that most votes go the way of the governing party, which will generally hold a majority in Parliament. In a ‘free’ vote MPs are given the freedom to vote the way their conscience dictates.
The incorporation of recommendations into US policy is more problematic. The position of the US Congress is divided and it seems unlikely that any changes will be passed in the near future. Currently, decisions are being taken at a level that is sufficient to keep things moving but no more. As was mentioned earlier, the NIH has adopted guidelines and these are more restrictive than the recommendations of the NBAC and are still being challenged.

At the EU level, in response to an amendment voted by the European Parliament calling for the exclusion from Community funding for projects leading to the destruction of embryos, the EGE has advised that projects should not be excluded a priori. Rather, they proposed that projects seeking funding for embryo research should be subjected to a systematic ethical evaluation at the Community level. A more recent report by the EGE tried to set out what they saw as ethical principles that should guide the activity of European institutions, and, while supporting the research on human embryos to develop new treatments, they considered premature the creation of embryos by SCNT.

While it appears that the formal advisory bodies will feed into the political process, the influence of more informal advice is hard to judge. Political actors have attended the various symposia held in Germany and it is likely that they have had some impact. Equally, reports produced by bodies such as DFG and The Royal Society, amongst others, are widely circulated and will probably help shape views.

One thing that is clear is that, as was mentioned earlier, the consideration of the science is just one of a number of aspects inherent in the debate on the use of stem cells. Ethical considerations have been seen as crucial and reflecting this the advisory bodies have included ethicists and theologians as well as scientists. Legal considerations have also been important as the debates are largely about the possible modification of laws. The possible economic implications of stem cell research are another factor in the debate but it is difficult to ascertain what role they have played. In the UK it was felt that economic factors were only of minor importance in terms of the advice – however that does not necessarily mean that they have been unimportant in political considerations. For example, in Germany the possible economic implication of stem cell research is currently at the forefront of the debate.
4 The EMF Case

4.1 Introduction

Electromagnetic fields (EMFs) describe an extremely wide frequency spectrum, from 0 to $10^{25}$ Hz or more. Within this wide spectrum a boundary can be established at around $10^{13}$Hz between ionising electromagnetic radiation (IEMR, above) and non ionising electromagnetic radiation (NIEMR, below). Among the former are UV light, X rays and gamma rays, which are known to cause damage to living cells or to their DNA structure, depending on the frequency. Among the latter, we find by ascending order of frequency: extremely low frequency waves (ELFs), which result for instance from power lines (50 Hz in most European countries), radio waves, microwaves captured and emitted by cellular phones or dish antennas, radar waves, IR light and visible light. As mentioned above, the severe health effects of ionising radiation are well known and are not the concern of this study. It is also believed that (even short term) exposure to non ionising (low to very low frequency) but high intensity EMF can cause health damages (destroy some living tissues or disturb brain waves and thus affect the development of a foetus). What is still uncertain, and thus at stake here, is whether exposure to non ionising and non very high intensity EMF can cause health damage in the long term. Two possible sources of such long-term emissions that are currently under investigation in European states are power lines in the area of ELFs, and cellular phones in that of microwaves.

There is no specific European legislation covering NIEMR, although a Council recommendation exists on the levels of exposure of the general public to EMFs of 0-300GHz, based on the recommendations of the International Commission on Non-Ionising Radiation Protection (ICNIRP), which is officially recognised by the World Health Organisation as a source of guidance and advice on the health hazards of NIEMR.

4.2 Background

The background to the EMF case in the various European countries under consideration in this study varies somewhat. Whilst in most countries EMF issues have at times been quite prominent in public and political debates, generally speaking the recent level of debate about EMF has been rather low. However in the many countries – such as the UK, Germany and Italy - the issue of health effects of EMFs generated by power lines and, especially mobile telephony equipment, is of slowly growing political significance. (In the US the debate about possible EMF effects from mobile telephony is also of growing importance).

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20 One exception would be the specific interest in Sweden in the health effects of radiation from computer screens and other devices, which has led to the development of specific regulatory standards.
4.3 The advice structures that were used

4.3.1 Type of structures used
In all the countries considered, standing advisory structures have played a very important role in shaping the policy response to the potential problems posed by EMFs. These bodies have tended to be standing bodies associated with the protection of human health, either generally or specifically (e.g., occupational health, or protection from radiation hazards), though in Sweden the most important actor has been the “work-life” research council (RALF), which has both funded basic research into EMF effects and conducted reviews of the scientific literature for Government (health, safety and radiological protection bodies have also been important in Sweden, of course). In the German case a communications industry-linked research association has also been an important actor in the advice process. In the US, the lead regulatory body for mobile EMF issues is the Federal Communications Commission, though an inter-agency group has been set up to co-ordinate mobile phone safety at the federal level (comprising FCC, Food & Drug Administration, Environmental Protection Agency, the Occupational Health & Safety Administration, and several other agencies).²¹

However in the cases of France, the UK, and Germany, more ad-hoc advisory structures have also played their part – sometimes reporting to the permanent advisory bodies. So, for instance, in France, an ad-hoc committee has been set up by the General Director of Health (GDH) in order to perform a review of scientific reports of EMF effects of mobile phone technology (whilst much earlier INSERM, the medical research agency, formed an ad-hoc ‘collective expertise’ body to deal with EMF issues). In the UK the Advisory Group on Non-Ionising Radiation (AGNIR - which could now be considered to be a permanent expert committee, having been in existence for ten years) was set up by the National Radiological Protection Board (NRPB - the statutory body responsible for assessing radiation risks to human health and making policy recommendations to ministers) solely in order to evaluate scientific studies of EMF effects on health. More recently in the UK, increasing public concern about possible health effects of mobile phone technology led the Government to set up an independent expert advisory group (IEGMP), wholly outside the existing structure of NRPB, in order to make a risk assessment and recommendations about risk management.

²¹ Whilst the FCC has the job of setting standards for emissions (based on recommendations from non-governmental standards bodies in the US and, as with most countries, from the ICNIRP), the FDA has the authority to take action if mobile phones are shown to emit a level of radiation that is dangerous to the user. The Agency is currently conducting a $1m research programme in collaboration with the telecoms industry – but in the absence of hard evidence of a health risk the issue of EMF from mobile phones is considered purely as a regulatory matter in the US.
Table 4.1 – Formal advisory bodies in the EMF case

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<th></th>
<th><strong>Permanent</strong></th>
<th><strong>Ad-hoc</strong></th>
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<tr>
<td><strong>France</strong></td>
<td>• High Council for Public Hygiene</td>
<td>• Committee formed by the GDH to review scientific studies on EMF effects</td>
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<tr>
<td></td>
<td>• General Director of Health</td>
<td>of mobile phones</td>
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<td></td>
<td>• Committee formed by the GSHP to review scientific studies on EMF effects</td>
<td>• INSERM committee for</td>
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<td></td>
<td>• INSERM committee for collective expertise</td>
<td>collective expertise</td>
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<tr>
<td><strong>UK</strong></td>
<td>• National Radiological Protection Board</td>
<td>• AGNIR (as originally founded?)</td>
</tr>
<tr>
<td></td>
<td>• AGNIR - Advisory Group on non-Ionising Radiation</td>
<td>• IEGMP (Stewart Group)</td>
</tr>
<tr>
<td><strong>Sweden</strong></td>
<td>• Council for Work-Life Research (RALF)</td>
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<td></td>
<td>• Occupational S&amp;H administration</td>
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<td></td>
<td>• Radiation protection institute</td>
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<td></td>
<td>• National Board of Occupational S&amp;H</td>
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<tr>
<td><strong>Germany</strong></td>
<td>• Commission for Radiation Protection</td>
<td>• 1993 Expert Hearing</td>
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<td></td>
<td>• Federal Office for Radiation Protection</td>
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<td></td>
<td>• Federal Committee for Post &amp; Telecommunications</td>
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<td></td>
<td>• Research Association for Radio Applications</td>
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<tr>
<td><strong>Italy</strong></td>
<td>• Higher Institute of Health</td>
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<td></td>
<td>• Higher Institute for Worker Security</td>
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<tr>
<td><strong>US</strong></td>
<td>• FCC</td>
<td>• Interagency group for mobile phone safety</td>
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<td></td>
<td>• FDA</td>
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4.3.2 The selection of advisors

The selection of advisors seems to depend to some extent on the role of the advisory structure, and its independence from Government. In all the European countries considered in this case study at least some nominees to scientific advisory committees considered in this case study are proposed by civil servants within ministries (or by bodies such as INSERM in France or NRPB in the UK).

However there are other mechanisms. In France analysis of the publication records of nominees to the original INSERM expert review group was used to ensure that the right expertise was being accessed. In Italy, whilst some members of the technical-scientific committees of the Higher Institute of Health and the Higher Institute for Worker Security are nominated by a number of ministries or research institutes, others are elected by the scientific community to represent specific disciplines. In the UK appointments to AGNIR, formerly made by the executive director of NRPB, are now made by the Chairman and Board of NRPB (themselves mainly scientific experts). In many cases, advisory groups, once in existence, can and have selected further experts on the basis of additional requirements for expertise, either as additional members or as participants in hearings, workshops or consensus conferences.
4.4 The operation of the advisory structures

4.4.1 The role of the advisory bodies

The bodies considered in the EMF case vary in terms of the roles they play in their respective national systems: in the UK AGNIR is intended to be purely an advisory, risk assessment body, which conducts only reviews of the literature, whilst NRPB has the responsibility of interpreting the assessments thus made and making policy recommendations to ministers. In contrast the UK IEGMP had a very specific role relating to evaluating the risks of mobile telephony. In France INSERM is a general research organisation, and GDH is a part of the Ministry of Health, though its advisory committees are independent. Different again, in the Swedish case, is RALF, which is a research funding body. While a number of the advisory bodies in this area do have research functions, in relation to this particular case their main role has been to review existing scientific studies of the health effects of EMFs. In most of the countries considered this has been an on-going process as new scientific studies are conducted.

4.4.2 The international context

The international context appears to be particularly important in the EMF case. The ICNIRP and its predecessor body is well linked to the national radiological protection bodies of various countries, and the recommendations it has released (which have been adopted as recommendations by the European Council) have been influential in many of the countries, including the US. Not surprisingly, risk assessment in each country takes account of the research conducted elsewhere in the world – and the French GDH went so far as to adopt the UK’s IEGMP report (with other studies) as the first stage in its two stage risk assessment/risk management process.

4.4.3 Transparency of the advisory structures

Transparency seems to vary between “risk assessment” and “risk management” functions. Whilst risk assessment reports are often published, the process of risk assessment, at least in the EMF case, appears to be not so open. So, in the UK, AGNIR publishes no minutes, though its formal advice to NRPB is published. In contrast NRPB publishes the minutes of its board meetings. Meanwhile, in Sweden, the review conducted by RALF, the work-life research council, has included both open workshops and a consensus conference. The ad-hoc IEGMP in the UK also held several open meetings at which experts and members of the public could make statements, whilst the German federal Government has attempted to generate a public (and on-line) debate about EMF issues. Generally speaking, then, it seems that those

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22 However, RALF, in their role as a research funder, did have a programme of research on EMFs that predated them being asked by the Government to examine the issue.
activities which are more explicitly recognised as having risk management functions seem to be more open. (Perhaps an exception to this rule is that of the US, where – although mobile EMF issues are considered to be regulatory, rather than policy issues – the FCC has consulted widely and publicly with a range of stakeholders including the public at large before issuing its safety guidelines.)

In terms of the independence of the advisory structures and the advisors, the situation varies. After recent changes, members of UK advisory committees now have to publicly declare any relevant interests (though, as in the case of the French GDH ad-hoc committee, they are not precluded from taking part simply because of industrial links). Criticism of advisory bodies for the involvement of industry experts is common, and the EMF case is no exception, with the French High Council for Public Hygiene’s committee on EMF having been criticised for the involvement of an expert from the electricity industry[23], whilst in Sweden too similar criticisms have been made of the RALF investigation. In contrast, the German Federal Ministry for Post and Telecommunication has specifically encouraged the development of a radio applications research association which could channel industrial expertise into the policy-making process.

4.5 Interaction between advisory structures and decision makers

4.5.1 Relationship between advisory bodies and decision makers

The independence of the advisory process from the policy making process in the EMF case varies from country to country. In France this is now enshrined in legislation, but nonetheless the GDH in the Ministry of Health will ultimately make risk management decisions. Again in Sweden, the system strongly separates executive agencies from policy-oriented ministries, and indeed there is a requirement to consult the relevant agencies in the development of legislation. In the UK AGNIR is not closely connected to the policy-making body, the Department of Health. On the other hand NRPB and AGNIR are very closely related (though there have been some recent attempts to introduce greater independence to AGNIR). In the Italian case it could be argued that it is the relationship between the different advisory structures that is most interesting, given the fact that the two Higher Institutes have differed in their decisions (taken at a six year interval) about the extent to which a precautionary approach to EMF safety is warranted. However, also important in the Italian case (and not surprisingly in the German case also) is the relationship between national and regional government, with the latter setting the pace in Italy by their introduction of more stringent maximum exposure levels.

4.5.2 The purpose of the advice

[23] Interestingly, the first French EMF study, performed by a committee set up by INSERM, was commissioned by the electricity company EDF, but the INSERM process was widely accepted as independent and autonomous.
In most cases the use of the expert advisors in the EMF case has been to review existing studies of health effects in order to make a risk assessment. However in some cases it is harder to distinguish between risk assessment and risk management. So in the Italian case, both the Higher Institute of Health and the Higher Institute for Worker Security made risk assessments, but there is no formal distinction between the former and risk management, and to some extent both advisory bodies moved into the latter territory as well, making recommendations on ways of minimising the risk to health of EMFs. Interestingly the two bodies seem to have interpreted the risks in different ways, and therefore produced differing recommendations as to risk management – with the result that Italy has adopted the EU recommendations for ELF radiation whilst in the case of high frequency radiation a more precautionary approach has been adopted. This may be partly explained by changes in the political climate between the two decisions (1992 and 1998) which have made the precautionary approach more acceptable or even desirable.

In the UK too risk assessment has often blended into risk management. NRPB has both roles (though it largely delegates the former to AGNIR), whilst the IEGMP – much like the Italian case - went beyond risk assessment to make recommendations about ways of minimising risks to human health of mobile phone technology in a precautionary way. In France, following the passing of the recent legislation on health protection, the two roles are separated - with risk assessment being the responsibility of the Health Watch Institute. However in the case of mobile telephony EMF it was considered that the UK’s IEGMP report, together with other studies, constituted an adequate risk assessment and consequently the GDH has set up a fixed-life committee of experts to make recommendations as to risk management, based on the assessment contained within these existing studies.

In all cases it seems the main purpose of the advice has been (a) to assess the risks posed to human health by various sorts of EMF and, in most cases (b) to advise ministries on suitable risk management measures. In some countries risk assessment and risk management seem to be particularly bound together – for instance in Sweden, where they are bound intimately in the consensus process. More fundamentally, it seems likely that the underlying purpose of involving advisory structures in some countries has been to postpone political decisions about EMF safety and to try to achieve closure in public and policy debates.

### 4.6 The incorporation of advice into policy

In most countries the advice-policy process is not complete. So in France there has been no decision thus far from GDH, as regards radio-frequency hazards from mobile telephony, whilst the current position on ELF is to continue to monitor research. In the UK too the AGNIR position on ELF is to continue to monitor research for any evidence of long-term health impacts. However policy on radio-frequency radiation has been influenced by the report of the IEGMP, which made a precautionary recommendation that children under 16 should not use mobile phones. The Government has adopted this recommendation and published (and publicised) guidelines about the use of mobile phones by children.
In Sweden the final report of the RALF review is still awaited, though interim reports have kept the issue ticking over and, in the meantime, the Swedish government have adopted the EC recommended levels. In Germany regulations also seem to be based largely on these recommended levels, whilst as reported for Italy the regulations covering environmental exposure to ELF, passed in 1992, are based on the EC recommendation, whilst those covering radiofrequency radiation are many times more stringent than the EC levels. The US situation regarding radio-frequency EMF remains that there is no proof of any risk to human health, and that therefore the issue remains purely one of enforcing the existing regulations (again influenced by ICNIRP).
5 Developing a classification framework

After a brief introduction, discussing both the general overview of scientific advice provided in chapter 2, and the two case studies covered in chapters 3 and 4, this chapter will introduce a preliminary classification framework for advisory bodies. This is then used to classify the advisory bodies discussed in the two cases considered in chapters 3 and 4. This exercise raises a number of further issues, which are explored in the penultimate section of this chapter. Unsurprisingly, this framework is found to be not without its limitations, both due to the restricted nature of this study, and as a result of the complexity of the processes being discussed. These shortcomings are discussed in the final part of this chapter.

5.1 Introduction

5.1.1 Overview

The overview of scientific advice structures in UK, France, Germany, Sweden, Italy, US and the EU (Chapter 2) stresses the variety of structures and processes that exist. Advisors operate at different levels of the political system, in a process which can be formalised (as is the case in France) or more flexible (as in the UK, Germany and Italy). Specifically considering the provision of advice in the legislative context, the sort of structure adopted appears to be partly a function of the relative power of the legislature compared with the executive. The level of engagement of advisors in the policy-making process also varies from performing only risk assessment to participation in making recommendations as to how risks should be managed. It is apparent that efforts are generally made to defend the advice process from accusations that those involved may have links with interested stakeholders. In France there is a strong preference for government advisors not to have any financial links with industry, while in the UK advisors, though not excluded on this basis, are expected to declare any interests. More generally, the openness of the advisory system is being recognised as an important factor in the robustness of advice. Many advisory structures are expected to publish information, reports and even minutes of meetings. The strongest moves in this direction appear to be in France and in the UK, where recent scandals have raised the profile of scientific advice – though it should be recognised that the trends may be strongest in these countries simply because their advisory systems were formerly less transparent than many other European countries. The way advice is incorporated into policy again varies, with different degrees of dialogue between advisors and policy makers. Finally, the impact of scientific advice on policy and on wider public debate obviously varies considerably from issue to issue. Science is just one aspect of a decision and economic, ideological, or ethical dimensions may often play a more prominent role.
5.1.2 The case studies

In chapters 3 and 4, the role of scientific advice in policy consideration of two issues - research on embryonic stem cells and the health effects of EMF radiation - were explored. The lessons that can be drawn from these cases are discussed below. However, before doing so it is important to consider how the two cases differ. One case deals with a relatively new policy issue, and one which has had a fairly high profile. This may reflect the emotive nature of the issue and the fact that pre-existing lobby groups with well-established positions on embryo research were able to bring the issue to prominence. In contrast, the second case, that of possible health effects of exposure to EMFs, has been a longer-standing policy issue, though with a rather lower public profile. However, the specific question of the health effects of mobile phones has in some countries emerged as a prominent issue in its own right. The cases also differ in the sense that the EMF case is concerned with a risk issue, in which established, successful and socially-useful technologies may or may not cause health problems. In contrast, the stem cell case is concerned with a question of whether contentious research should be allowed that could lead to the development of health treatments in the future. Assessment of the science in the stem cell case has largely been concerned with possible benefits rather than risk. Perhaps the most important risk issues for the stem cell case have been ethical rather than ‘purely scientific’ considerations.

5.2 Characterising scientific advice

The main purpose of this study was to ‘describe and typify’ the scientific advisory structures that were used. Given the time constraints on the project, the scope has been limited to only two cases, making it difficult to draw out anything other than tentative recommendations for a possible typology of scientific advice structures. However, the following represents one possible approach to categorisation, which is then used in tables 5.1 and 5.2 to classify the bodies discussed in both the stem cell and EMF cases.

5.2.1 Categories for characterising advisory structures

Based on a systematic exploration of the characteristics of each of the advisory bodies encountered in the two cases considered in this report, a categorisation scheme was developed. The scheme focuses on a number of characteristics, or dimensions, in which advisory bodies may vary, from case to case or country to country. These characteristics are listed below, along with a brief explanatory note. Where necessary a keyword, which is used in tables 5.1 and 5.2, is included in parentheses.

- **Initiation**
  How is the advisory process initiated in a particular case? Is advice commissioned? If so by which actor(s)? The institution that ‘hosts’ the advisory body? Another advisory body? Or is advice offered proactively, by the advisory body itself, without any request for help? For the purposes of the categorisation, we have identified the following options:
    - (HoG) Head of Government
- (Ministry) Responsible Ministry
- Legislature (or Legislators)
- Public(s)
- (Other) Other advisory body
- (Self) Decision to look at issue self-initiated

**Status/permanence of body**
Is the advisory body a statutory one (that is, established in a particular role by legislation), set up as a standing non-statutory body, or set up for a fixed period of operation only? For the purposes of the categorisation, we have identified the following options:
- (Statutory) Statutory body
- (Standing) Non-statutory standing body
- (Ad-hoc) Fixed-term (ad-hoc) body

**Scope for action**
What is the scope for action of the advisory body? Was it set up solely to advise decision makers or does it have a wider scope, perhaps able to enforce regulations, license particular activities or set standards. Alternatively, does the body have a broader legislative function? For the purposes of the categorisation, we have identified the following options:
- (Advisory) Purely advisory
- (Monitoring) Monitoring role with power to act if regulations breached
- (Licensing) Charged with issuing licenses, e.g. for research in a particular area
- (Standards) Charged with setting standards
- (Legislative) Wider legislative function

**Role**
Is the advisory body charged only with assessing risks on behalf of policy-makers, or does it also have a role in developing policy options to manage those risks? It is assumed that bodies engaged in risk management will have to engage in some form of assessment. For the purposes of the categorisation, we have identified the following options:
- (Assessment) Risk assessment
- (Management) Risk management

**Remit**
What is the extent of the remit of the body? Is it narrowly focused (on one or two particular risk questions), does it cover a number of issues within a particular area, or is it broad, encompassing a range of areas and issues? Alternatively, does the body have no fixed remit in terms of focus, allowing it to provide advice on any area or issue of interest to policy-makers?
- Narrow
- Area
- Broad
- No remit
Consultation
Does the body rely entirely upon the deliberations of its members in assessing risks or making policy recommendations, or does it consult more widely?
- (None) No external consultation
- (Interview) Body receives external views via interviews or hearings with other specific experts
- (Consultation) Body conducts a consultation process aimed at other experts
- (Wide consultation) Body conducts a wider consultation, going beyond scientific experts to include stakeholders etc.

Research
Can the body conduct or commission further research in support of its mission, or is its role solely to examine existing research results. It is assumed that bodies that commission research will also review existing research.
- Review
- (Commission) Able to commission (or conduct) research

Transparency
How open and transparent is the operation of the advisory body to the wider public? Is only the outcome (advice) made open, or is the process by which that advice is generated transparent?
- (Report) Outcome is made open, usually via published report
- (Partly) Partly transparent process e.g. some open meetings etc.
- (Very) Very transparent process, e.g. open meetings, minutes/agenda and other information on web, etc.

Composition
How is the body composed? Is it made up of scientific experts, is there a mix of scientific and non-scientific experts, and are legislators involved?

Employing these categories, the tables below (5.1 and 5.2) characterise the main advisory bodies that were used in the stem cell and EMF cases. Having made such an attempt at categorisation, a question must be asked about the value of this (indeed of any) classification system. The section following the tables will therefore discuss the lessons that can be drawn from the categorisation attempt before going on to explore the problems of classifying scientific advice structures.

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24 Due to the time constraints of the project and the lack of sufficient detail concerning the US and EU cases, only the UK, German, French, Italian and Swedish advisory bodies are classified in these tables.
<table>
<thead>
<tr>
<th>Initiation</th>
<th>Permanence</th>
<th>Scope for action</th>
<th>Role</th>
<th>Remit</th>
<th>External consultation</th>
<th>Research</th>
<th>Transparency</th>
<th>Composition</th>
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<tr>
<td>CE (Fr)</td>
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<td>Report</td>
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<td>Report</td>
<td>MPs</td>
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<td>Review</td>
<td>Report</td>
<td>Mix of scientific and non scientific experts</td>
</tr>
<tr>
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<td>Standing</td>
<td>Advisory</td>
<td>Broad</td>
<td>Wide consultation</td>
<td>Review</td>
<td>Report</td>
<td>Mix of scientific and non scientific experts</td>
</tr>
<tr>
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<td>Advisory</td>
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<td>Review</td>
<td>Report</td>
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<td>Standing</td>
<td>Advisory</td>
<td>Broad</td>
<td>Interview</td>
<td>Review</td>
<td>Very</td>
<td>MPs and scientific experts</td>
</tr>
<tr>
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<td>Parliament</td>
<td>Standing</td>
<td>Advisory</td>
<td>Broad</td>
<td>Interview</td>
<td>Review</td>
<td>Very</td>
<td>MPs and scientific experts</td>
</tr>
<tr>
<td>Parliamentary committee on Biotechnology (Sw)</td>
<td>Parliament</td>
<td>Ad-hoc</td>
<td>Advisory</td>
<td>Area</td>
<td>Consultation</td>
<td>Review</td>
<td>Very</td>
<td>MPs</td>
</tr>
<tr>
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<td>Advisory</td>
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<td>Wide consultation</td>
<td>Review</td>
<td>Partly</td>
<td>MPs and experts</td>
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<td>Advisory</td>
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<td>None</td>
<td>Review</td>
<td>Report</td>
<td>Mix of scientific and non scientific experts</td>
</tr>
<tr>
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<td>Report</td>
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Table 5.1 – Characterisation of advisory bodies for the stem cell case
<table>
<thead>
<tr>
<th>Composition</th>
<th>Transparency</th>
<th>Remit</th>
<th>External consultation</th>
<th>Research</th>
<th>Role</th>
<th>Scope for action</th>
<th>Permanence</th>
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<td>Advisory</td>
<td>Ad-hoc</td>
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</tr>
<tr>
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<td>Narrow</td>
<td>Wide consultation</td>
<td>Review</td>
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<td>Advisory</td>
<td>Statutory</td>
<td>AGNIR (UK)</td>
</tr>
<tr>
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<td>Narrow</td>
<td>Wide consultation</td>
<td>Review</td>
<td>Management</td>
<td>Advisory</td>
<td>Nationalised industry</td>
<td>IEGMP (UK)</td>
</tr>
<tr>
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<td>Broad</td>
<td>Wide consultation</td>
<td>Commission</td>
<td>Management</td>
<td>Advisory</td>
<td>Ministry</td>
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<td>None</td>
<td>Review</td>
<td>Reports</td>
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<td>Assessment</td>
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<td>Review</td>
<td>Reports</td>
<td>Management</td>
<td>Advisory</td>
<td>Ministry</td>
<td>CSHFP (Fr)</td>
</tr>
<tr>
<td>Mix of scientific and non scientific experts</td>
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<td>None</td>
<td>Review</td>
<td>Reports</td>
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<td>Advisory</td>
<td>Ministry</td>
<td>Expert Group on Mobile Phones 2000 (Fr)</td>
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<tr>
<td>Mix of scientific and non scientific experts</td>
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<td>None</td>
<td>Review</td>
<td>Reports</td>
<td>Monitoring</td>
<td>Assessment</td>
<td>Standing</td>
<td>SSK (Ger)</td>
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</table>
5.3 Discussion

5.3.1 Initiation

In the case of the EMF issue, advice has generally been commissioned by a Ministry or similar body, whereas the stem cell case sees a range of different initiating actors or institutions, notably legislatures and heads of governments. Why is this? A possible explanation lies in the emotive nature of the debate surrounding the use of stem cells in research compared to the more ‘technocratic’ discussions over EMFs. Are issues which are generally felt to be ‘technocratic’ more likely to be dealt with by ministries whilst those with more prominent social, ethical or philosophical dimensions are of wider political concern, particularly to parliamentarians and the executive centre of government? The fact that Italy and the UK do not appear to adhere to this pattern reminds us that it is important not to lose sight of the major role of political cultures in shaping institutional and policy responses to issues.

5.3.2 The status and permanence of advisory bodies

When confronted with problems with a prominent scientific dimension, policy makers have a number of options. They can turn to existing advisory bodies, which are likely to be statutory or at least standing bodies, for advice. Where these do not exist or are deemed insufficient for whatever reason, they can set up new structures. These could be new standing (perhaps statutory) bodies or they could be fixed-term, ad-hoc, and issue specific bodies.

At first glance, the distribution of statutory, standing and ad hoc structures across the two cases seems to be rather similar. However, on closer inspection, we can see that all of the ad hoc bodies connected with the EMF issue were, in fact, convened to address recent worries surrounding the specific question of mobile phones. By contrast, scientific evidence concerning the health effects of power lines, which has now been an issue of public concern for around a decade, has generally been dealt with by standing, often statutory, bodies. Why is this? We might postulate that the contemporary political environment, marked by the rise of the so-called ‘risk society’ (e.g. Beck, 1992), favours the establishment of new, ad hoc bodies to deal with new and emerging issues of uncertainty and controversy such as mobile phones. Factors such as operational flexibility and the politically-important symbolic value of appearing to take action may be relevant in the choice to establish a new ad hoc body.

However, this putative hypothesis is slightly undermined by the stem cell case where, in addition to the important ad-hoc bodies, a number of statutory and permanent bodies were involved in the advisory process. Further, it should be borne in mind that the statutory and permanent bodies dealing with this issue tend to have much wider remits than simply providing advice on the use of stem cells in research. These bodies may themselves choose to establish internal ad-hoc structures (e.g. committees, sub-groups, etc.) to examine such specific issues.

The tables also suggest that some countries are more likely to favour one type of structure over others – for example, Italy and France account for almost all of the
statutory bodies in our sample. In France in particular, much of the advisory system is now enshrined in law (see page 9).

- Consideration needs to be given to why particular structures are used in particular cases. Are ad-hoc bodies more likely to be set up when an issue has a particularly high profile? When, and why, are existing permanent structures deemed insufficient? Is the need to apply more focused, specific expertise than that possessed by standing bodies a factor, or do factors such as the political need to be seen to take quick action play a more important role? Is there a trend towards more use of ad-hoc, issue specific bodies? If so, what are the reasons behind this?

- There is a problem here concerning the unit of analysis. Should the focus be on the wider organisation/advisory body in general in cases where a specific sub-structure has dealt with the issue? Clearly this question has implications for the meaningfulness of the ‘status’ category of the classification framework.

5.3.3 The scope for action by the advisory bodies and their role in the policy process

Here, the tables suggest that virtually all of the advisory bodies examined provide only advice, without exercising any formal powers for enforcing regulations, licensing, etc. Unsurprisingly, the few exceptions are all standing or statutory bodies, which tend to have wider remits.

However, although the majority of bodies studied were formally concerned only with advice, this is not to say that they may not have an important role in policy formulation. As discussed in the overview of advice structures, an important consideration in terms of the interaction between advisory bodies and decision makers is the nature of advice that is asked for – essentially a question of risk assessment versus risk management. Do advisors concern themselves solely with scientific risk assessment, and leave policy-making to the policy-makers, or can the advisors enter into the policy process, for example by suggesting policy options stemming from their risk assessment? In the stem cell case, all the advisory bodies have been concerned with risk management – in other words, whilst they are expected to assess the scientific evidence, they are also expected to make recommendations in light of that evidence. In the EMF case the picture is more complicated, with three of the advisory bodies apparently restricting themselves to risk assessment. In fact, while many of the advisory bodies are charged with risk assessment rather than risk management, in practice the line between the two seems often to be blurred.

- Is it possible (or desirable) to separate risk assessment and risk management? In the act of assessing a problem, are advisory bodies inherently engaging in risk management? Does this depend on the nature of the issue?
5.3.4 The remit of the advisory bodies

The remit of the advisory bodies can be seen from the tables to differ significantly. Whilst both show a wide distribution of breadth of remits for the advisory bodies studied, the most popular appears to be a ‘broad’ remit, where a range of issues are covered. Unsurprisingly, there is significant correlation between the status or permanence of an advisory body and its remit. All of those advisory bodies with a ‘broad’ remit are standing or statutory ones, as are those that have no specific remit and can be asked to look at any ‘issue’. Meanwhile, all of the advisory bodies with a ‘narrow’ focused remit are ad-hoc. The picture is slightly less clear for bodies with a remit covering a particular ‘area’ encompassing a number of issues. Three of this type of advisory body have been identified and while two are ad-hoc, the third, AGNIR, is standing. This brings us back to the unit of analysis problem inherent in the classification scheme: AGNIR is a long-standing body, but one which nonetheless could have been considered to be ad-hoc when it first was established by the NRPB.

- Remit once more seems to be tied up with choices about the appropriate unit of analysis: the more specific the unit of analysis, the more likely the remit may be narrow.

5.3.5 How does the advisory body gather information?

Whilst a number of the bodies involved in our cases conducted wide consultations during the course of their considerations, others performed no external consultation at all. For the two cases considered, France and Italy account for the entire ‘no external consultation’ category. Indeed, none of the Italian bodies covered in this study appear to have conducted any form of external consultation.

It is also worth reflecting upon the affect of the particular issue in question. All the bodies concerned with addressing the contemporary issue of mobile phone safety seem to have consulted widely. This is in contrast to the older issue of health effects of power lines, where little or no consultation seems to have been the norm. If Italy were to be excluded, then the same phenomenon can be seen in the stem cell case, with (often very broad) consultation the norm on this very contemporary issue. It could be argued that we are witnessing a shift towards attempts to foster a more inclusive culture in the generation of advice to policy makers. Moreover, this behaviour is not the preserve of newly established ad-hoc bodies, but can also be seen in permanent and statutory bodies as well.

As to the question of whether the advisory bodies reviewed existing research or whether they also commissioned or conducted further research, the results are far less polarised. The vast majority of bodies reviewed research results only, with just three commissioning new research. These bodies were all involved in the EMF power-line case, and were all statutory bodies with broad remits.
5.3.6 Transparency and openness of the advisory process

The tables show that, for the most part, the openness and transparency shown by the advisory bodies examined in this study extends only to the open publication of advice in reports. Only four bodies can be described as very transparent, and these are all in Sweden. In fact the difference between the countries is striking in the way it does not vary between issues. As has already been implied, Sweden would appear to have the most transparent arrangements, followed by Germany with its more partial arrangements. For the UK, France and Italy openness is almost exclusively confined to the production of reports only. This picture would seem to resonate with common perceptions of the openness of political cultures in certain Member States, with Sweden and Germany both more noted for open policy-making than the UK, France and Italy.

- Is there any evidence of a real move towards greater transparency in the advisory process? If so then is it the result of greater media and public interest in the use of science in policy as a result of recent scandals, does it reflect an increasing role for science in politics, or is it part of a wider trend towards more open government? Is the level of transparency likely to differ between ad-hoc and more permanent bodies? Could a greater interest in ensuring the transparency of the advisory process partly explain decisions to set up new bodies?

5.3.7 The composition of advisory bodies

The more emotive stem cells issue sees a broader range of actors represented in advisory bodies in many countries, whilst in the EMF case bodies are more likely to be composed of scientific experts alone. Some differences between countries are again noticeable: the UK and Italy stand out due to the lack of involvement of legislators in the advisory bodies. This no doubt results at least in part from the general political culture in these countries. However, it may also reflect a sampling bias in our study. UK Parliamentary Select Committees may not look out of place in the company of some of the advisory bodies considered in the other Member States, having been active recently in reviewing scientific evidence and providing recommendations connected to both mobile phone risks and stem cell research. However, UK Select Committees play no direct role in either considering or initiating legislation, and are thus several steps removed from the policy-making process.

5.4 Limitations of the classification scheme

There are obvious limits to the explanatory use of this putative classification scheme. One simple demonstration of the problems faced by such schemes can be seen in the Italian EMF case, in which the scheme categorises ISS and ISPESL identically. This disregards and offers no explanation for the fact that the two bodies nonetheless came to such different conclusions regarding risks from high frequency radiation. Fundamentally, any such scheme will be preoccupied with basic questions of the structure and function. However the cases demonstrates that the scientific advisory process is extremely complex and contingent, involving numerous subtleties which
simply cannot be captured in a reductive classification system of the sort explored above. The complexity of scientific advice defies reduction, and many of the apparently discrete ‘characteristics’ or ‘dimensions’ considered above are in fact intimately inter-linked or even overlapping.

5.4.1 The issue-specific nature of the advisory process

As has been clear throughout this study, the actual problem that is being examined must be an important consideration when thinking about scientific advice. The difference in nature between the emotive and very public debates over the use of stem cells in research (and over the health effects of mobile phones) and the less contentious, more ‘technocratic’ debates surrounding the health effects of EM radiation from power lines, has been harnessed to account for a number of differences seen in tables 5.1 and 5.2. In order to classify the operation of advisory structures a way needs to be found of including the issue under consideration. Typifying complex, multi-dimensional issues would be a big enough challenge. The problem is further complicated because the nature of the issue is, of course, not constant but changes over time. In a multi-national study such as this, the extent to which an issue may have very different meanings, and raise different concerns, in different countries must also be considered. The need to confront the issue-specific nature of advice to policy-makers represents a profound challenge to any attempt to develop a categorisation scheme for scientific advisory structures.

A focus on the nature of specific issues also brings us back once more to the unit of analysis problem. The ad-hoc bodies in this study have proved relatively easy to classify in comparison with the standing/statutory bodies because they have been set up to deal with a specific issue. As already noted, in classifying the standing/statutory bodies a problem arises as to whether they are being classified with respect to their general function or in light of the specific issue considered in the case study. Whilst we have not always been able to follow this advice in the course of the present study, it is our contention that the focus should be on the (sub) unit that deals with the specific issue being examined in a case study. Otherwise structures and bodies can only be compared in the broadest (and perhaps most superficial) terms.

5.4.2 The ‘fuzziness’ of negotiated outcomes – relationships between advisory bodies and decision-makers

An important factor which is difficult to deal with in a classification system is political influence on the advisory process and the relationship between advisory bodies and decision-makers. Given the negotiated nature of these relationships, it is difficult to see how certain subtleties could be classified. Take as an example the selection of advisors. At first glance this may seem relatively straightforward – in all cases the stated concern is “getting the best people for the job”. This selection process does of course differ from case to case, both within countries and from country to country. The selection may be informal (e.g. Sweden), may be governed by particular bureaucratic procedures (e.g. the UK) and could involve an examination of publication records (e.g. France), nominations from within a scientific discipline (e.g. Italy), or the expert may be proposed by civil servants, politicians or political parties.
However, whether the involvement of members holding specific scientific expertise is felt to be sufficient or whether other expertise or even lay members are felt to be required, will differ from case to case, country to country.

- What does ‘best for the job’ mean? Does this differ from issue to issue, structure to structure? Who decides who is ‘best for the job’ and what the processes by which these decisions are arrived at?

A second question concerns the way in which the remits of advisory bodies are set. Clearly the overall remit has a vital role in guiding the advisory process, setting the framework within which the advisors work.

- How are the remits of advisory bodies set? Is there a process of negotiation between the advisory body and decision-makers over the exact remit? Is there scope for the remit to evolve through the advisory process? If the remit can evolve then does there have to be opportunities to alter the membership of the advisory body to take account of the change?

Thirdly, consideration needs to be given to how the final advice is produced. While in some cases advice may be ‘presented’ to decision-makers, in others policy-makers will be much more involved in ‘co-producing’ the final outcome.

- Is the final outcome of an advisory process solely the product of the advisory body or is it the product of negotiation between the advisors and decision-makers?

The recent inquiry into how the British Government handled the BSE problem (see Phillips, 2000) made clear the complex interaction that occurred between the advisory bodies and civil servants within the relevant Ministry (the Ministry for Agriculture, Fisheries and Food, MAFF, in this case), highlighting the subtle influences that could prompt the advisory bodies to follow particular avenues of investigation and reach particular outcomes. Such interactions cannot be confined to one case, and any detailed study of advisory systems needs to give them important consideration. However, it is difficult to see how a classification framework could be sensitive to the potential for such interactions.

5.4.3 Beyond the national context

A further important aspect in considering the operations of national advisory bodies that has not been captured in our classification is the international context. Clearly there are factors beyond the national level that play an important role in national advisory processes. This is clear in the EMF case, where guidelines set by the International Commission on Non-Ionising Radiation Protection (ICNIRP) were very influential (and even, in a number of countries adopted as the standard). However the impact in one country of advice from bodies in other countries has also been important in the cases discussed. The debates on both stem cells and the health effects of EMF (and in particular, mobile phones) have not occurred simultaneously in every country studied. Hence, the position taken in one country often had an effect on others. This is most clearly seen in the case of the IEGMP in the UK, whose report
has been directly incorporated as an input into the advisory process in France. Again, the relatively early publication of the CMO’s Expert Group report on stem cells (UK) and the NBAC report (US) has meant that they too have had an input into the debate in other countries. It is unsurprising that one of the first considerations, in approaching a policy question with a prominent scientific component, is the state of the debate in other countries. A related international issue which can be seen in the stem cell case is the question of differences between regulatory regimes in different countries, and specifically the suggestion that strict regulation on one country may result in the flight of research activities to less regulated countries.

• What are the relationships between national and international advisory bodies? How open are governments to the experience of other countries? With regard to national policy, is there a desire to be seen to reach conclusions in a national context? Are foreign experts used at national levels?

5.4.4 The impact of advice

No study of this kind can ignore questions concerning the impacts of scientific advice. It is difficult to assess the extent to which advice has had impacts on policy in relation to stem cell research and EMFs because, in many of the countries considered, the policy processes relating to both these issues are still ongoing. However, where recommendations have been made, they do seem to have had impacts on policy. Regarding EMFs, the most interesting case is Italy, where the two main advisory bodies have provided the Government with different recommendations, resulting in a much more precautionary approach being taken on high frequency radiation compared to extremely low frequency radiation. This approach resulted from the decision of the Italian Government to follow the advice of ISPESL and ignore advice from ISS – a decision that clearly cannot have been made on a ‘purely scientific’ basis, and one that lays bare the political nature of all such decisions.

Another example of impact can be seen with recent actions by the UK Government, which, in response to the IEGMP report, has issued widely publicised precautionary advice, particularly relating to the use of mobile phones by children. It is worth re-emphasising for the EMF case that, where national advisory bodies have not reported, governments have for the time being tended to adopt the recommendations of the international advisory body, ICNIRP.

For the stem cell case, the advice process has only just been completed in the UK, where the recommendations of the CMOs Expert Group have been very influential. Indeed, in light of the recommendations made by the Expert Group, Parliament has recently voted to adopt changes in the regulations to extend the allowed research on human embryos. It is more difficult to assess the impacts of advice in the US, largely due to the existence of a Congress profoundly divided on political and religious issues.

• The example of the deadlock in the US Congress regarding stem cells highlights an important factor that must be considered when exploring the impact of advice. It would clearly be wrong to classify ‘impact’ as changes in legislation or regulation. Advice may have impacts on policy which lead to no
action being taken, but which still constitute an impact. In any case it is always likely to be difficult to attribute causality to specific advice which may be simply one amongst a range of factors influencing the direction of policy.

- More generally it is also important to consider the impact that advice may have on the broader debate surrounding an issue. Such an impact may be more obvious where there is a high level of public debate, e.g. the stem cell case, but impacts may also be felt on more contained debates such as the EMF case. If impact is defined by the effect on the debate then where does responsibility lie for disseminating findings? Should (do) advisory bodies operate independently in this respect?

In light of the above discussions the following chapter will outline the preliminary conclusions that can be drawn from this study.
6. Conclusions

6.1 Brief conclusions on the classification framework

As has been clear from the above discussions, our attempts to develop a classification framework have helped to highlight a number of important issues regarding the role of advisory bodies in the two case studies considered. It is also clear that a great deal of further work would be needed in order to refine this classification system. It is our contention that the ‘role’ category as it stands has little value, as all advisory bodies seem to be involved to some degree in risk management. That is not to say that all advisory bodies can be regarded as the same in this dimension – that is clearly not the case. Rather, this issue points to the fact that a much more sensitive characterisation of the role of advisory committees needs to be developed. As noted at the end of the previous chapter, another question that bears heavily on any further attempts at this sort of classification is that of the appropriate unit of analysis, a factor that has a bearing on a number of dimensions in our classification framework.

In short, we have tried, through our own efforts at classification, to show that attempts to reduce the diverse and complex reality of scientific advice provision into an overly rigid (and largely structural-functionalist) classification scheme is to risk omitting a range of important but subtle factors. While a more detailed study of scientific advice cases could lead to a more developed classification framework, it is our contention that, if the reality of scientific advice processes is to be taken into account, then the use of such classifications should only form one component of such a study.

6.2 Wider issues

6.2.1 Scientific advice and governance

The term ‘governance’ is increasingly used by political scientists to describe a situation in which decision-making power is widely and unevenly dispersed, not only within central government, but also beyond it, throughout industry and civil society. In this context policy is applied through a process of negotiation amongst different actors and institutions, the outcomes of these negotiation processes being heavily dependent upon the range of resources each actor can bring to bear (see e.g. Rhodes, 1997). Clearly, such a description of distributed, emergent decision-making fits well with the reality of scientific advice for risk-related policy-making as described in this report. Scientific advice, then, should be considered as simply one part of a wider system of governance.

‘Good governance’ emphasises transparency, accountability and effectiveness as necessary conditions for successful public policy (CEC, 2000, p.3). Thinking specifically about the relationship between science and governance, Kyriakou and di Pietro (2000) refer to “the mechanisms, and the challenge of devising them, so as to allow science and the processes of decision making in society to work together in ways that are effective, credible, accountable and transparent”. This report shows that that there is some movement in this direction, but that there is still some way to go,
especially in some Member States. Here, we are thinking specifically about (a) openness and transparency and (b) wider stakeholder involvement.

a) The importance of openness and transparency has been stressed throughout the study. One aspect of this concerns the selection of advisors. There has been a move in certain countries (e.g. the UK) to try to formulise the selection processes, and it appears to be generally accepted that the membership of an advisory body should be made public and any interests should be declared. A second aspect of transparency relates to the operation of advisory bodies, from the setting of their remit to the publication of their final reports. It has been suggested that there has been a move towards greater operational transparency, with particular use being made of the Internet for publishing reports, minutes, agendas etc. Inevitably, some power and influence is wielded by advisory bodies, especially given the difficulty of divorcing risk assessment from risk management. When scientific advice is considered as a component of a wider system of governance in this way, full transparency and accountability in operation becomes imperative. In this respect, transparency of outcome clearly does not go far enough.

b) Engagement with a wider range of stakeholders, and the form such arrangements could take. One possibility would be for advisory groups to undertake wide consultation exercises, allowing for input from a diverse range of concerned actors. Indeed this sort of consultation has been used in some of the countries considered in this study. However, should the membership of advisory bodies themselves be limited to narrowly-defined scientific ‘experts’? Should a wider range of stakeholders be more intimately involved in the advisory process? It is often argued that members of advisory bodies need sufficient technical expertise in order to understand the issues, a stricture that would rule out wider involvement. While this might hold if it were really possible to restrict the advice process to risk assessment alone, in reality, scientific experts are no more qualified than other stakeholders when it comes to issues of risk management. The fact that countries such as the UK are now including ‘lay’ members on many advisory committees implicitly recognises the ultimately political nature of these committees. Whilst the involvement of a range of stakeholders could increase the time it takes to reach a negotiated decision, if the advice produced was more robust (in the sense of having been produced in a context of ‘good governance’), then it is likely to be more ‘effective’ in the long run.

6.2.2 Scientific advice and the role of the EC

In areas where the EC has legislative jurisdiction, there is a clear role for scientific advice and, indeed, many of the issues faced may be similar to those faced by nation states. In addition, our discussion of the wider international influence of scientific advice raises another possible role for the EC. This report shows that an inherent part of advisory processes is to consider advice that has been given by other bodies in other countries. Hence, by seeking advice on issues that are beyond any legislative jurisdiction, the EC could perhaps provide a lead for advisory processes in Member States. This can be seen in the stem cell case where the Member States have full legislative control but advisory processes at the EU level have inputted into national discussions. A possible further role could be in facilitating the exchange of advice
between Member States, bringing together members of different advisory bodies so that information and approaches can be shared. However, in the light of the discussion of scientific advice and governance in the previous section, perhaps the most important contribution the institutions of the EU can make would be to promote ideas of ‘good governance’ in relation to scientific advice. It is clear from the study that there is much variety in the way that advice is sought and there is no ‘best practice’ as such. However, once this is acknowledged, it is possible to learn much from ‘good practice’ conducted elsewhere. Some or all of these activities could be advocated within the context of the EC’s proposals for the development of a common system of scientific and technical reference within the European Research Area.

6.3 Questions for further research

Given the short timescale of this project, it is perhaps inevitable that more questions have been raised than answered. Below we summarise what we believe to be the three main categories of questions for further research. These, we feel, can best (perhaps only) be answered by detailed exploration of particular cases of the operation of scientific advisory bodies.

The first set of questions relates to the issue-specific nature of scientific advice:

- Why are particular arrangements used in particular cases? In which ways does the nature or profile of the issue affect the types of structures used?
- How are experts selected, and how is the definition of ‘best person for the job’ set?

The second category of questions concerns trends in scientific advice:

- Is there a trend towards the use of more ad-hoc, issue specific bodies?
- Is there an increasing trend towards transparency? If so, then what form does this take? Are advice procedures becoming more open not simply in a cosmetic but rather in a fundamental way?
- Is there a trend towards greater use of a more precautionary approach by advisory bodies when dealing with issues of uncertainty? How is precautionary advice ‘received’ by decision makers and wider publics?
- If these trends are observed then what effects are they likely to have on the advisory systems?

The final, fundamental set of questions concern the wider political role of scientific advice in democratic systems:

- What is the political role of scientific advice? Should it be to inform policy or should it to make a wider contribution into the general debate? If we take the second point, then are existing structures adequate or do there need to be fundamental changes in the advisory system with, perhaps, greater participation, or more sources of advice?
- Can we realistically make a separation between the functions of risk assessment and risk management, and is this desirable? Is this issue dependent?
• What are the relationships between national and international advisory bodies? What is the influence in other countries of advice produced by national bodies and what sort of role can international bodies play?

• Further, if scientific advice is only one part of the wider system of governance, could a greater understanding of both decision making in a system of governance, and the role of scientific advice within it, be gained through comparative study with other forms of advice to policy-makers, for instance advice on economic issues?
Interviews conducted

France:

Mrs Elisabeth GOMARD – INSERM, head of the mission “animation of biological and medical research”
Mrs Marie-Anne BACH – INSERM at the mission “animation of biological and medical research” and Ministry of health, at the General Directorate of Health
Mrs Anne BISAGNI – INSERM, head of the mission “animation of clinic and therapeutic research”
Mrs Véronique FOURNIER – cabinet of Health Minister, in charge of the revision of bio-ethics laws
Mr François HIRSCH – INSERM, head of the mission “Quality of non clinic research” in the Service “Ethics and quality of research programmes”; at the origin of the creation of the internal task group mentioned in the report
Pr William DAB – director of the Unit of the scientific support of the General direction of health (ministry of health), former deputy director of EDF medical Unit, former member of CSHPF working group
Dr Gilles DIXSAULT – chief of the Unit on natural and food risks, General direction of Health, Ministry of Health, former member of CSHPF working group
Pr Gérard BREARD – scientific director of INSERM (in charge of public health)
Dr Catherine COURVALIN – former responsible of the program ‘Environment and health” at the ministry of environment
Dr Ghislaine FILLIATREAU – chief of the scientific survey unit at the ministry of research

Italy:

Official at the Ministry of University and Scientific and Technological Research
Former official at the Ministry of University and Scientific and Technological Research
Scientific expert of ISPESL on electromagnetic pollution
Scientific expert of ISS on electromagnetic pollution
Official at the Health Ministry, expert of electromagnetic pollution
Official at the Health Ministry, secretary of the Dulbecco Commission
President of the National Committee for Biosafety and Biotechnology, member of the Dulbecco Commission

Germany:

Margot von Renesse, MdB, – head of the Enquete-commission “law and ethics of modern medicine” of the German Bundestag (Federal Assembly)
Wolf-Michael Catenhusen,MdB – parlimentary state secretary in the Federal Ministry for Education and Research (BMBF)
Dr Annette Schmidtmann – the responsible person for research on stem cells in the German Research Community (DFG)
**Sweden:**

Elisabeth Birke – Program Manager, Council for Work Life Research  
Stefan Karlsson – Head of Section, Ministry of Health and Social Affairs  
Ola Persson – Head of Section, Ministry of Industry and Trade  
Gustaf Brunius – Administrative Director, Swedish Gene Technology Advisory Board  
Erik Forsse – Deputy Director, Ministry of Research and Education  
Lena Jonsson – Deputy Director, Ministry of Health and Social Affairs, Member of Governments Medical Ethical Advisory Board  
Monica Mörtberg-Backlund – Head of Section, Ministry of Industry and Trade  
Aija Sadurskis – Committee secretary in the Parliamentary Committee on BioTechnology

**UK:**

Edmund Quilty – Director, Science in Government Directorate, Office of Science and Technology  
Anthony Taylor - Secretary to the Chief Medical Officer’s Expert Group on Stem Cells, Department of Health  
Dr John Stather - National Radiological Protection Board
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January


December

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Office of Science and Technology (1997) *The Use of Scientific Advice in policy Making*, Department of Trade and Industry, March


Science and Governance: the case of France

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Science and Governance: the case of France

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Sources
1 Describing and typifying the scientific advice structure in the policy making process

The aim of this report is to identify and typify the various structures through which scientific advice is incorporated into the policy process in France. This report doesn’t present the nuclear related issues. It doesn’t assess the results of the process.

1.1 The context of the science and governance issue in France

1.1.1 The drama of the contaminated blood as the reference event

Poor functioning of the scientific expertise function and its lack of proper linkage with decision makers have led, in the late 80s, to the contamination of hundreds of persons by the AIDS virus through blood transfusion and their subsequent death. This brought a former Prime minister and two of its ministers to court, producing a long lasting trauma both in the public and among politicians. The Law ‘on the reinforcement of public health surveillance and of the control of the safety of products concerning humans’, passed on 1 July 1998 is a direct consequence of that.

The drama of the contaminated blood has brought the consciousness of the necessity to invent a new relationship between science and decision making somehow a new form of democracy.

The political system has seen from close both its moral rejection and legal condemnation; scientists have experienced generalised disbelief and suspicion. The new organisation of scientific expertise, the attention to the precautionary principle and the important role of bio-ethics must be understood in this context.

1.1.2 The precautionary principle as a relevant moral and political principle

A Law on the Environment passed on 2 February 1995 puts forward the Precautionary principle (PP) as a moral and political principle: ‘the absence of scientific certainties must not delay action aiming at preventing risks of damages which may be important and irreversible, the action being economically acceptable’.


*note: the essence of the PP is that uncertainty on scientific results should not, in certain cases, prevent to take action. It is a principle of decoupling between knowledge and action.*

1.1.3 An early and continued concern with bio-ethics

The sensitivity of the public to the ethical questions raised by the quick advances in biotechnology has resulted in the creation of a National Consultative Committee of Ethics on health and life sciences (Comité national d’éthique, CCNE) in 1983 and in a Law ‘on the
respect of the human body’ (29 July 1994). France is one of the rare countries to have passed legislation on the ‘respect’ of the human body.

1.2 The French institutional structure of scientific expertise

1.2.1 The backbone of the scientific advice structure in the policy making process: the Law of 1st July 1998

The Law ‘on the reinforcement of public health surveillance and of the control of the safety of the products concerning humans’ organises the surveillance and expertise functions for government in all matters related to public health security, be they concerned with food, drugs, medical products or environmental exposure to contaminants.

A first dimension of the Law is to bring some degree of separation between risk assessment through scientific expertise and political decision-making dealing with the management of those risks. Expertise has thus been externalised from ministries into dedicated agencies the role of which is to have scientific expert groups function, the experts being chosen among scientists from academia and the public research institutions.

A second dimension is to separate surveillance and monitoring functions from expertise (assessment) functions.

This is why the Law creates a national committee of the health security, a national Institute for public health surveillance (Institut de veille sanitaire, IVS) and two agencies in charge of expert advice: the AFSSA for food products and the AFSSAPS for drugs and medical products. It organises a feasibility study for a third expert advice agency in the area of environmental exposure to contaminants (AFSSE). Such a separation into several agencies – which is different from the FDA model – had been discussed by Parliament.

1 The national committee of the health security (Comité national de sécurité sanitaire – CNSS)

It is chaired by the minister of Health and composed of the Directors and Chairmen of the scientific boards of IVS, AFSSA and AFSSAPS. It is in charge of analysing events which may be threats for public health and of the co-ordination between the IVS and the Agencies in charge of the scientific expertise.

The link between political level and assessment level is done by the CNSS. The ministry of Health is in charge of the transmission to the prime ministry.

In the future, the idea would be to replace the CNSS by a more formalised interministerial co-ordination structure (with the participation of ministers in charge of health, environment, agriculture, and industry…).

2 The national institute for public health surveillance (Institut de veille sanitaire, IVS)

The IVS has to monitor continually the health of the population, to detect all threats for public health and to alert public authorities; to gather, analyse and interpret information on public health risks, the causes and evolution; to do all needed action necessary to fulfil its missions.

It is decentralised thanks to its regional offices.

All public organisations having detected a threat for public health have to refer to IVS.
3 The environmental surveillance institute (Institut de veille environnementale, IVE) (project)

It would have, in the field of environmental risks, the same role as the IVS, starting as a co-ordination function among existing research institutions working in this field.

4 French agency for safety of products for human health (Agence française de sécurité sanitaire des produits de santé – (AFSSAPS)

AFSSAPS, placed under the ministry of Health, has to assess risks using the epidemiological data produced by IVS. It provides expertise on medical products (including cosmetics) for human purposes to the minister of Health and is consulted on the preparation on legislative and regulatory texts. In addition, AFSSAPS has itself control and also regulatory powers regarding withdrawal of authorisation for drugs, medical products and devices applied to human health.

AFSSAPS is 800 persons strong (2/3 are scientific personnel), plus a network of 1000 external experts.

5 French agency for safety of food (Agence française de sécurité sanitaire des aliments – (AFSSA)

AFSSA, placed under the ministries of Health, Agriculture and Consumption (ministry of Economics and Finance), has to assess safety and nutritional risks of food, from raw products to the consumer, this including water, veterinary products, pesticides and fertilisers concerns. It is consulted on the preparation of legislative and regulatory texts on the official demands of the ministers. It then submits the question to its own scientific committees. The answer and comments of the later is integrated in the AFSSA final recommendation or advice. Every advice or recommendation is transmitted to the minister and made public. Contrarily to AFSSAPS, AFSSA has no regulatory powers.

AFSSA is 700 persons strong, plus a network of hundreds of external experts.

The watch, warning and control functions rest upon the DGCCRF (Direction générale du contrôle de la concurrence et de la répression des fraudes, ministry of economics and finance) and the DGAL (Direction générale de l’alimentation, ministry of agriculture), with its network of veterinary inspectors.

6 French agency for safety of the environment (Agence française de sécurité sanitaire de l’environnement – (AFSSE) (project)

The Law states that a feasibility study on the creation of such an agency should be prepared by the government and discussed by Parliament. AFSSE could have the same attribute as AFSSA.

In fact the Prime minister asked a report to two members of Parliament, which recommends creating both AFSSE and IVE (Aschieri – Grzegrzulka report, Nov. 1998). The agencies could be created by the end of this year.

They also recommend a formalised interministerial co-ordination on overall public health risks, the creation of a High level scientific council made of the chairmen of the various existing committees.
1.2.2 Other scientific expertise structures dealing with public health risks in government

7 Committee on prevention and precaution of the ministry of Environment
Established in 1996, it has a mission of assessing environmental risks and alerts the minister in charge of the environment. It is particularly concerned with the health risks of water, air, soil quality, as well as noise, biological and chemical substances; it is also concerned with ionising radiations.

8 Other scientific committees (with advisory or regulatory role)

Committees under the ministry of Health
Conseil Supérieur d’hygiène publique de France and its various committees

Committees under the ministry of the Environment:
Commission d’évaluation de l’écotoxicité des substances chimiques
Commission du Génie biomoléculaire (with ministry of agriculture)
Comité de bio-vigilance
Conseil national de l’air
Conseil national du bruit
Conseil supérieur des installations classées
### Table 1: Synoptic View of the Various Science-Governance Functions for Public Health Security

<table>
<thead>
<tr>
<th>Area Concerned Function</th>
<th>Food and Veterinary Products</th>
<th>Human Drugs and Medical Products</th>
<th>Environmental Exposure to Contaminants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organisation of Expertise</td>
<td>AFSSA 700 persons</td>
<td>AFSSAPS 800 persons</td>
<td>[AFSSE] Committee on prevention and precaution (min. of Env.) Committee on assessment of ecotoxicity of chemicals</td>
</tr>
<tr>
<td>Surveillance and Warning</td>
<td>Veterinary service (1300 persons) DGCCRF (4000 persons)</td>
<td>IVS (140 persons) Regional public health authorities</td>
<td>[IVE] regional public health authorities</td>
</tr>
<tr>
<td>Control and Regulatory Decision</td>
<td>DGAL (min. of Agric.) DGCCRF (4000 persons) (min. of Economics and Finance)</td>
<td>AFSSAPS under min. of Health</td>
<td>min. of Environment min. of Health min. of Industry</td>
</tr>
<tr>
<td>Public Research in Direct Support of Expertise and Regulation</td>
<td>AFFSA labs</td>
<td>IVS labs</td>
<td>INERIS INRS</td>
</tr>
<tr>
<td>Public Research Organisations</td>
<td>INRA (8600 persons, 2000 scientists) IFREMER</td>
<td>INSERM (4700 persons, 2000 scientists) Universities (medical research labs)</td>
<td>INSERM, CNRS</td>
</tr>
<tr>
<td>National Policy Advisory Councils</td>
<td>National Food Council</td>
<td>National Health Conference High committee on public health</td>
<td></td>
</tr>
</tbody>
</table>
Activities not included in this table:
- Nuclear industry (OPRI in charge of measurements for professional and environmental nuclear safety; IPSN in charge of expertise and related research)
- Aeronautics safety, ground transportation vehicles and systems and buildings,
- professional risks, which rest on a different expertise system.

Parliament has its own assessment institution (S&T assessment office – Office parlementaire d’évaluation des choix scientifiques et technologiques – OPECST).

OPECST, which was set up by Act n° 83-609 in 1983, following a unanimous vote of Parliament, aims, within the terms of the act, "to inform Parliament of scientific and technological options in order, specifically, to make its decisions clear." Regarding this, OPECST "collects information, launches study programmes and carries out assessments."

OPECST is a particular structure within Parliament: its members, who are nominated in order to guarantee a proportional representation of political groups, belong both to the National Assembly and to the Senate. It is composed of eight Members of the National Assembly and eight Senators.

It is customary for the chairman to be a member of either assembly, alternately, for a period of three years. Internal rules stipulate that the vice-chairman shall belong to the other assembly. Only Members of Parliament may refer matters to OPECST.

Matters can be referred to OPECST by the board of either assembly (at the request of the chairman of a political group, or on the initiative of sixty Members of the National Assembly or forty Senators), or by a special or permanent committee.

Until now, the topics dealt with have belonged to four main subjects: energy, environment, new technologies and sciences of life (bioethics). Its advices are made public.

OPECST acts as an intermediary between the political world and the world of research. In order to carry out its task, OPECST is assisted by a Scientific Committee (composed with fifteen leading scientists) reflecting the diversity of scientific and technological disciplines in
its composition. The scientific committee doesn’t participate by itself to the expertise. OPECST calls for external experts who assist it or are consulted during the inquiries.

The Law ‘on the respect of the human body’ (29 July 1994) mentions the obligation of its periodical assessment by OPECST.

1.2.3 Ad-hoc expert advice

This relates to the set up of ad-hoc committees to address an issue: the National council on AIDS, the committee on prions (later integrated in the AFSSA system) are examples of them.

Another point to be considered here is the organisation of research institutes themselves:
- internal committees to address new issues, such as the Committee of ethics and precaution of INRA,
- the ‘Collective expertise ‘procedure set up by INSERM, by which the institute produces a scientific state of the knowledge on an issue at the request of a ministry or public body.

1.2.4 informal expert advice and the direct relationships between scientists and government

Under this category one finds the scientists acting in ministers staff (‘cabinet’), but also the scientific services of the ministry of research. It must also be said that the general directions of the public research organisations are consulted by ministers or their staff.

By definition, such informal relationships are difficult to characterise and assess.

1.3 Assessment of the evolution of the science – governance issues and concepts in France

1.3.1 The three models of the science – governance relationships

To assess evolutions, we define three models of the science – governance relationships.

- **model 1** - the ‘Scientific truth’ model
  A scientist or a committee makes statements in the name of ‘science’. This is the classical mode of relationship between science and society, which has been dominant until the 70s, but still present in many ways. Leads to the unacceptable dilemma of science governing society (‘despote éclairé’) versus society having to reject science and its arrogance as the only possibility for democratic government.

- **model 2** - the ‘Prince’s counsel’ model
  A scientist or a committee named by the minister provides advice on a confidential basis. This is another classical model, which is the basis of the technocratic mode of government. The recent crisis leading to a loss of confidence in both science and political system are a direct consequence of the fundamental limitations of this model.

- **model 3** - the ‘socially embedded science’ model
  Scientific experts, their linkages to the issue having been disclosed, argue their opinion on the issue at stake in a public way; there is no recommendation as such by the committee.
The model 3 is based on K. Popper’s notion of science as an enterprise of permanent refutation (falsification) of existing theories, supposed never definitively established: the controversy is the essence of science. It states that all scientific expertises are necessarily partially subjective, thus non-independent.

This model goes hand in hand with the Precautionary principle, since it is precisely a guide for action in a context of lack of certified knowledge, which is the general case here. It says that, in certain circumstances, action can be based on mere hypothesis of the scientists. The role of the decision-maker is to assess whether such ‘certain circumstances’ are there.

This model is gaining weight, but its translation in functioning institutional processes is still in experimentation.

### 1.3.2 The fundamental evolution: a move towards model 3

Models 1 and 2 are largely considered inadequate for handling the science – governance issues in the actual context. The reasons are their demonstrated inability to help produce acceptable decisions, to prevent catastrophes and to protect decision-makers from the tribunals.

The move towards model 3 can be seen as a move by the political system both to protect the citizens and to protect itself. The solution is seen as one of transparency, explicitation and clarification of roles and steps.

### 1.3.3 A major consequence: the rise of the issues of procedures and quality assessment for scientific expertise

In model 3 the key points are the procedure of expertise and its formalisation.

In this respect, many aspect of the expertise agencies AFSSA and AFSSAPS are worth mentioning as typical of such evolutions:
- no scientist from industry can be named in the experts group and a declaration of no personal interest on the matters discussed is to be signed by every expert;
- the public research institutions provide the agencies with some sort of assessment of the scientific standing of the researchers applying to be experts with the agencies; but the final decision rests with the agencies.
- analysis on how to protect and integrate dissenting opinions in the expertise process is being made,
- all advices are published on the Internet,
- no cost-benefit is performed in the agencies in order to keep strictly in the scientific debate, but, in turn, systematic transmission of such scientific advice to ‘socio-economic’ bodies is under consideration: the scientific arena (scientific committee) would thus feed into socio-economic arena (socio-economic bodies) which then expresses for the decision maker scenarios of possible decisions and their outcomes,
- needed research programmes are often presented as a result of the advice, in the philosophy of the Precautionary principle,
- analysis of the reliability of the scientific sources is made,
- discussions are under way to build a quality standard for expertise production.
1.3.4 A still on-going evolution: the ambiguities of the present situation

1  ambiguities linked to the procedures of expertise

This is not to say there are neither ambiguities nor contradictions in the functioning of such expertise processes. It is for example puzzling to see that in some cases, the scientific groups are asked to produce not only advice, but also recommendations to the decision maker; another aspect is the fact that the agency recommendations which include the comments and the advices of expert groups are signed by the director of AFSSA, which can bring an element of ambiguity.

2  ambiguities linked to the functions of the Agencies

The expertise production agencies do have, to various extend, both research functions and regulatory functions. There are reasons to believe this addition of functions puts the quality of the expertise process at risk.

3  limitations linked to the insufficient feedback of research needs towards the public research institutions

The whole Precautionary principle rests on the assumption that steps in decision making go in parallel with the gaining of new knowledge. This requires a linkage with the strategy of the public research institutions, which is so far not formalise (no formal committee does exist).
2 French case study on the use of stem cells from human embryos

2.1 Legislative framework

In 1994, were adopted two highly important laws, known as “bio-ethics laws”. They meant to set the rules for all medical activities related to:

1. gift and use of elements and products from human body,
2. medically helped procreation and to prenatal diagnosis.

Although it was not as clear as today to which extent embryonic stem cells could be useful for therapeutic improvements, this issue is obviously connected to both objects of these laws. At first sight, one could then imagine that decision makers already made their job.

Still, a very important point is that these laws were designed to be reconsidered every five years, in order to meet the evolving requirements of social demand (including that of researchers). Although they should have been re-discussed last year, this has been not planned yet.

Another important point is that these laws are not equally explicit on the whole range of situations where medical researchers may use embryonic stem cells. Current texts are ambiguous and, according to some speakers, some laboratories had an abusive interpretation of law, claiming that what was not explicitly forbidden might then be allowed.

Therefore, the whole debate on this issue has to be considered in the perspective of the planned revision of the laws. Some very strong conflicts of interests occur here: some researchers want the therapeutic assets to be fully weighted while decision makers wish not to miss any part of the question again (what about international research co-operations? What about results of abortions?…).

2.2 Major consultations for expertise to help decision-making process.

As the debate is growing, several institutional actors decided to deal with this issue, without any clear co-ordination between their respective initiatives. Then, we will present these actors by order of importance, as we do not see any other relevant plan for this brief synthesis.

2.2.1 The “Conseil d’Etat” (CE)

The Council of State (Conseil d’état, CE) is an extremely important institution in the French Constitution, since it is, among other tasks, in charge of checking the juridical acceptability of any new law voted by the Parliament, defining itself as an adviser of the Government. In other words, although it is not a scientific advisory body per se, it was asked to think about this issue, with the help of many external experts’ advice, and its statements are extremely influent both in terms of interpretation of current laws and suggestions of new ones.

Indeed; in 1999, responding to the request of the Prime Minister, the studies section of the CE published a report in the perspective of the renewal of the bio-ethics laws. The writing of such a report has the particularity to rely on the expertise of external personalities (many biologists
and doctors but also representatives of religious and philosophic trends…). In this report, it is suggested, in particular:

1. to explicitly forbid any attempt of reproductive human cloning;
2. to allow, under very strict regulations, research activities on non-desired frozen in-vitro embryos

But the report also acknowledges that some very important related questions remain open (should this authorisation apply to research aimed at improving the results of procreation assistance techniques?) and suggests any decision to be experimental, for a period of five years.

It should be noted that the CE report, relying on the pluralist reflection that was set up, goes as far as proposing some draft texts for the new law.

2.2.2 The “Office Parlementaire d’Evaluation des Choix Scientifiques et Technologiques” (OPECST)

The S&T assessment office of French parliament (Office parlementaire d'évaluation des choix scientifiques et technologiques, OPECST) is a kind of advisory commission of the Parliament, composed of MPs only (but assisted by a scientific council), which they decided to create in order to be able to “independently consider Government’s decisions” on science or technology matters. Its reports are explicitly aimed at easing the work and judgement of MPs and therefore need to be “of immediate use for parliamentary work or budget discussion”. Of course, the reflection of OPECST relies on numerous interviews, notably with scientists, some of which may be open to the press.

Once the study completed, the OPECST internally decides whether the report can be published and thus available to a large audience. Here, both relevant reports (1999, about the application of 1994 bio-ethics laws and 2000, about cloning, cellular therapy and use of embryonic cells) were published. It must be known that the former was already planned by the 1994 laws themselves, as the OPECST is in charge of their periodic assessment before renewal. They decided afterwards to have further reflections and analyses, which led to the latter report.

Although such reports mean to help MPs decisions (political families’ shares are respected in the composition of the OPECST), they also mean to stick to their advisory role

2.2.3 The “Comité Consultatif National d’Ethique” (CCNE)

The National consultative committee of ethics on health and life sciences (Comité consultatif national d’éthique, CCNE) was established by a decree in 1983 and enacted in the 1994 bio-ethics laws. It is an independent body linked to ministers of research and health, and its role is strictly advisory. Its 40 members are eminent personalities named either for their ethics or scientific competencies. As a very independent body, it may be questioned by parliamentary assemblies, members of government and a large range of public institutions; it publishes its reports, notably via press conferences and on the web.
Compared to CE, this body has a quite weaker position, but it benefits from the public’s confidence and therefore its opinion may be of some political importance. Although its mission is specifically ethics oriented, its composition allows it to claim to take scientific and juridical considerations into account.

In 1998, responding to the request of the President of Republic, it provided an advice on the re-examination of bio-ethical laws, considering favourably the authorisation, under strict supervision, of research activities on non-desired frozen embryos. On the other hand, it strongly maintained its objection on reproductive human cloning, as well as on the production of new embryos for research purposes, whatever the method.

2.2.4 Other bodies

Other institutions did take part to the discussion; although they are not directly linked with decisions makers, their audience may have helped their advice to be taken into account. In 1998, the Academy of Medicine published a report in favour of research on embryos in order to improve the efficiency of medically assisted procreation techniques. In 1999, the National Consultative Commission on Human Rights declared it was favourable to research on non desired frozen embryos, under strict supervision. So did the National Union of Family Associations, in the same year.

2.3. Other internal initiatives to contribute to the debate

We found three public institutions which were concerned with this issue and which can contribute to the linkage between expertise and decision. It goes without saying that the internal bodies or taskforces we found have very few or no impact at all beyond the boundaries of their institution.

The first one is the INSERM, the French institute for health and medical research (Institut national de la santé et de la recherche médicale). An internal task group was very recently set up in order to develop and promote the consideration of ethical aspects of research projects. This can be regarded as a quite important step, all the more as research laboratories (not necessarily making part of INSERM) had been severely judged as beyond moral and sometimes legal limits before 1994 laws were passed; some people have a similar assumption today.

The second one is the Ministry of Research, inside which was created the “Comité de Coordination des Sciences du vivant” (CCSV). Still, as far as we know, the CCSV never addressed this issue of human embryos stem cells so far.

Lastly, Health Ministry is the most important here, for two reasons: it is preparing the proposals for a new law and its is in charge of setting up what good practices are in all medical activities. An important body here is the “Commission Nationale de Médecine et de Biologie de la Reproduction et du Diagnostic Prénatal” (CNMBRDP), currently in charge of licensing all procreation assistance establishments but which could be significantly reorganised in coming months.

Beside, according to the projects of Health Ministry, a new institution could be created in a near future, to become the competent body to authorise any research project on human embryos stem cells. Although its mission would rather be to check that research projects comply with then-existing law, it could provide feedback experimented advice to policy makers.
<table>
<thead>
<tr>
<th>What is the juridical background?</th>
<th>OPECST</th>
<th>CCNE</th>
<th>CE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994 bio-ethics laws</td>
<td>Permanent</td>
<td>Permanent</td>
<td>Permanent</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Permanent or ad-hoc?</th>
<th>Permanent</th>
<th>Permanent</th>
<th>Permanent</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>What advice structure are there concerning this issue?</th>
<th>OPECST</th>
<th>CCNE</th>
<th>CE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permanent</td>
<td>Permanent</td>
<td>Permanent</td>
<td>Permanent</td>
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<tr>
<td>Permanent</td>
<td>Permanent</td>
<td>Permanent</td>
<td>Permanent</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Formal or informal advice?</th>
<th>Formal</th>
<th>Formal</th>
<th>Formal</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Who is being advised?</th>
<th>Parliament</th>
<th>Government, parliament, civil society and the President of Republic in particular</th>
<th>Government and the President of Republic</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Risk assessment / management?</th>
<th>Both</th>
<th>Assessment</th>
<th>Both</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Who makes up these bodies?</th>
<th>8 deputies and 8 senators (plus a scientific board)</th>
<th>Presidents, 5 personalities from main spiritual families, 19 “competent” personalities, 15 research personalities</th>
<th>Mainly magistrates, plus some French or foreign personalities</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>How are they selected?</th>
<th>Named according to the sharing of political families</th>
<th>The first 7 are named by the President of Republic; others named by various institutions (ministries…)</th>
<th>Magistrates from CE mostly come from ENA school but some are named by Government</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Are they providing strictly scientific or broader advice?</th>
<th>Broader: recommendations must “be of direct use for Parliamentary work”</th>
<th>Obviously a broader advice</th>
<th>The specificity of CE is to deal with juridical and administrative acceptability of new laws</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Do the type of structures used vary depending on the state of the issue?</th>
<th>OPECST involved as soon as MPs feel like needing a “customised” scientific or technical expertise</th>
<th>Only involved when it comes to ethical matters (not in the EMF case for instance)</th>
<th>Specially focuses on the problems of how to write a relevant law and how to comply with it.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Preliminary scientific state of the art?</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Do they commission research?</th>
<th>Not in this case, though it is possible</th>
<th>I do not think so.</th>
<th>I do not think so.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Are experts called to give evidence?</th>
<th>Yes: experts auditions are the main investigation tool. Some may be open to the Press.</th>
<th>If necessary</th>
<th>Yes</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Does the advisory body just give their personal opinions</th>
<th>No</th>
<th>Somehow yes, since the CCNE is made up of personalities chose on purpose</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>How do they deal with uncertainty?</th>
<th>They document the current debate</th>
<th>CCNE regularly re-launches the discussion on matters it regards as important</th>
<th>The report is public.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>How transparent are their operations?</th>
<th>The Office first examines whether their report can be published. If so, it is quite easily available.</th>
<th>Seances are not public but recommendations are widely published and available on line.</th>
<th>The report is public.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>How do they select subjects they look at?</th>
<th>In general: commissioned by the heads of both assemblies, 60 deputies, 40 senators, or parliamentary commissions</th>
<th>They may decide by themselves or be commissioned by MPs, ministers, public institutions…</th>
<th>Most of studies’ subjects are chosen by the Prime Minister. This was the case here.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>How independently do the advisor operate?</th>
<th>The report is aimed at MPs, so that they can “independently consider Government decisions”</th>
<th>Largely independent and strictly consultative body</th>
<th>An independent advice with major consequences on Government decisions</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Are advisers asked to comment on policy options?</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>How is uncertainty dealt with?</th>
<th>Depending on each MP’s decision</th>
<th>Rather ‘precautionary principle’ oriented</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Are there clear signs of policy impacts?</th>
<th>The political decision may be quite similar to their respective proposals or advice, but we are still waiting for it…</th>
<th></th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Do different policy actors interpret the advice differently?</th>
<th>Yes</th>
<th>Seldom in practice</th>
<th>Quite unlikely</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>What is the position of scientific advice with regards to other influences on this issue?</th>
<th>A major one but not the only one to be considered</th>
<th>One among others, not overshadowed at all</th>
<th>A rather important one, among others</th>
</tr>
</thead>
</table>
3 French case study on scientific advice structure for the effects of electromagnetic fields on human health

This chapter is divided into two parts. The first one develops the effects of power lines and low frequency electromagnetic fields on health presenting a brief historical overview of the French debates.

The second describes the advisory structure which has been recently created for the expertise of the effects of mobile phones on health.

This study observes a difference between the way of expertise before the law on “the reinforcement of public health surveillance and of the control of the safety of the products concerning humans’” passed on July 1998 and the way after.

3.1 Scientific expertise for the effects of high voltage electromagnetic fields on human health

3.1.1 First Step: INSERM collective expertise

The first scientific expertise, still taken in consideration, has been done in 1992 by INSERM, the French national institute for health and medical research. This expertise was ordered and funded by the French national electricity company, EDF, and was established following the methods later developed by INSERM, the “collective expertise”. This consists in producing a state of the arts in the field with contradictory debates by a panel of specialists and publication of the report.

INSERM is an autonomous institution created in 1962. Its missions and statutes have been redefined by the law of “orientation and planning of research and development” passed on July 1982 (law 82-610 published on 15 July 1982). Since 1982, INSERM has had the statutes of a public scientific and technological organisation, jointly overseen by the French ministries of health and research.

Its chairman and general director are named by the Cabinet on the proposal of the ministries of research and of health. Members of INSERM scientific committees and scientific council are partly elected and partly named by the ministries of health and research.

In 1992, INSERM created the process of “collective expertise” as a part of the institute's public health vocation. Collective expertise consists in providing an update on scientific and medical knowledge of a precise subject. In response to a request from the public or private sector, INSERM gathers a multidisciplinary group composed of scientific and medical experts, who review the relevant world literature and write a summary report. Recommendations are then made to enable the institution that requested the report to make fully informed decisions.

Experts of each collective expertise are named in an independent way by the general director of INSERM on the basis of their skills and knowledge (eventually identified and confirmed by bibliometric analyses).
The independence of the collective expertise is guaranteed because 1) of the autonomy of INSERM and 2) of the exhaustive bibliographic analysis on which the methodology is based.

Since 1993, the whole process has been organised by a special Unit of “collective expertise” which assumes the scientific secretary.

The expertise demanded by EDF on the effects of high voltage electromagnetic fields was the first example of collective expertise. The group of experts performed a analysis of all the epidemiological studies on the field and the collective expertise concluded that 1) in the state of arts, a possible effect of electromagnetic fields on leukaemia can be admitted, 2) the risk must be confirmed by an epidemiological meta analysis.

A lot of publicity has been generated by the INSERM report which has been used for many years as a reference for decision makers.

3.1.2 Second Step: Formal advises of the high council for public hygiene in France
In 1993, the High Council for Public Hygiene in France (Conseil supérieur d’hygiène publique de France, CSHPF) reported its first advice on this topic.

The CSHPF is an advisory scientific and technical committee set under the auspices of the ministry in charge of health. It deals with the scientific expertise in the fields of public health risk assessment. Its responsibilities decreased since the creation of the French agency for safety of food (AFSSA) in 1998.

The first CSHPF advice considered that in regards to the state of the arts, the effect of electromagnetic fields on health has not been sufficiently established to justify specific measures. A working group was constituted for follow up and continuous analysis of scientific publications and data. This group was constituted with 8 experts including the representative of the General Direction of Health (Direction générale de la santé, DGS) of the ministry of health.

Few years later, in 1996, the CSHPF reported its second and last advice on the basis of the actualisation of data and recommendations of the working group. In this report, the CSHPF considered that no new scientific evidence could modify its previous advice on high voltage electromagnetic fields and that a continuous evaluation of the risk has to be conducted. More precisely, it indicated that recent international publications (e.g. by Doll) have not demonstrated the links between some cancers (eg brain tumors) and electromagnetic field for professionals. In the case of children leukaemia, the conclusion was that the recent scientific publications were still controversial (Linet et al, Feychting et al, Verkasalo et al) but did not allow to conclude on the risks of power lines and domestic electromagnetic fields.

Furthermore, the report underlined the possibility of interaction of electromagnetic fields with biomedical advises even if the effect on health had not been clearly demonstrated.

Since 1997, the ministries of health and of environment had reported on the basis of the CSHPF advice.

Consumer associations repeatedly discussed the CSHPF report because the composition of the working group: the member of the CSHPF in charge of the epidemiological report was the deputy director of the EDF medical study unit. Moreover, the group itself included the
director of the EDF medical unit, and one counsellor of the commissioner of nuclear energy (CEA).

The last event consisted in the organisation of a conference under the auspices of the French parliamentary (March 1999) where experts exposed their view. This led to the proposal of an amendment for the classification of power lines which was adopted by the national assembly and rejected by the senate in May 2000.

Now the public debate on the risk of very low frequency electromagnetic fields on human health is still opened but not really active in France. The General Direction of Health (DGS) of the Ministry of health considers that it does not deserve further study.

To conclude, it must be noted the important weight of 1) the independent (even if funded by the concerned company) expertise done by INSERM, 2) the scientific evidence given by international publications. The debates illustrate 1) the confusion existing between experts, decision makers, and stakeholders 2) the difficulty of relationship between expertise and decision which contributes later in France to the establishment of the recent law on public health watch and control of security of products concerning humans.

3.2 The effects of mobile phone on health.

The organisation of the scientific expertise on this fields is different from the previous one. The context of the French law on ‘the reinforcement of public health surveillance and of the control of the safety of the products concerning humans’ has totally changed the concept of the expertise.

One must consider that the law on ‘the reinforcement of public health surveillance and of the control of the safety of the products concerning humans’ passed on 1st July 1998 has organised the surveillance and expertise functions for government and has separated the scientific expertise from the decision.

3.2.1 Role of the General direction of health /Ministry of health

The risk of mobile phone on human health is dealt by and under the control of the general direction of Health (DGS) of the Ministry of health. DGS has been recently reorganised for better adaptation of its missions in regards to the law on health watch and security.

The unit for scientific support of DGS is in charge of scientific expertise and considers that any risk must be taken in charge in a two-steps process:
1. The first one is the step of risk assessment. The role of the scientific expertise is to establish the diagnosis by a state of the arts. For this step, the national institute for public health surveillance (Institut de veille sanitaire, IVS) services must be called upon.
2. The second one is the step of risk management which directly addresses to the policy makers.

\[\text{one of the pillars of the law on the reinforcement of public health surveillance and of the control of the safety of the products concerning humans} \]
3.2.2 Risk assessment for mobile phones effects on human health
In the case of mobile phone, it was assumed that the first step has already been done, e.g. by the UK independent Expert Group on Mobile Phones which published its report on May 11, 2000. Therefore, the IVS services was not called upon by DGS which decided to engage the second step.

3.2.3 Expertise for risk management of mobile phone effects on human health
Considering the previous reports which suggested caution, especially in regards to children, DGS engaged itself in a process of risk management.

For this purpose, it constituted a committee of experts for scientific advice on risk management.

The characteristics of the committee are the following:

1) It must answer to precise questions.
The main question is relevant to the assessment of the risks of mobile phone for human health in consideration with the conclusions of previous reports (“do the conclusions of recent reports justify a modification of the French legislative rules ?”). Therefore, it implies that the committee:
   • has a critical analysis of the various reports, and specially the British one, and performs a “meta-analysis” of them
   • evaluates the consequences in terms of risks and protection for public health
   • recommends measures for surveys
   • defines the needs for related research

2) The committee will have a short-term existence (from June to December 2000)

3) The contractor is the General Director of the Health, but no the Ministry.
   The independence from DGS is guaranteed : a light administrative support is offered by DGS (for example for the management of the meetings) but no DGS representative assists to the meetings. The committee is free to organise the methods and the conditions of its expertise.

4) The committee has been created in the following ways:

The General Director of Health has first named the president. The president is not himself a specialist of the field but he is the garant of the expertise methodology.
After the President’s advice, 5 members have been named by DGS. They represent various disciplines: biology, toxicology, epidemiology, biophysics…
Each member has to declare his possible link of interest with industry. The declaration is made public but does not exclude the member from the committee.
Experts are not funded or remunerated for their participation to the expertise.

The committee began to work in June 2000. During the first three months, it defined the method for expertise. This method was made public. It included the list of the reports to be examined and the definition of criteria to evaluate the quality of the reports (established on good practices of expertise inspired from international consensus, e.g. : Evaluation and use of

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5 This point appears controversial during the interviews. It seems that one representative of DGS assists to the meetings.
epidemiological evidence for environmental health risk assessment”, WHO-Europe, Copenhagen, 2000). The committee will analyse the very recent scientific publications in the field.

The process will also include auditions of representatives of “official” science and of “marginal” science, auditions of representatives of opinion leaders and auditions of representatives of consumer associations.

The committee will produce a final report to be made publicly available.

DGS indicated to the committee that it will take the responsibility to follow or not its recommendations. Finally, DGS will take its own decision.

To conclude, the whole process in this case is an example of the application of the French law on health watch and security with the main distinction of two steps: scientific expertise and decision. Here, the scientific expertise step has been divided in two distinct parts: for risk assessment (already done by expert groups outside France) and for risk management. This scheme would be the prototype of the future scientific expertise activities of the DGS.
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<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Background to the case study</strong></td>
<td>PUBLIC HEALTH CODE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Permanent or ad-hoc?</td>
<td>Ad hoc and short term (less than one year)</td>
<td>Permanent; working sub-group for a few-years period</td>
<td>Ad hoc, and short term (6 months)</td>
</tr>
<tr>
<td>Formal or informal</td>
<td>Written decision of the INSERM DG</td>
<td>Formal (defined by the health public code)</td>
<td>Written decision of the DG of DGS</td>
</tr>
<tr>
<td>Who is being advised?</td>
<td>The requestor (EDF)</td>
<td>General direction of Health, Ministry of health</td>
<td>General direction of Health, Ministry of health</td>
</tr>
<tr>
<td>Risk assessment / management expertise?</td>
<td>Risk assessment</td>
<td>Both</td>
<td>Risk management</td>
</tr>
<tr>
<td>Who makes up these bodies?</td>
<td>Around 10 scientific experts</td>
<td>Working group: 7 experts</td>
<td>6 scientific experts</td>
</tr>
<tr>
<td>Are they providing strictly scientific advice?</td>
<td>Not only: evaluation of public health consequences</td>
<td>Not only, e.g. public health consequences</td>
<td>Not only, e.g. public health consequences</td>
</tr>
<tr>
<td>How are they selected?</td>
<td>On scientific (scientific publications) and medical competencies</td>
<td>On scientific and medical competencies, and on professional positions</td>
<td>Scientific and medical competencies</td>
</tr>
<tr>
<td>Preliminary scientific state of the art?</td>
<td>Yes, complete using bibliometric data base)</td>
<td>Updating of previous state of arts</td>
<td>Synthesis of existing reports</td>
</tr>
<tr>
<td>Do they commision research?</td>
<td>Yes (epidemiological studies ++++)</td>
<td>Yes (epidemiological studies ++++)</td>
<td>They have the mission to do</td>
</tr>
<tr>
<td>Are experts called to give evidence?</td>
<td>Only based on scientific publications and opinion of the expert body</td>
<td>Only based on scientific publications and opinion of the expert body</td>
<td>Yes, auditions of scientific experts</td>
</tr>
<tr>
<td>Does the advisory body just give their opinion</td>
<td>yes</td>
<td>yes</td>
<td>Yes but interviews of stakeholders</td>
</tr>
<tr>
<td>How do they deal with uncertainty?</td>
<td>By documenting the debate</td>
<td>By documenting the debate, and regular updating</td>
<td>By documenting the debate, by auditions of the different stakeholders</td>
</tr>
<tr>
<td>How transparent are their operations?</td>
<td>Publication of the report and large dissemination</td>
<td>Seances are not public but recommendations and reports are available (on special demands)</td>
<td>Publication of the report</td>
</tr>
<tr>
<td>How do they select subjects they look at?</td>
<td>With preliminary discussions with the requestor</td>
<td>They may decide by themselves or be commissioned by DGS</td>
<td>Commissioned by DGS, but possible enlargement</td>
</tr>
<tr>
<td>How independently do the advisor operate?</td>
<td>Fully independently</td>
<td>consultative body, but not fully independent (participation of representatives of DGS, of national electricity company . . .)</td>
<td>Probably fully independent</td>
</tr>
<tr>
<td>Are advisers asked to comment on policy options?</td>
<td>No (only scientific debate)</td>
<td>Not really</td>
<td>Yes (auditions of &quot;opinion leaders&quot;)</td>
</tr>
<tr>
<td><strong>4. Interaction between advisory groups and decision makers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clear signs of policy impacts</td>
<td>Yes, Citation of the report</td>
<td>Yes (citation of the report) (too early)</td>
<td></td>
</tr>
<tr>
<td>Other influences</td>
<td>Not really taken into consideration</td>
<td>Not really taken into consideration</td>
<td>Not really taken into consideration; only concerns on health effects and public protection.</td>
</tr>
<tr>
<td>Different interpretation of policy actors</td>
<td>Probably yes Because of uncertainty</td>
<td>Probably yes Because of uncertainty</td>
<td>(too early to answer)</td>
</tr>
</tbody>
</table>

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6 EMF : electromagnetic field
7 General direction of Health
8 National electricity company
Sources:


Groupe d’experts sur les téléphones mobiles, leurs stations de base et la santé (2000) Rapport d’étape au Directeur général de la santé, 16 octobre


Interviews:

Mrs Elisabeth GOMARD – INSERM, head of the mission “animation of biological and medical research”

Mrs Marie-Anne BACH – INSERM at the mission “animation of biological and medical research” and Ministry of health, at the General Directorate of Health

Mrs Anne BISAGNI – INSERM, head of the mission “animation of clinic and therapeutic research”

Mrs Véronique FOURNIER – cabinet of Health Minister, in charge of the revision of bioethics laws

Mr François HIRSCH – INSERM, head of the mission “Quality of non clinic research” in the Service “Ethics and quality of research programmes”; at the origin of the creation of the internal task group mentioned in the report

Pr William DAB – director of the Unit of the scientific support of the General direction of health (ministry of health), former deputy director of EDF medical Unit, former member of CSHPF working group

Dr Gilles DIXSAULT – chief of the Unit on natural and food risks, General direction of Health, Ministry of Health, former member of CSHPF working group

Pr Gérard BREARD – scientific director of INSERM (in charge of public health)

Dr Catherine COURVALIN – former responsible of the program “Environment and health” at the ministry of environment

Dr Ghislaine FILLIATREAU – chief of the scientific survey unit at the ministry of research
**SCIENCE AND GOVERNANCE:**
*describing and typifying the scientific advice structure in the policy making process*
- Two German Case-Studies -

This report has been prepared for the ESTO study SCIENCE AND GOVERNANCE: describing and typifying the scientific advice structure in the policy making process – a multinational study.
It is concerned with the way in which German government receives and demands scientific advice – as a basis for regulative decisions that rely in part on it.

The report has been conducted as a culmination of work carried out by VDI Technology Centre between September and November 2000. VDI-Technology Centre takes sole responsibility for the content of this report and gratefully acknowledges the valuable non-departmental contributions.

The study took part in two phases: Evidence on the general German „Science&Governance System“ was collected in the first phase (including an inventory of think tanks and an illustration of the legislative proceedings structure). In the second phase two distinct case studies (on how scientific advice is utilized by government) have been prepared: one example representing an exante analysis on the „human stem“ cell discussion, another example representing an expost analysis on the „electrosmog“ debate.

Both case studies consist of a chronology, a literature review on the respective case, a representation of the public debate as mirrored/displayed by the media, an inventory of relevant networks, stakeholders, and regulations; and a summary of the outcome of the interviews with policy-makers concerning the role of Science for Governmental action (National R&D and Funding Programmes, Legislation and legal aspects).

Since this country report is only part of a bigger comparetative study, it refrains from distinct conclusions and recommendations for improving the quality of scientific advice received by government and the way that it is used in policy development.
Part I: A general overview of scientific advice in Germany

The German system of science and research is determined by federalism, with a formal and informal communication network between federal and state level. There is a division of competencies between the federal Government on the one hand and the Länder on the other hand. The legislation and administration regarding education and science are implemented by the individual Länder themselves. The Ministries on the federal level are relatively independent actors, responsible for their own resort and concentrated on finding solutions for particular problems within their issue area. This 'department principle' is involved to a great extent in the preparatory drafting of regulation within numerous working groups and in the implementation.

The Ministers and State Secretaries are active within the decision-making process. The autonomy of the Ministries is strengthened by the fact that in practice the departments are distributed between the different parties of the ruling coalition government. This autonomy has developed a governance approach within each department to solve problems in close cooperation with the committees of the Parliament, the Bundesrat and all relevant interest groups concerned (see below). These networks are trying to find an optimum (concerning their interests as well as the core of the problem) solution which should be based on as much expertise as possible (scientifically relevant 'issue-networks'). Their established co-operation with different societal and scientific actors and representatives of interests provide the basis for issue-oriented problem-solving which is based on the expertise and mutual trust of the partners.

Sources of Scientific Advice

In Germany the major (official) partner and mediator in the dialogue between government, science, trade and industry are the so called Projektträger, the project management agencies of the various Federal Ministries. On behalf of their respective Ministry they are responsible for and in charge of preparing publicly funded scientific programmes, their implementation and administration. Their responsibilities include technical and administrative assistance through all phases of a project: national and international project partner brokerage; support during the initiation and realisation of a project, assistance with applications for government funding; dissemination of project results (technology transfer); and organisation and management of the exchange of experience. They mostly act as a National Contact Point within the EU Framework Programmes. (Database of support programmes: [http://www.bmwi.de/](http://www.bmwi.de/))

The most famous German organisations for research promotion are the Deutsche Forschungsgemeinschaft and societies that are running research institutes, such as the Max-Planck-Gesellschaft, the Hermann-von-Helmholtz-Gesellschaft, the Deutscher Forschungszentren, the Wissenschaftsgemeinschaft Gottfried Wilhelm Leibniz and the

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1 For a detailed description see [http://eng.bundesregierung.de/frameset/index.jsp](http://eng.bundesregierung.de/frameset/index.jsp)
2 Contact: Deutsche Forschungsgemeinschaft e.V., Kennedyallee 40, 53175 Bonn, Internet: [http://www.dfg-bonn.de](http://www.dfg-bonn.de)
3 Contact: Max-Planck-Gesellschaft zur Förderung der Wissenschaft e.V., Hofgartenstraße 2, 80539 München, Internet: [http://www.mpg.de/english](http://www.mpg.de/english)
4 Contact: Helmholtz-Gemeinschaft Deutscher Forschungseinrichtungen, Ahrstraße 45, 53175 Bonn. For a list of Helmholtz-Centres go to: [http://www.helmholtz.de](http://www.helmholtz.de)
5 Contact: Wissenschaftsgemeinschaft Gottfried Wilhelm Leibniz, Ahrstraße 45, 53175 Bonn. For a list of institutes of the WGL go to: [http://www.wgl.de/](http://www.wgl.de/)
Fraunhofer Gesellschaft. Among their tasks is the expansion and establishment of universities.

The Wissenschaftsrat (Scientific Council) has been established by the Federal Government and the federal Länder as official scientific advisory board. It does not offer direct research promotion, but gives recommendations concerning the contents and structure of science and research, as well as the development of universities, research and the establishment of universities.

Various think tanks provide governmental and non-state actors with ideas and policy research from outside the bureaucracy. Party foundations, for instance, are a mixture of think tanks, do-tanks and advance teams for their respective parties. Many German think tanks are affiliated with universities or operate in a semi-academic environment like the Max Planck Institute for the Study of Societies.

**Selection of Advisors**

The parallels to the EU governance approach are obvious: like Germany, the EU is based on multi-tiered governance regimes as just described. And for both, the EU and Germany, consultative bargaining and consensual decision-making procedures are characteristic of their governance arrangements. The consensual character of German policy-making is demonstrated by the permanent endeavour to balance opinions, to equalize divergent powers, to avoid isolated leadership situations and to present multilateral (scientific) input and expertise.

Within the essential conditions that have shaped the development of West German federalism until today, joint decision-making and interlocking politics (Politikverflechtung) between Federal Government and Länder have developed which characterises the German federalism and the joint decision-making process as a kind of co-operative problem-solving.

German political culture and policymaking have been shaped by coalition-building, corporatist structures of interest mediation, interlocking federalism, and consensus orientation on the basic tenets of the German "social state." Moreover, "non-ideological pragmatism" can also be attributed to an exceptionally strong scholarly disposition (Wissenschaftlichkeit).

None of our German scientific actors dominate the German S&T policy arena - there is no obvious centre of political power. All the actors are simultaneously - and most of them indeed primarily - members of their "home system": they belong to the science system, the industrial system or the political system (in a narrow sense).

The way the actors see themselves in the S&T policy arena is clearly a product of the orientations and interests of their systems of origin. The S&T policy arena as such has not yet become a deeply rooted, permanent institution (with exclusive, auto-referential codes), rather it exists as an intermediary hybrid governance structure in endangered balance.

This immediately runs into the question of whether or not science itself is political. The creation of `scientific evidence´ and its diffusion are intangible activities which are difficult to

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6 Contact: Fraunhofer-Gesellschaft; Leonrodstraße 54, D-80636 München, Internet: http://www.fhg.de/english.html
define. They are definitely not measurable in terms of what we normally think of as statistical variables.
Part II: The German Governance of the „Electrosmog“ debate

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In the following it is being retrospectively attempted to characterise the significant milestones of the interaction between politics and science in Germany with the example of “electrosmog”. Electromagnetic fields (electrosmog) develop when electrical power flows but nature also brings a natural strain with it. Through the increasing electrification of our everyday lives (mobile phones etc.) electromagnetic fields with more or less ubiquity veritably exist.
Throughout the broadness of the theme, the following view is focussed on the Federal Ministry for Environment, Protection of Nature and Reactor Safety (BMU) which has been responsible up until now for the most important electrosmog ordinance (26. BlmSchV;26. Ordinance through implementation of the federal emission protection laws from 16.12.1996).

Chronology

Since the beginning of the nineties, the German press has reported more and more on the possible health risks of electronic and magnetic fields. Especially from the USA, reports about concerning results came out whereby owners of mobile phones brought claims for compensation. The extension of the mobile phone network in Germany and with that the newly planted broadcasting masts lead to numerous protests throughout the country and the formation of over 200 citizen initiatives.

The BMU convene the Commission for Radiation Protection (Strahlenschutzkommission SSK) which has been made available since 1974 as the advising institution in the area of reactor safety and protection from radiation. Working on recommendations and guidelines in the area of electrosmog is also within its jurisdiction. In 1991 the SSK recommended to the BMU it should be oriented towards the limits of the International Radiation Protection Association IRPA since there had been no concrete regulations for the protection of persons from the effects of electromagnetic fields in the federal republic.

Background

1992  The BMU assigned the SSK to summarise the current knowledge stand of the biological effects of low frequency fields on people and to work on recommendations for protection against these fields. At the end of 1992 the SSK and the Federal Office for Radiation Protection (Bundesamt für Strahlenschutz, BfS) held a symposium about the effects of low frequency fields.

1993  The Federal Committee for Post and Telecommunication invited the federal post, scientists from industry, worried citizens and critical scientists to an expert hearing. The BfS regularly brings out information brochures in which the consumer is informed about the current situation in relation to the electrosmog discussion.
In 1994 the BfS joined the claim of the SSK with regard to the international regulatory limits in opposition to the industry and recommended the refusal of building of kindergartens, schools and apartments directly under high voltage power lines. After the BMU took a clear position for the IRPA recommendations (along with most of the other EU countries), the industry opposition waned. Due to the height of these limits, the industry feared the investment of billions.

The Research Association for Radio Applications (FGF) was founded in 1992 through the initiative of the Federal Ministry for Post and Telecommunications. The federal government relied on the activities of the FGF for research requirements which had been funded by the industry. The critics argued that the activities carried out were not sufficient due to the link between the FGF and the industry.

1995 The BMU put forward a draft of “the ordinance of low and high frequency EMF emissions for the implementation of laws for the protection against emissions”. The planned ordinance was pushed upon critics in many quarters and as a result the original time plan to put forward the draft in September to the federal assembly could not be kept.

1996 The Bundesrat (federal assembly) agreed with this ordinance with the consideration of additional points of view. On the 16.12.1996 the ordinance came into effect and is still valid today throughout electromagnetic fields (26. Ordinance for the Implementation of the federal laws for the protection against emissions (26. BlmSchV). The regulations of this ordinance is based significantly on the recommendations of the International Radiation Protection Association IRPA respectively the International Commission on Non-ionising Radiation Protection ICNIRP. Critics argue on the one side that the limits should be lowered still further and on the other side that not all frequency areas are taken into account. The opposition party SDP supported putting a neutral scientific advisory body in place which would identify the main research focus and assign corresponding projects.

1997 After the worrying results, which were presented by an Australian research group under the leadership of Dr. Repacholi, The SSK decided that from these results such a conclusion about the danger to public health was incorrect and saw no reason to change the limits.

The Federal Office for Post and Telecommunication implemented a measurement for the examination of transmitters in over 1300 places. The result showed that the already written limits were being kept.

1998 Jürgen Trittin became the environment minister. The SSK recommended taking over the guidelines of the ICNIRP for those frequency areas which the 26. BlmSchV had not covered as yet.

1999 The BMU invited citizens, producers, communal politicians, engineering organisations and scientists to the “Bürgerforum Elektrosmog”. With this there should be a push towards a broad societal dialogue given about the supposed health risks of electrosmog. On the platform [www.elektrosmog99.de](http://www.elektrosmog99.de) a two day electrosmog congress could be prepared. The platform still exists today but is not longer kept-well. The number of forum contributions is very small.

The federal minister Tritten, placed himself in an internet chat for questions on the theme electrosmog. The BMU expressed the desire for a strong participation of the public in the disputed questions. Politics should take on the task of moderation. Trittin announced a change in the ordinance of electromagnetic fields. In the future, the ordinance should spread across all the frequency areas. In the course of the revision, the existing limits and new scientific knowledge about possible health risks should be examined.
**Interview with government**

On a parliamentary request in 2000 the federal government takes the following position in relation to “mobile communication and electrosmog”

[http://www.bmu.de/sachthemen/strahlen/fragen.htm](http://www.bmu.de/sachthemen/strahlen/fragen.htm)

**Question:**
Which scientific research activities, examinations and studies with respect to possible health threats form the basis at present for the decision of the government concerning the question of radiation limits?

The federal government including its advisory bodies includes all accessible national and international research results in its evaluations and decisions.

**Question:**
Does the federal government itself actively support research activities which are independent of industry? If not, why not? If yes, which type of research on which themes?

The federal government initiates and supports industry independent research activities. The federal environmental ministry and its body of experts pursues all indications of the possible effects of electromagnetic fields. For this purpose the department of research of the federal ministry supports research projects and with that serves

To examine scientific hypotheses on the possible effect mechanisms,
To validate research results with direct relevance to health,
To examine indicators of possible influences
To record the individual exposition in consideration of technical innovations,
To recognise possible long term effects
With that not only the frequency of mobile communication is observed, instead the whole frequency area of the non-ionising rays, that means from static fields to ultraviolet rays and ultrasounds. The results of the research programmes of the federal ministry are regularly published.

**Question:**
Are the Government aware of examinations and studies which show that negative effects could be caused to human health as a result low frequency pulsed high frequency mobile broadcasting?
If yes how are these examinations estimated and which conclusions are reached.

The federal government are aware of the scientific studies where pulsed high frequency electromagnetic fields can cause effects at biomolecular and cellular levels. The federal government is supported by national and international bodies of experts in the evaluation and the view that a healthy significance of these effects for people could not as yet be proven. Such effects require further scientific examinations. The federal government are not aware of any scientific studies or examinations which prove that human health is being damaged with permissible expositions.
**Question:**
Does the federal government plan a change of these rules including the enhancement of the participation of the public? If not, why not?

The federal government plans to amend the 26. BlmSchV during this legislative period in order to expand its area of use to all the registered frequencies which have been recommended by the EU ministry advice. In this context it will also be decided how far an extension of the participation possibilities of the public can take place.

**Question:**
Does the federal government consider to sink the permitted limits in the sense of a precautionary deal. If not, why not?

The recommendation of EU advice includes the same limits which are laid down in the rules of the 26. BlmSchV. The federal government examines in the frame of the amendment of the 26. BlmSchV, whether there is reason for further precautionary rules after the actual stand of the scientific knowledge. This will be supported by the commission for the protection against radiation.

**Question:**
On which scientific criteria should the Federal Ministry for Economy and Technology make rules for the protection of persons in electromagnetic fields after § 12 of the draft law of the Federal Ministry on Broadcasting and Telecommunications Facilities (Bundesratsdrucksache 464/2000)?

The planned ordinance of the boundary of electromagnetic fields after the § 12 FTEG-draft should in future replace the ordinance 306/97 of the Federal Ministry for Post and Telecommunication which has been in use up until this time. The hereafter realised position process for broadcasting has to respect the particular limits for electromagnetic fields.

**Question:**
How does the federal government evaluate the first results which were put forward in the ARD programme “report” from the 22.08.00 of a scientific examination on behalf of the Bavarian Environmental Ministry in which animals which were put near to mobile broadcasting grounds behaved significantly different to those which were on farms with no radioactive influence and the number of deformities with cattle failure when near to mobile broadcasting rays?

The Bavarian Environment Ministry commissioned a so-called “bovine study” in July 1998. The study is not yet completed and the conclusive report it seems will not be given before October 2000. Also part evaluations are not yet available (source: press release of the Bavarian Ministry for Country Development and Environmental Questions from 22.08.00/1). After presentation of the study the federal ministry will hand over these as with other studies to the Commission for radiation protection to assess.

**Question:**
How is the present stand of the scientific knowledge on the dangers to health through the use of mobile phones?
With the use of mobile phones high frequency electromagnetic fields are being produced. After the present scientific knowledge stand, high frequency electromagnetic fields can damage human health when certain field strengths are overshot. Therefore the EU delivered a recommendation for the protection of the public. If the corresponding limits of the mobile phone are observed, with today’s position of knowledge such damages to health could be prevented. A corresponding recommendation was delivered with the introduction of this technology in 1991 by the commission for protection against radiation.

Scientific reports became known over the last years whereby the use of mobile phones lead to, among other things, changes of the electrical activity to the brain, response time and sleeping patterns. From the view of the World Health Organisation and other international radiation protection bodies, these changes are not damaging to health as long as the recommended limits are observed. The results require scientific examination. The research in this area will be continued with intensity.

The operation of the advisory bodies

From the preceding chronology, it becomes clear the manner and ways in which science and scientists have been included in the German decision processes on the theme of electrosmog. Primarily, the publications play the most important role. These are being traced and evaluated by advisers of the different ministries (who also have access to the unpublished results of the supported projects), committee members, and policy advisers. An evaluation is necessary to differentiate the scientific results obtained from the partly subjective conclusion. Important with this is the discussion of the scientists among each other.

Those scientists who work in international bodies have a special influence and have a say in the guidelines and limits. Just now the presented example shows the relevance of international bodies for German legislation.

The BfS stressed repeatedly, that one should abandon the specialist literature of recognised international bodies (ICNIRP and WHO) and forewarn of “private” evaluations of the individual scientists.

A really independent scientific advisory body for the Government respectively a Federal Ministry for electrosmog affairs does not exist in Germany as yet. Presently this is being dealt with by the SSK. The SSK take on an advisory monitoring function for the BMU. It is however, in spite of the restructuring and new statute, on the initiative of the Trittin Federal Ministry, dependent on the BMU.

References

http://www.bmu.de
http://www.ssk.de
http://www.bundestag.de/
http://www.bfs.de
http://www.elektrosmog99.de
Elektrosmog Report:
http://www.datadiwan.de/netzwerk/index.htm?/esmog/es_001d_.htm

**Relevant authorities**

ICNIRP, International Commission on Non-Ionizing Radiation Protection  
IRPA, International Radiation Protection Association  
http://irpa.sfrp.asso.fr/

World Health Organization  
http://www.who.int/

BMU, Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit  
http://www.bmu.de

BMBF, Bundesministerium für Bildung und Forschung  
http://www.bmbf.de

BfS, Bundesamt für Strahlenschutz  
http://www.bfs.de

SSK, Strahlenschutzkommission  
http://www.ssk.de

Regulierungsbehörde für Telekommunikation und Post  
http://www.regtp.de/

BauA, Bundesanstalt für Unfallschutz und Arbeitsmedizin,  
http://www.baua.de/

FGF, Forschungsgemeinschaft Funk e. V.  
http://www.fgf.de

RWTH, Forschungszentrum für Elektro-Magnetische Umweltverträglichkeit der Rheinisch-Westfälischen Technischen Hochschule Aachen  
http://www.femu.de
Part II: The German Governance of „Human Cloning“

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Approach to the study

In the context of the IPTS/ESTO project “Science and Governance”: describing and typifying the scientific advice structure in the policy making process – a multinational study”, three expert interviews on the theme of “stem cell research/embryonic stem cells” were undertaken in October 2000. The goal of the interviews was to get answers to questions, how scientific advice structures respectively scientific knowledge is being included in the political decision making process.

The interviews were undertaken by means of a questionnaire which contained questions on the structure of advice, the quality of the advice or the dealings with the advisory service for example.

The interviews were undertaken with:
1. Margot von Renesse, MdB, head of the Enquete-commission “law and ethics of modern medicine” of the German Bundestag (Federal Assembly) (Federal Assembly).
2. Wolf-Michael Catenhusen, MdB, parliamentary state secretary in the Federal Ministry for Education and Research (BMBF)
3. Dr. Annette Schmidtmann, the responsible person for research on stem cells in the German Research Community (DFG).

The selection of the interview partners resulted from the consideration that the political decision process on the theme of “stem cell research/embryonic stem cells” would be fulfilled on a legislative and executive level.

On the Ministerial level, the Federal Ministry for Education and Research (BMBF) as well as the Federal Ministry for Health (BMG) are especially involved in the theme “stem cell research/embryonic stem cells”. In spite of the repeated requests, the various requests for an interview from the side of the BMG could not be achieved due to time and capital reasons. There would however be material made available on the symposium on “reproduction medicine in Germany”.

In addition to this the perspective of science should be taken into account in order to document which experiences the scientists have collected in the inclusion of their advice into the political decision making process. Therefore an interview was made with a representative of the German research committee (DFG).

Background

In a controversial move, the US President, Bill Clinton, gave federal scientists the green light for stem cell research and in Britain, Prime Minister Blair publicly announced his support for qualified therapeutic cloning and will shortly put the matter to the vote in the House of Commons. Now Romano Prodi, the President of the European Commission is calling for an open, pan-European debate on the matter. The technique of cloning for therapeutic purposes...
raises major ethical questions,' he said. Legislation on the matter varies greatly between different countries in the EU. For example, research leading to the destruction of human embryos is forbidden by law in Germany, Austria and Ireland, yet permitted under certain conditions in Denmark, the United Kingdom, Spain and Sweden. Because of this, the EGE report says it would be "inappropriate to impose one exclusive moral code".

As germ track therapies for humans (besides the ethical problems in experimenting with human embryos) open the door to human breeding and to attempts to improve the gene pool of entire populations (eugenics), germ track gene therapy in Germany was prohibited by the 1990 Embryo Protection Act. This decision was based on the results of the work of a series of commissions which had been looking at the possible impact of gene therapy and the need for statutory regulation since 1983. In contrast to the prohibition on development and use of germ track gene therapy, they saw no need for the most part for special statutory regulation of the development of gene therapy for somatic cells. They argued that the restriction of the therapy to the individual being treated meant that somatic gene therapy did not involve any new ethical problems. Somatic gene therapy could, in their view, be regarded as an extension of existing therapeutic options. Accordingly, the generally accepted principles and regulations for therapeutic trials were to be applied. Meanwhile, however, a debate has emerged over the need for specific statutory regulation for somatic gene therapy as well. As responsibility for the relevant statutory regulation in Germany is a matter for the Länder, the German Upper House - the Bundesrat - suggested in October 1992 a review of the adequacy of existing statutory regulations for covering gene therapy. To consider this issue the German Federal Government set up an inter-ministerial joint Federal-Länder Working Party under the aegis of the Federal Ministry of Health.

Overall, controversies about technology appear to be inevitable in modern societies where life is becoming increasingly dependent on technology in both the positive and negative sense, and accordingly also on political decisions relating to science and technology. With the scope for using new technologies and technology policy decisions growing steadily, it is not surprising that the legitimacy of – and basis for – such decisions are increasingly the subject of (political) discussion. To this extent, there seems to be no way of escaping the problem of acceptance, but only ways of approaching it. It is likely that the problem of technology acceptance is less a matter of widespread hostility to technology than of greater demands on the part of the public for control and a socially-acceptable form of technological progress. TAB working report No. 25, 1994, http://www.tab.fzk.de/engl/projekte/Zusa/AB25.htm

Chronology of the human cloning debate in Germany

(The following chronology figures the relevant German stakeholders in bold letters, while non-German events are displayed in smaller characters.)

• 1990: GenTechGesetz (gen technology law)

• 1991 Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz - ESchG)

• 1995 the Federal Republic of Germany takes part in "Human Genome Project".

• 1997 The Bureau for Technical Assessment of the German Bundestag demanded the Research Centre for Biotechnology and Law of the European Academy for Environment and Economy at the end of 1997 to make a report concerning the legal aspects of animal and human cloning. The report was presented to the German Bundestag to help them decide if certain regulation is needed. In this report the legal situation of animal and human cloning has been examined in the United States and some other countries of the European Community including Great Britain, France, Austria, the Netherlands, Switzerland and Greece.

• April, 1997 the Federal Minister for Education, Science, Research and Technology (BMBF) recommended to the Council for Research, Technology and Innovation reporting to the Federal Chancellor to implement measures to foster bioethic reflection and debate. In the context of his statement on the cloning of humans the Minister then announced an initiative to strengthen ethical reflection in German research.

• The Deutsche Forschungsgemeinschaft (DFG) held a symposium about "Current requirements for bioethics research" in December 1997, and about the same time launched an invitation to submit preliminary ideas for a "bioethics reference centre". On 5 February, 1998 the Federal Government published guidelines for the funding of such a centre. On 25 August 1998 the BMBF announced that it would make available the necessary funding for a period of five years beginning on 1 January, 1999.

• In November 1998 two groups in the US and Israel reported that they had been successful for the first time to keep human pluripotent stem cells in permanent tissue culture. These capacities promise a number of revolutionary scientific and medical novelties affecting, for example, treatment of cancer, Parkinson's disease, Alzheimer's disease, or diabetes. (http://www.dfg.de/english/press/spec_inform.html)


• January 1999: founding of the German Reference Centre for Ethics in the Life Sciences (www.DRZE.de)

June 1999 the German Research Council demands: "Germany needs a national Genom initiative". Due to scientific and economic perspectives of the Genom Research a clear increase of the governmental expenditure on that issue is necessary.

June 1999: the German medical profession claims that in view of the medical progress with embryonic stem cells in the USA and Great Britain a German reorientation regarding clones of such cells is required.

September 1999: the planned Bundestag Enquete-Commission on Bioethics was cancelled

September 1999: the German press agency (dpa) reported: The parliamentary collection of European advisers spoke out against the patenting of genes and cells. Neither the genetic genotype of people, animals, plants, cells, organs or fabrics could be regarded as an invention. This was a recommendation on Thursday in Strasbourg to the governments of 41 European states. With this decision the collection of parliamentarians went against the previous EU guidelines which allowed the patenting of genes, cells, and organs of people, animals and plants (see the entry from 30 July 1999)

November 1999: the biotech online-service "life science.de" reported: The results of human genetic research will in the coming century make the right of not knowing important. Uwe Claussen, the director of the institute for human genetics and anthropology in the university of Jena works at this end. The physician feels that without human solidarity against weaknesses, human cohabitation will be even less possible in the future. That is valid also for the practice of private insurers to scan the genetic sickness risks and to enter it into the contribution account. Business-wise, everybody whose sickness predisposition is known will automatically be stigmatised warns Claussen.

December 1999: the research politician of the SPD Bundestags fraction, Stephan Hilsberg, spoke out against his coalition partners on the establishment of an enquete commission on bio-medicine. Such a commission, with the inclusion of ethical criticism in the research, would not be held in the development of bio-medicine, it would however lead to the migration of future research from Germany.

February 2000: the Bundesärztekammer, discussion paper on a guideline on reproduction medicine

February 2000: the "Frankfurter Rundschau" reported: The European Patenting Office (EPA) in Munich wrongly granted patent to gentechnic manipulated human embryo. The office verified the corresponding information on Monday to the environmental protection organisation “Greenpeace”. “That was a big mistake” quoted the speaker Rainer Osterwalder to the EPA director for biotechnology, Christian Gugerell. Oswalder conceded that the university of Edinburgh granted patent number EP 695 351 also the manipulation of human genotype information which contained these so-called germ systems. Since the patent was granted, the office could take it back if protest arose. Independent of this there would also be a transfer of patents illegally in Germany and also widely in the EU states announced the EPA speaker. The federal government and the politicians of the various parties announced corresponding protests against the granting of the patent.
• On 29 March 2000 a “Statusseminar” has been organised by the German Ministry for Education and Research (BMBF) on the present state-of-the-art in stem cell research in order to obtain actual knowledge on this research area, since only well-founded knowledge is the basis for an open discourse and future decisions on legal conditions. The statusseminar on: "the use of human stem cells in medicine - on the current status, perspectives and boundaries " brought together around 250 scientists, ethics experts, politicians, and theologists from various countries. Apart from the purely scientific aspects also questions of moral responsibility in science and legislation were addressed. In his inaugural address the parliamentary secretary Wolf Michael Catenhusen outlined the problems of stem cell research and its consequences. He stressed that scientists must bring their expertise actively into the ethical discussion in a transparent and understandable way. Catenhusen stressed that while the Federal Government progresses in the preparation of suitable legislative steps, particularly on the reproduction medicine, the BMBF is particularly active in the support and promotion of a transparent public discussion. [http://berlinews.de/archiv/981.shtml]

• March 2000: the “Frankfurter Rundschau” commented that the decision of the federal association of doctors would support the introduction of primary plantations diagnostics as follows: The federal association of doctors (BÄK) had revoked the consensus. The selection of human embryos and their destruction should be allowed in future, supports the BÄK. Indeed it is contrary to the present embryo protection law that the primary plantation diagnostics (PID) are illegal. With the PID the embryos would undergo a genetic test. If the result was positive they would be transferred to the birth mother of a woman otherwise destroyed. If the people wanted it.

• March 2000: the German press agency (dpa) reported: “the federal association of doctors (Cologne) strictly reject gene tests as a precondition for insurance. We should not allow that modern diagnostic methods of medicine are being misused for commercial means announced the president doctor Jörg-Dietrich Hoppe on Tuesday in Berlin. No one has the right to demand gene data he announced with regard to the guidelines of the association from 1998. He reacted with that on notices from Great Britain. Subsequently London wants to allow insurance’s which demand gene tests from customers.

• March 2000: the state secretary Wolf-Michael Catenhusen in an interview with the German newspaper “Zeit” explained that the failures in the German federal genome research can scarcely be corrected: since it is no use when the German state tomorrow forks out another 500 million marks for research ( cf. Interview with the state secretary Mr. Catenhusen for this project)

• March 2000 : The Federal Assembly (Bundestag) decided with the votes of all factions that the stablishment of the enquete commission “law and ethics of modern medicine” would deal with all perspectives, problems, and consequences of the gene technic manipulation of people. [http://www.bundestag.de/gremien/enquete/medi_ue.htm]

• April 2000: the Federal Ministries supported Edelgard Bulmahn (BMBF) in view of the decoding of human genomes in an interview with the Berlin newspaper “Laws on ones genotype”. It neither allows patenting human genes of forcing people into having a gene test. “we need in Germany clear rules so that no one must be forced into giving their genome data”. Bulmahn stresses still further that “interference’s in the germ systems of people so germ manipulation should not be allowed just as little as the cloning of people”.
In addition to that, the federal government inserts a patenting restriction on human sequences so that the access and also rash steps in medication can be safeguarded against.

- April 2000: In the ZDF programme “Berlin Mitte” the German research minister Edelgard Bulmahn on the 27th of April announced a law initiative which should prevent that genome data must be passed on to another party. On this he stressed that interference’s on the human germ system must in future be taboo.


- In May 2000 the German Health Ministry organised a Symposium on reproduction medicine. The discussion activity of the federal ministry should simultaneously smooth the way for the preparation of a fort plant medicine law. A central theme in this context is the role of the so-called pre-implantations-diagnostic (PID) with which the genotype of unborns can be examined. In the frame of this three day symposium the federal health minister, Andrea Fischer on the 26th of May explained that she strives for a new law before the election in 2002 on fort plant medicine that should replace the March ten year old embryo protection law.

- June 2000: the Frankfurter Rundschau reported: “The German research organisation (DFG) in the frame of its focus programme wants to import embryo stem cells from the USA. The federal republic had no objections to it. The critics fear that this could open the door to cloning of humans. In Germany it is only legal to use embryos from legal abortions for research. The gaining of embryo stem cells from surplus embryos is from the view of the DFG in this country entirely forbidden by the embryo protection laws. Indeed the question is whether such stem cells are allowed to be imported from abroad. The DFG responsible person for research on stem cells Annette Schmidtmann explained therefore on request that the import is legal. (cf. Interview with Dr. Schmitdmann for this project)


- July 2000: Wolf-Michael Catenhusen, secretary of state in the federal ministry for education and research indicates that the federal government wants to spend more money and develop a new programme so that it will be second to the USA world-wide. The support of genome research and bio-medicine will in the coming year be stocked up with 54 million marks. Together with the so-called “green gene technic” and the bio-informatics the household goods would rise from the present 83 to 144 million marks. The representative of the German research organisation welcomed this step. Catenhusen showed at the end of March a raise in the budget for genome research was ineffective.

- July 2000: the president of the German research organisation, Ernst Ludwig Winnacker explained that interference’s with human germ systems is justifiable. Indeed the technical preconditions have not yet been filled.


• August 2000: the Allensbach Institut für Demoskopie made public a representative questionnaire for every second German on the decoding of human genomes. Within a short time a large number of the German public (84% over 16 years of age) had heard of the decoding. The Germans reacted differently to the results. Only every third person tied the scientific success with hopes, 44% against it with fears. The west Germans were more sceptical than the east Germans: 39% of those questions in the new Bundesländern were positive, 37% negative. In the old Bundesländern 45% reacted negatively, 32% positively. The fear of genetically modified goods was excepted in this context.

• August 2000: the allowance of the British government for cloning of human embryos for therapeutic goals was given. They followed this with a recommendation of experts. The copying of whole people should remain forbidden. The plan requires the consent of the parliament. The corresponding debate is expected in Autumn.

• August 2000: the “Washington Post” reported that after much procrastination, the research of stem cells in the USA would in future be financed by the state. It is expected that researchers are only allowed to use frozen embryos from fertility clinics that were not going to be planted and were being disposed of. The donor of the embryos is not allowed to be paid and has no influence on which institution the stem cells are researched on. With this rule the Washington government hopes that the trade of embryos would be safeguarded. Individual projects in the USA will be supported by private means.

• September 2000: the parliament speaker in Strasbourg explained that the European parliament plans an introduction of its own committee on biotechnology. The parliamentarians want to react on the plans of Great Britain to allow the cloning of embryos for research purposes.

• September 2000: the Frankfurter Rundschau reported that the doctor Brigitte Boisselier supporter of the realists sector wanted to clone a new baby from a dead baby. The procedure should be pushed through by the Klon-firm “Clonaid” in the Bahamas. Here the identical copying of people after the “Dolly project” is not forbidden. US genetic researcher David Kirby would on the one side like not to believe in its success but on the other side would not be surprised if there was in the future a human clone.

• September 2000: In an interview in the weekly newspaper "Die Zeit", from the 21st of September, Mark Hughes, one of the developers of primary plantations diagnostics (PID) explains that genetic tests on embryos are ethically unharful and medically necessary. The examination of genes is not magic instead it is in many cases nothing more than an ultrasound picture. When a decision made by a doctor on a pregnancy is allowed, than
that means for me: do it as quickly and precisely as possible. Therefore I maintain PID is as ethically unharmful as fruit water examinations. The scientists take the fears of the critics who fear that in the future children will be selected on intelligence. My opinion is that research would probably never be in the position to do so.

- November 2000: Public online discussion on the consequences of genetic diagnostics with 5 representatives from the Bundestag Enquete Commission ‘Law and Ethics of Modern Medicine’

Legislative background

Research towards preimplantation diagnosis (PID) of genetic diseases is done considering the aim of helping those couples who would prefer selection to occur at this stage rather than during pregnancy. In Germany a local ethics committee did not approve the first German PID trial. The reasons for this were not explicitly of ethical nature but questions concerning the legal situation. PID is affected in Germany by different laws. At first there is the Embryo Protection Law. This law is intended to protect embryos from "improper use" and to protect against improper use of modern reproductive technologies. Therefore it is forbidden to make any investigations on totipotent cells.

However on the other hand abortion is allowed in Germany when the conditions for a medical indication are fulfilled. Genetic counseling and prenatal diagnosis procedures are regulated by guidelines, but not by a law. In summary, there is ethical disagreement seen in the regulation of the PID in Germany. The selection of healthy embryos before the beginning of a pregnancy is forbidden, however, an abortion some weeks later, with the same indications, is allowed.

A mere national prohibition of cloning would have a weak footing in view of international research. Scientists would then select more permissive countries. Broadening the scope of offenses liable to prosecution to include those committed in foreign countries by supplementing appropriately the (German) International Criminal Law might gain political ground only if a not insubstantial number of other countries were to ban cloning in their respective national laws. Although the legal situation in other countries cannot be dealt with in detail here one can conclude in summary, however, that on an international scale a rejection of cloning of humans prevails widely. The human rights agreement for biomedicine does not mention cloning in explicit terms; however, it is reasonable to assume that a ban is implicit in

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7 Further Regulation and Guidelines
Bundesärztekammer (Federal Medical Association) - Guidelines, recommendations and statements List of all guidelines, recommendations and statements of the Bundesärztekammer (Federal Medical Association)
http://www.bundesaerztekammer.de/bak/owa/idms.show?id=103102

Committee for Public Relations and Ethical Issues of the German Society of Human Genetics Das Urteil des Bundesgerichtshofes zum "Tübinger Fall" und seine Bedeutung für die genetische Beratung http://gfhev.de/kommission/BGH.htm, Position Paper of the German Society of Human Genetics http://gfhev.de/kommission/eng/e_pospaper.htm

8 Votum der Ethikkommission der Medizinischen Hochschule zu Lübeck vom 19.08.1996.
article 13. Any moves aimed at formulating an explicit ban of cloning of humans in this protocol deserve emphatic support. one should also remember the decision of the European parliament of March 16th, 1989, demanding a ban of cloning reinforced by penal provisions, and the recommendation No 1046 (1986) of the Council of Europe, which also declares itself in favor of a comprehensive ban of cloning in humans. 11

The Embryo Protection Act (Embryonenschutzgesetz) 12

Research with human embryonic stem cells in Germany is regulated by the Embryo Protection Act (Embryonenschutzgesetz). The prohibitions enshrined in the Act aim at ensuring the protection of human life and human dignity from the very beginning of life. The Act prohibits all in vitro experiments with an embryo which do not pursue the preservation of the embryo. From the protection of human dignity also follow the prohibitions on cloning human beings, on creating chimeras or hybrids, and on carrying out germ line interventions. Every extraction of cells from embryos for research purposes is prohibited, even if the embryo is not harmed or disturbed in its development. With some restrictions, access to embryonic stem cells can be obtained by importing the cells from states where the use of embryos for research purposes is permitted. A way to obtain "individualised" embryonic stem cells, namely by transfer of a human somatic cell nucleus into a human enucleated egg, falls under the prohibition on cloning a human being. The provisions regarding the creation of chimeras and hybrids only refer to processes involving at least one human embryo or one human gamete. According to the wording of the Act it is thus not forbidden to create human-animal hybrid cells by the transfer of a human cell nucleus into an enucleated non-human egg. The production of pluripotent embryonic germ cells from primordial germ cells is permitted in Germany. The extraction of the cells from aborted dead foetuses is subject to the guidelines for the use of foetal cells and foetal tissues of the Bundesärztekammer. There are several restrictions on the use of human pluripotent embryonic stem cells and embryonic germ cells in research, above all the prohibition the use of pluripotent cells for the creation of an embryo or of the modification of an embryo and the production of germ cells from pluripotent stem cells. Hence, the German embryo protection law prohibits any research on and with embryos if the embryo is not the immediate beneficiary. Accordingly, removal of pluripotent cells from an embryo is prohibited in Germany.

Nuremberg Code 14

The criticism in Germany on biomedicine and its bioethics is focused on issues such as genetic testing and embryo research as gate to genetic therapy and germline intervention, but also on the theme "research on people unable to consent". The reason why research on people

13 § 6 of the German embryo protection law (referred to subsequently as 'ESchG' = Embryonenschutzgesetz) in force since Dec. 15th 1990 forbids cloning by law:
'(1) Those who, by artificial means, effect that a human embryo with the same genetic information than another embryo, a fetus, an adult, or a deceased person, is generated, is liable to sentence of imprisonment of up to five years or liable to penalty. (2) Likewise under liability are those who transfer into a woman an embryo as delineated in Section 1. (3) The attempt is liable to prosecution.' The discourse following below of whether § 6 ESchG - and possibly other relevant regulations contained thereon - will require amendments in view of the novel developments and conceivable further technologies will be restricted to legal questions of cloning involving the human genome; the problem of whether cloning of animals should or should not be regulated legally will not be addressed.
14 http://www.ncgr.org/gpl/odyssey/privacy/NurCode.html
unable to consent is the focus of public attention and criticism in Germany lies in the fact that here the breach of historical experience becomes particularly significant. Although the number of codes regulating ethical issues in the fields of health care and biomedical research on humans has been increasing since 1947, the year of the Nuremberg Code, systematic international study of the phenomenon has started only recently. Referring to examples of codes as well as of ethical problems in reproductive medicine, it is argued that it is not sufficient merely to produce codes, but that it is also necessary to bundle, to harmonise and to focus them, if they are to be of any value in responding to practical ethical difficulties.

In view of the terrors of Nazi-medicine the Nuremberg Code was phrased by the Nuremberg judges as generally accepted international basis of medicine. It was the fundament of the legal judgement of medical experiments, for which the name Auschwitz stands. The Nuremberg Code is part of the Nuremberg judgement and thus has the character of International Law. The historic evidence and a view on the Code undeniable speaks for the claim of a general validity. Telford Taylor, the chief prosecutor of Nuremberg stated in his introduction that the trial was no mere murder trial, since the defendants were physicians having sworn the Hippocratic oath, and thus having become murderers in the execution of their profession. Logically, the judges created with the Nuremberg Code a basis of judgement of crimes which became possible within the bounds of medicine. The judges described the statements of the Code as basic principles "which must be followed so that human experiments comply with moral, ethical and legal principles". It is obvious that the informed consent is the core of the Nuremberg Code. The Nuremberg Code of 1947 thus is a really brilliant link between the Hippocratic ethics of physicians' responsibility and human rights. The Code is characterised by human rights and lawfulness, and it is an ethical code for a humane medical research.


The operation of the (different) advice bodies

The operation of and the interaction between the advisory bodies and decision-makers

The interviews showed that since the beginning of the discussion on “stem cell research/embryonic stem cells”, there has been a persistent and continuing exchange of information between science and politics. The advice takes place through the participation in symposia, membership in commissions and advisory councils but also through informal contacts. The advisory structure shows this informal level especially between the BMBF and the DFG.

Besides this informal advisory structure, formal bodies exist which safeguard the continuity of the advisory process. These would be the advisory council on ethics of the Federal Health Ministry or the enquete commission “law and ethics of modern medicine”.

With the implementation of the Enquete-Commission “law and ethics of modern medicine” through the German Bundestag (Federal Assembly) a committee was created that merges scientific expertise with politics.

These issues are discussed in the following sections.
The advice structures that were used

The dispute respectively involvement in the theme “stem cell research/embryonic stem cells”, began at the end of 1998/beginning of 1999 in Germany.

The German Research Foundation (DFG) decided for the reason of publicising of two working groups from the USA and Israel in November 1998, in which for the first time the work with stem cells was reported to refer and get involved on the theme quickly if possible. With this the DFG would advise on legislative and executive questions on science. The president on consultation with the senator commission for principal questions on genetic research of the DFG decided to introduce a working group with external experts and decided on an opinion of the problem. This opinion was made public in March 1999. There it stated:

The DFG stand absolutely behind the embryo protection laws to forbid the cloning of people independent of the employed methods as well as the forbiddance of the creation of people with synthetically different gene type for example through germ system intervention or through the creation of hybrids. The DFG sees that the research with stem cells can result in therapeutic and diagnostic goals which has a large potential for medicine. The scope of which can not yet be exactly estimated. The DFG however also sees that from the gaining of stem cells there are many lawful and misgivings. Regarding research on human stem cells the DFG perceives no (trade) requirement to change the German law.

Presently the opinion is being updated for the reason of new developments in the area of adult stem cells. Discussions were held between the BMBF and the DFG and within the DFG itself. Since July 1999 a new working group of the senator commission of the DFG are working on the opinion.

The activities of the DFG on the theme “stem cell research/embryonic stem cells” are many: working on opinions, setting up focal point programmes “embryonic and tissue specific stem cells – regenerative cell systems for cell and tissue substitutes” or the work of the senate commission “principal questions on genetic research”. After questions and themes the senate commission set up an up-to-date working group which is made up of experts from specialist areas. The senate commission set up a working group on "stem cells". Altogether stem cells make up a large part of the work of the senate commission. On this the DFG set up a “working circle on ethical questions” which is made up of moralists, philosophers, judges and journalists and is thought to be a discussion circle for the focal point programme.

Because of the importance of the “stem cells” theme, the DFG decided to apply a focal point programme. The content of this programme is not exclusively the work of embryonic stem cells. Much of the work is on adult stem cells. There are only a few projects which use embryonic stem cells. Therefore the DFG considered: when one wants a scientific comparison between the potential of different cell types, different cell types must be used. There could be an argument that a project which works with imported stem cells is supported by the DFG and all the problems which are tied to that. When funded by science, the statement should be made that adult stem cells know all that embryonic stem cells know. This will only work when embryonic stem cells are tested also.

The actual position of the DFG (Professor. Dr. Winnacker ) is that at the moment there is no need to change the embryo protection law (EschG). At the moment means that this opinion could change within the next six months.
The Federal Ministry for Education and Research (BMBF) has been involved in the theme “stem cell research/embryonic stem cells” since 1999. The starting point was discussions with scientists who were interested in the research support. Through the continuous involvement of the BMBF with the theme “health research”, the theme “stem cells” can be recognised early. The stem cell research will be theorised in the pages of the BMBF under the following points:

1. scientific relevance
2. International development in the support of research
3. Individual support programmes
4. Ethical evaluation/renewal of the embryo protection law

The Federal Ministry for Health works on the further development of the law framework for the reproductive medicine. The planned law should replace the embryo protection law from 1990 and regulate the widespread reproductive technology.

The Enquete-Commission “law and ethics of modern medicine”, was put in place on request of the factions SPD, CDU/CSU, BÜNDIS 90, DIE GRÜNEN and FDP on the 23.03.2000. Its implementation followed the discussion on the execution of the European “Bio-medicine convention”. The introduction of the Enquete-Commission was motivated by the assumption that during the work of the Enquete-Commission there were no decisions on the important questions of biotechnology and modern medicine the Bundestag (Federal Assembly). The Enquete-Commission would prevent decisions being made for a long term. This suspended effect could be gone round firstly through an agreement that the commission would accompany the running legislation. On the task of the commission it is said:

The commission should serve the parliamentary and economic requirement to answer questions on the development and uses of biotechnology and modern medicine and prepare work on the decisions of the Bundestag (Federal Assembly). To deepen the public discussion and the preparation of political decisions the commission has the task of working on taking into account the concerned business groups, institutions and organisations as well as the church, recommendations for ethical evaluations and work on the adMinistrative trade for future medical questions.

The thematic focus of the Enquete-Commission arranges itself in three complex themes:

1. Reproductions medicine and embryo protection (primary plantations diagnostics, human genetic advice etc.)
2. Practical medical research/new diagnostics and therapeutic methods (diagnosis/prevention, Xenotransplantation, use of stem cells, allocation problems, gene therapy etc.)
3. Genome analysis (business aspects, accessibility, limits of use etc.)

The theme “stem cells/embryonic stem cells are taken into account mainly in one and two.

In the legislation of the Federal republic of Germany it is possible to introduce an Enquete-Commission for the preparation of decisions in complex issues. This happens on behalf of a quarter of the representatives of the Bundestag (Federal Assembly). With this a committee exists which uses external analytic expertise to prepare and discuss political decisions. The goal of the Enquete-Commission is to create a report and submit it in time so that a statement
about it from the Bundestag (Federal Assembly) can follow. A completed report cannot be returned. The commission must prepare an in between report on which basis the Bundestag (Federal Assembly) decides if the Enquete-Commission should continue or stop its work.

Thirteen members of the Bundestag (Federal Assembly) and 13 which are not in the Bundestag (Federal Assembly) or the experts of the Federal government belong to the Enquete-Commission “law and ethics of modern medicine”. The faction of the SDP named five members and five experts. The faction of the CDU/CSU named four members and four experts. The faction BÜNDIS 90/DIE GRÜNEN names two members and two experts and the faction F.D.P and the PDS named one member and one expert. Chairperson is Margot von Renesse (SDP). Her deputy is Hubert Hüppe (CDU/CSU).

The experts come from various specialist and theme areas: sociology. Theology, psychology, law, feminism, medicine, handicapped questions, natural sciences etc. With this it is ensured that the Enquete-Commission represents no “medical committee”. The experts for example work as judges, lecturers in universities or as researchers.

In the choice of experts the SDP faction for example have relied on the representatives which have spent years working on the specific complex themes. The particular “expert scene” was consequently known.

The work of the experts is not to create reports instead it is on the one hand to illustrate the scientific opinions and on the other hand to act as pilot. This means that an expert must not know the whole width of the theme but knows which expert they can rely on. Consequently, in the Enquete-Commission there is no expert with exclusive specialist knowledge on the theme “stem cells”.

The work of the Enquete-Commission is accompanied by constant external advice. This results from a placing reports through consultations on for example “bio-patenting guidelines” but also through expert talks which take place in a small frame. The external advice ensures that the whole width of the theme is observed from all sides. The question on the theme “primary plantations diagnostics” for example would be what is an embryo? With the answer of this question, diverse aspects (among others, variations of the cells) are relevant which require further expert knowledge.

A number of institutions and organisations apply themselves unsupported also to the Enquete-Commission in order to bring in their opinions and expertise to the work. These requests can not always be granted.

The work of the Enquete-Commission is being supported by a secretariat. The formal responsibility of the allocation of the secretariat lay with the Bundestag (Federal Assembly)s management. With the choice of managing the secretariat, the head of the commission was enlisted. On this the working group speaker worked out the criteria for further allocation of the secretariat. Critical for the choice was that the people had already worked on the implementation of an area of medicine. The secretary itself performs no content work. It can be termed as a “service organisation” and examines for example with the allocation of reports, if the required financial means are forthcoming.

The Ministries have by law no entitlement to participate in the sittings of the Enquete-Commission. They are however represented in the sittings. It is requested from the pages of the Enquete-Commission which work has been performed in the Ministries
So that this can flow into the work of the commission.

Since the delegates are also members on the board of the specialist committee which works on the themes of the Bundestag (Federal Assembly), the integration of the specialist committee is safeguarded.

Since the BMBF has been involved in the theme “stem cell research”, it has relied on external advice. This advice results from the German research community and from experts which pioneer the stem cell research. Wolf-Michael Catenhusen was among others head of the Enquete-Commission “chances and risks of gene technology” of the German Bundestag (Federal Assembly). An intensive communication and a large information exchange between Ministry and science on the theme “stem cell research” takes place. Also the technical department (fachreferat) has a specific interest to be informed about new developments.

For the BMBF the communication is an important element, wherefore special informal advisory structures are being used. The advice takes place on all levels. These levels could also independently decide, whether and through whom advice should result. The technical department relies especially on external advice. The responsible technical department analyses the information got through advice and transmits actual developments in knowledge to the management of the Ministries.

The knowledge about the advice respectively the expert scenes results from:
- the permanent monitoring of research scenes through the technical department
- internet research
- the integration of the specialist level with the research scene
- sending invitations to the state secretary, Wolf-Michael Catenhusen

The BMBF is continually involved in the theme “health research” and especially with the extraction of tissue wherefore the advisory and expert structures are long known. Through the knowledge of the medical developments on this area the theme “stem cell research” had been identified early through the Ministry.

The choice criteria for advisors is scientific excellence. On request of the DFG, the BMBF inform about who the leading scientists are. The circle of advice is clear. The specialist scene is very small and therefore the people are known to the BMBF. The scene was invited by the BMBF in March 2000 to the status seminar “The Use of Human Stem Cells in Medicine-Perspectives and Limits”.

The advisors/experts on the theme “stem cell research/embryonic stem cells”, are researchers and leaders of research groups. With the research support, the area of teaching is secondary. In future it would be possible, if scientific infrastructures in the area of stem cells were created, to also take into account scientific management for advice.

The advisory structure of the BMBF could be characterised as independent and informal. Formal structures exist for example through the health research advice. Also in the area of research support (tissue engineering) formalised structures exist. Science also offers advice without request. This is especially in the area research support. With the sensible theme such as stem cell research, early talks from the science side are being sought by the BMBF. The procedure is accepted by politics.
The Federal Ministry for health also relies on external advice. An ethics advisory board was constituted on the 15.11.2000. On this board are medical experts, judges, theologians, philosophers, business people and psychologists. Altogether 13 experts belong to the advisory board. First of all two themes fields stand in the center. These are to find a framework and laws on human genetic tests and to change the spectrum of reproductive medicine.

The Federal health Minister, Andrea Fischer, formulated the purpose in her speech, on the occasion of the constituent sitting, in the following way:

“A fundamental ethical-political debate on the possibilities and effects would be useful but we the Federal government, can not lead it. We need advice on the concrete developments of science and research in the area of medicine in which far-reaching changes to consequences for medical treatment to individuals or business can be given and where we must ask ourselves whether laws or other actions exist for policy.

In May 2000 the Ministry together with the Robert-Koch- Institut presented a symposium on “reproductive medicine in Germany”. The symposium should serve the ethical, judicial, and industrial questions. It should also answer the question of whether in the embryo protection law of the last 10 years was still a sufficient foundation.

The advisory service resulted from the DFG, from the working level of the Ministries on to the Federal government. When it for example so is that there is a research group between the BMBF and the BMG on the theme of reproductive medicine than a request is for one expert. Then it is the level of the head of the department. At this level one head of department writes to the head of the specialist area: the DFG has up until now had on the theme “Clinical Research” the programme “XY”, which has run out. What does the DFG plan to do in the future? That is the official level. The request comes in writing and goes over the leading area levels. There is also the possibility that a Minister writes directly to the DFG. The advice takes place consequently on all levels. The higher the level is, the more formulised is the procedure.

Especially on the working level between the DFG and BMBF a constant exchange about news results so that everyone knows the stand of the others. For example the BMBF reports that there is a large request in the area of cloning. This informal co-operation depends also on personalities. Frequently, the informal exchange functions so well – this is especially the case between the DFG and the BMBF- that it requires no official path.

The timeframe of the advice runs very differently: the BMG had first at the end of October sought the contact with the DFG. The BMBF had from the beginning sought the exchange with the DFG. When the Federal health Minister announced that it would in this legislative period, give a law on reproductive medicine, it was attempted to get the head of the department draft. The DFG never got the statement whether there is a head of department draft.

It seems to be that the Ministries can not get an overview on all the actual developments in all research areas. In order to see the up-to-date stand of knowledge, one needs experts. What expert is on what area is known by the BMBF through its precise programme. Where there is no programme, the Ministries also do not know what expert there is. The DFG knows also in these cases exactly who does what and who one can ask. The inflow of good scientists results from the DFG. The DFG knows what scientists are responsible for what and how good that
are. The DFG also know which scientists are available for international co-operation and contact therefore the internationality is safeguarded.

The DFG knows the diverse advice structure from independent to ad hoc, from formal to informal, from open to closed. The advice results regularly from when it is concerns formal membership in the commission. There are also ad hoc groups concerned with a once-off advisory service. Especially in the area of stem cells an informal advisory service continually takes place. The advice is executed through participation in meetings and symposiums.

The DFG is also active itself. It was for example secured in genome research that the BMBF had not enough means to do. This resulted in an estimation from the president as a result of letters which scientists wrote to the president of the DFG. In this case the president applied himself to the Ministry and drew attention to the fact that Germany could in the area of genome research, fall back on science and international comparisons.

Quality of the advice

From the form of advice – meetings, Enquete-Commission, advisory boards, informal contacts – the quality of the advice i.e. the degree influence can be defined.

The experts have equal rights and this results in them participating in the extraction of information and in the decision making process. From the point of view of Ms Renesse, these processes should not be separated from each other. Naturally the external experts also contribute to the decision making through their specialised knowledge.

All the factors have to taken into account in the opinion process. How is the stand of the technology?, how did it develop?, what is the stand in international comparison? After this an evaluation of the present state-of-the-art of ethical, industrial, economic, judicial and research political points of view result. This collection of facts will be correlated with the expected future development and research in order to make an evaluation especially on the law ethics of the Federal Constitutional Law. Especially in the evaluation the opinions of advisors and analytical experts flow in. Since the Federal Constitutional Law stands over the whole thematic discussion, it is not about creating new values, but to fulfil ethical and legislative values. This is also especially the case with stem cells.

The control of the experts/advisers on the political decision making is formulated through the instrument of the Enquete-Commission. On a Ministerial level there are no regulations on what influence that they should take on the political decision making process and judgements.

With the BMBF, the opinions of the experts can be found in the drafts of the department heads. These drafts take the formal path from the head of the department to the state secretary and on to the Minister. It is noted which scientific advice was relied upon. The political leadership of the Ministry makes the final judgement. Especially with ethical questions the independent judgement is particularly important. With the interests of the scientists the political leadership sits together with the scientists in talks. There is also feedback from the DFG.
Also the status seminar “The Uses of Human Stem Cells in Medicine – Perspectives and Limits” serves not only the extraction of information but the dialogue with experts and the specialist scene on the theme “stem cell research/embryonic stem cells”. The Ministry invited about 250 moralists, scientists, politicians and theologians from many lands. As well as the scientific aspects questions were discussed on the moral responsibility of science and legislation which political leadership can take into account. Altogether the advisory process is presented from an independent information exchange and dialogue between science and Ministries. Formulations exist in the area of research support.

The BMG seeks the information exchange with external advisers and formed, with the ethical advisory board, an independent community that should guarantee a broad pluralistic and multi-scientific ethical discussion. The statement on the appointment of the committee is:

“The health Minister requires a qualified and scientific well invested advisory committee on the ethical questions in the various problem fields and from that to probe the growing legislative call for action”.

In her opening speech at the symposium “Reproductive Medicine in Germany”, the health Minister made it clear that this meeting was not just about extracting information but also to include the results in the shaping of public opinion:

“The symposium understands itself as a prelude to a more extensive discussion which will eventually discharge into legislative process. On the basis of the results of the symposium and other further activities, the task of the faction of the German Bundestag (Federal Assembly) is to make thoughts about the further procedure on legislation. In my opinion only one process comes into question, to find a consensus among the delegates”.

The public will be informed at the earliest possible time about the stand of the discussion. The longer that there is public discussion, the more possible it is for an enlightenment to be reached before the legislation is changed too quickly. All opinions of the DFG as well as the opinions on the issue “Human Embryonic Stem Cells”, will be made public, presented to the press and translated into English. Research and health Ministers etc. on the Federal and country level will likewise receive these comments.

The perception that there is independence of the adviser can not be guaranteed since the advice through research is always tied to the own interests of the research. Important is however that both sides play with their cards open. If one has the concept that independence and neutrality are the same, the question on independence can be answered negatively when an own position or opinion is concerned.

The inclusion of the public and the transparency of the advisory service has a special importance for the controversial theme “stem cell research/embryonic stem cells”

For the work of the Enquete-Commission the involvement of the public portrays an important factor. By the transparency of the evaluation and decision making for the public it is ensured that the Enquete-Commission is more present to the public than other commissions. The internet is used in particular to inform and involve the public. For example publications and on-line conferences will be put on the internet. The public should however also be involved in dialogues on the work of the Enquete-Commission. The comprehensibility of the decision
making is being safeguarded through the medium of the internet but also through public events.

The BMBF secures the transparency of the advice – as in the case of the statusseminar – through the dialogue with scientists and business groups. On that the state secretary Wolf-Michael Catenhusen in his opening speech: “Only where science and research mediate their goals and their means to the public in a transparent and understandable way and have discussions can a workable consensus on the important freedom for the medical research and limits for protection of human dignity be reached. The results of the seminar will be made public in a book on the internet and therefore commonly accessible. The BMBF participate through contributions to the public debate and signalises how the evaluation is and where the priorities lie.
The incorporation of advice into policy

Scientific advice already lies in the forefield of law initiatives and therefore flows into the decision making process. The exposure to controversial opinions resulted from pages of the BMBF constructively and realistically. The BMBF prepared itself thoroughly and discussed with the scientists. This does not concern a concluding rendition but a debate. The BMBF places itself therefore in discussion long before drafts on new laws emerge so as to show how they will go about dealing with the scientific arguments. There is a large proportion of trust between science and politics. The dialogue between science and the Ministries will be permanently pushed forward.

Situations changes cause that the question catalogue for scientific advisers will be changed by the BMBF in order to take into account and examine the relevance of different alternatives. With this it is possible that the responsible experts will be called in. Especially in informal advisory circles situation changes will be worked on flexibly. The DFG reacts to situation changes – as for example through the insertion of adult stem cells – by working on a new opinion. The main task of science is to react on the actual developments and research results as soon as they have consequences for politics or research. New knowledge will be exchanged on an informal level with the BMBF.

How opinions arise are not always easy for the public to comprehend. In the case of the statusseminar “The Uses of Human Stem Cells in Medicine – Perspectives and Limits” the transparency was safeguarded through communication. Every advisory process of the DFG is documented and archived so that on request this process can be reproduced.

For the BMBF a use was given through external advice. It was not enough however to answer all the questions on the themes. Therefore it is important to undertake internet research for example, in order to be informed about the research stand in Great Britain and America. The national perspective is not enough.

**Perspective**

The advice on the theme “stem cell research/embryonic stem cells” will be continuously worked on. Especially for the reason of actualising the matter, an independent and continuing exchange is necessary.

The BMBF possesses a so-called early warning system which recognises new developments in science especially through the department heads. In the area of genome research one can also talk about a “linkage” to science. New insights are being promptly informed in both directions, wherefore the advisory system has already developed its own dynamic.

The advisory system is especially dependent on persons who are without ideological coinages about the theme and therefore promptly react as soon as new developments emerge. Therefore wasting time is avoided. With the theme “stem cell research a continuing information exchange at least between the BMBF and the DFG exists.

**Summary of stakeholders**

**The German Research Foundation DFG**

The possibility of cloning humans opens up entirely novel lines of action that confront us with ethical questions hitherto unknown. Answering these questions will require an intensive discussion of all matters concerned. The more so as these activities touch on our basic attitudes towards life and personal dignity. Even a preliminary evaluation by the German Research Union DFG and the Research Council (cf. Annex III and IV) clearly
demonstrated - on ethical and legal grounds - in a first analysis that cloning of humans is ethically unjustifiable as far as aims as well as means are concerned.\textsuperscript{17}

On March 18\textsuperscript{th} 1999, the executive board of the Deutsche Forschungsgemeinschaft (DFG) has discussed and passed a statement concerning issues of human embryonic stem cells. In the last month this paper had been compiled by a group of experts and the senate committee for fundamental questions of genetic engineering called together by the president of the DFG.

The DFG realises that research on and with human stem cells would allow the pursuance of fundamental diagnostic and therapeutical goals, the great potential of which for medicine cannot be assessed yet precisely in its entirety. The DFG is aware of the fact also that for various motives legal and ethical reservations exist against currently known methods of preparing pluripotent stem cells.

The DFG concludes that currently there is no need to alter the German legal status concerning research with human pluripotent stem cells. It is the view of the DFG that the process of shaping opinions concerning ethical and embryological questions in relationship with research on stem cells has only just begun in Germany and abroad. The DFG suggests that this opinion-shaping process should take place on a broad basis and will take part in it. At the same time the DFG will make efforts to work towards the development of uniform European standards in this matter which will include also a due assessment of existential values such as human dignity and health which are fundamental and guaranteed by the constitutional law. With respect to future research on and with human stem cells the DFG believes that under all circumstances measures must be taken to rule out that embryos, sperm cells or oocytes will be allowed to develop from human pluripotent stem cells. In addition, effective measures will have to be taken to prevent cloning of human beings or generation of human beings with artificially altered genetic information. As an appropriate way the DFG suggests the establishment of a central commission assessing research projects with stem cells on the basis of ethical, legal, and scientific point of views, and fulfilling the role also of a supervisory attendant body.

\textsuperscript{17} Statement of the DFG concerning questions of human embryonic stem cells, Alterations of legal status in Germany unnecessary, \texttt{http://www.dfg.de/english/press/spec_inform.html \textbf{)}, Interview with Winnacker, DFG, www.dfg.de/aktuell/v2000_elw.html
The Federal Health Ministry

In May 2000 the German Health Ministry organised a Symposium on reproduction medicine. The discussion activity of the federal ministry should simultaneously smooth the way for the preparation of a fort plant medicine law. A central theme in this context is the role of the so-called pre-implantations-diagnostic (PID) with which the genotype of unborns can be examined. In the frame of this three day symposium the federal health minister, Andrea Fischer on the 26th of May explained that she strives for a new law before the election in 2002 on fort plant medicine that should replace the March ten year old embryo protection law.

With delicate questions on gene-manipulated seeds up to clones the “green” Health Ministry plays on time and rather wants to mediate in conflict situation instead of actively engaging in the decision making process.

The German Minister for Health, Andrea Fisher, warned against making 'hasty decisions' and stressed the need to 'weigh up the pros and cons of possible dangers', according to reports in the German press.

(Cf. Interview with the Federal Minister for Health, A. Fischer, www.dialog-gesundheit.de/imdialog/Interview/Interview27.htm)

The Federal Ministry for Education and Research (BMBF)

On 29 March 2000 a “Statusseminar” has been organised by the German Ministry for Education and Research (BMBF) on the present state-of-the-art in stem cell research in order to obtain actual knowledge on this research area, since only well-founded knowledge is the basis for an open discourse and future decisions on legal conditions. The statusseminar on: "the use of human stem cells in medicine - on the current status, perspectives and boundaries" brought together around 250 scientists, ethics experts, politicians, and theologists from various countries. Apart from the purely scientific aspects also questions of moral responsibility in science and legislation were addressed. In his inaugural address the parliamentary secretary Wolf Michael Catenhusen outlined the problems of stem cell research and its consequences. He stressed that scientists must bring their expertise actively into the ethical discussion in a transparent and understandable way. Catenhusen stressed that while the Federal Government progresses in the preparation of suitable legislative steps, particularly on the reproduction medicine, the BMBF is particularly active in the support and promotion of a transparent public discussion.

• Interview with Wolf-Michael Catenhusen, bmbf, www.wodarg.de/politik/themen_bioethik.html


18 http://berlinews.de/archiv/981.shtml
The Federal Assembly’s Enquete Commission on “law and ethics of modern medicine” is made up of experts and delegates and should during the legislative period, participate in the advice on plans and the preparation of decisions of the Bundestag. In the enquete commission, parliamentary, scientific and practical experience are combined by the equal cooperation of the experts and delegates. It deals with all perspectives, problems, and consequences of the gene technic manipulation of people.

An online discussion on the consequences of genetic diagnostics with 5 representatives from the Bundestag Enquete Commission `Law and Ethics of Modern Medicine´ is planned for November 2000.

The Office of Technology Assessment at the German Parliament

The Office of Technology Assessment at the German Bundestag (Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag, TAB) was created in 1990 with the objective of improving the information base for the deliberations and the decision-making processes of the German Bundestag relating to research and technology. TAB’s work is strictly oriented towards the information needs of the German Parliament and its committees. The political control organ is the Committee on Education, Research and Technology Assessment, which decides on the initiation of TA projects. Motions to start a TA project can be submitted by parliamentary political groups on the Committee on Education, Research and Technology Assessment or in other committees. The Bureau for Technical Assessment of the German Bundestag demanded the Research Centre for Biotechnology and Law of the European Academy for Environment and Economy at the end of 1997 to make a report concerning the legal aspects of animal and human cloning. The report was presented to the German Bundestag to help them decide if certain regulation is needed. In this report the legal situation of animal and human cloning has been examined in the United States and some other countries of the European Community including Great Britain, France, Austria, the Netherlands, Switzerland and Greece

German Reference Centre for Ethics in the Life Sciences (DRZE)

The DRZE’s role is the central, comprehensive and current collection, documentation, provision and preparation of relevant national and international information, documents and literature on ethics in the life sciences, including relevant material from regarding legal, social and scientific issues. The centre aims

• to enable and facilitate access to such information
• to highlight the German contributions to the international debate.

The services of the DRZE are designed to meet the needs of researchers and teachers in the areas of

• the life sciences
• medicine
• ethics
• the law

as well as representatives from

• politics
• the media
• society.

The DRZE makes its services available through a modern reference library and the internet. The work of the DRZE assists in enhancing the conditions for the process of judgment formation; it neither can nor wants to replace that process.

Further stakeholders:

• Akademie für Ethik in der Medizin e.V., Göttingen (AEM) http://www.aem-online.de/main.htm

• Arbeitskreis Ethik in der Medizin, Universität Ulm http://www.uni-ulm.de/uni/intgruppen/med-ethik/index1.htm

• Biotechnik, Gesellschaft und Umwelt - Forschungsschwerpunkt, Universität Hamburg (FSP BIOGUM) http://www.rrz.uni-hamburg.de/BIOGUM/

• Center for Ethics and Law in Medicine, Freiburg (ZERM) http://www.ukl.uni-freiburg.de/zerm/homede.html

• Center for Medical Ethics, University Bochum (ZME) http://www.ruhr-uni-bochum.de/zme/

• European Academy for the Study of Consequences of Scientific and Technological Advance Bad Neuenahr-Ahrweiler GmbH http://www.europaeische-akademie-aw.de/

• German Reference Centre for Ethics in the Life Sciences, Bonn (DRZE)
• http://www.drze.de/

• Institut für Deutsches, Europäisches und Internationales Medizinrecht, Gesundheitsrecht und Bioethik der Universitäten Heidelberg und Mannheim, Mannheim (IMGB)
• http://www.uni-mannheim.de/fakul/jura/imgb/eingang1

• Institut für Ethik in der Medizin e.V., Leipzig http://www.uni-leipzig.de/~ksi/ksi9.htm

• Institut für Geschichte und Ethik der Medizin, Universität Köln http://www.uni-koeln.de/med-fak/igem/

• Institut Technik-Theologie-Naturwissenschaften, München (TTN) http://www.ttn-institut.de/
Institute of Science and Ethics, Bonn (IWE) http://www.uni-bonn.de/iwe/iweframe.htm

Inter-departmental Center for Ethics in the Sciences and Humanities, Tübingen (IZEW) http://www.izew.uni-tuebingen.de/

Interdisziplinäres Zentrum für Ethik, Europa-Universität Viadrina Frankfurt (O.) http://viadrina.euv-frankfurt-o.de/~wwwize/

Ethics Commissions according to § 17 section 7 Medical Products Act (MPG)


Ethik-Kommission der Medizinischen Fakultät der Albert-Ludwigs-Universität, Freiburg http://www.ukl.uni-freiburg.de/zerm/frameset3.html

Ethikkommission der Georg-August-Universität Göttingen http://www.mi.med.uni-goettingen.de/ethik/

**Inventory of the Public Discussion as Displayed by the Media**

The media base their reporting on political events. They do not see themselves primarily as a channel for scientific information, but rather as an arena for political debate. To this extent technology is a clearly political issue in the political and news sections of the media, in contrast to the scientific sections. As such it is generally portrayed appropriately, i.e. giving due consideration to all positions.

Discussion paper by the Federal Medical Association for the preparation of guidelines on Preimplantation Genetic Diagnosis, 03.03.00, http://www.bundesaerztekammer.de/bak/owa/idms.show?id=111920
(Deutsches Ärzteblatt 97, issue 9, page A-525 [DOKUMENTATION: Bundesärztekammer])

The current debate about the discussion paper by the Federal Medical Association for the preparation of guidelines on Preimplantation Genetic Diagnosis (PGD), http://www.bvkm.de/aktuell/02-00/bvpid.html

Ulrich Bahnsen (Die Zeit 2000, Nr. 39, Wissen)

Stefan Winter, Department of Science and Research, Federal Medical Association
Bio-medicine within a European framework
http://www.bundesaerztekammer.de/bak/owa/idms.show?key=statwinter

Ärzteblatt 97, issue 18 of 05.05.00, page A-1198-1200
Brave new world: do we have to do everything we can do?
http://www.aerzteblatt.de/archiv/pdf.asp?id=22814 By Frank Ulrich Montgomery

By Hans Schuh (Die Zeit 2000, No. 10 Bildung und Wissen)
Checking the genetic make-up of embryos: PGD could ease a lot of suffering
http://www.archiv.zeit.de/daten/pages//200010.pid2_.html
Checking the genetic make-up of embryos: PGD ushers in a new eugenics
http://www.archiv.zeit.de/zeit-archiv/daten/pages/200010.pid1_.html
By Volker Stollorz (Die Zeit 2000, No. 10 Bildung und Wissen)

Decision by the Ethics Commission of the Medical University at Lübeck regarding
preimplantation genetic diagnosis
http://link.springer.de/link/service/journals/00481/bibs/9011005/9011s016.htm
By Manfred Oehmichen (Ethik in der Medizin 11 (Supplement 1) March 1999, 5, S16-S22)

Discussion paper for the preparation of guidelines on Preimplantation Genetic Diagnosis:
preliminary remarks
http://link.springer.de/link/service/journals/00481/bibs/0012001/00120044.htm
By Gisela Bockenheimer-Lucius (Ethik in der Medizin (2000) 12, S. 44-45)

From predictive to preventive medicine - Moral aspects of Preimplantation Genetic Diagnosis
http://link.springer.de/link/service/journals/00481/tocs/t9011005.htm
( = Ethik in der Medizin 11 (Supplement 1) March 1999)

Introduction to a public dialog about moral problems in medicine
http://www.bundesaerztekammer.de/bak/owa/idms.show?key=statfuchs
By Christoph Fuchs, Chief Executive Officer, Federal Medical Association
(Bundesärztekammer) and German Medical Conference (Deutscher Ärztetag)

Moral and legal aspects of reproductive medicine
http://www.bundesaerztekammer.de/bak/owa/idms.show?key=statsewing
By Karl-Friedrich Sewing, Chair, Scientific Council of the Federal Medical Association
(Bundesärztekammer)

Open letter from Doctors for Life, Munich, to the President of the Federal Medical Association (Bundesärztekammer) regarding the discussion paper for the preparation of guidelines on Preimplantation Genetic Diagnosis
http://www.aerzte-fuer-das-leben.de/AKTUELL/aktuell.html

Preimplantation Genetic Diagnosis considered as a responsibility
Executive of the Scientific Council of the Federal Medical Association (Bundesärztekammer)
(Deutsches Ärzteblatt 97, issue 17 of 28.04.00, page A-1137)

Preimplantation Genetic Diagnosis: human being from the beginning
Language: German By Joachim Cardinal Meisner (Deutsches Ärzteblatt 97, issue 14 of 07.04.00, page A-888-890)

03.03.00
Preimplantation Genetic Diagnosis: on the edge of a slippery slope
Language: German By Norbert Jachertz (Deutsches Ärzteblatt 97, issue 9, page A-507)

21. September 2000, Präimplantationsdiagnostik rechtlich absichern
Rainer Beckmann (Die Welt, 08/01/2000), "Der Verlust von Menschenleben wird in Kauf genommen" http://www.welt.de/daten/2000/08/01/0801ws183012.htx


Philipp Grätzel (Online Ärzte Zeitung, 08/21/2000), Was erwartet uns hinter dem "offenen Tor zu einem neuen medizinischen Zeitalter"?: Therapeutische Klonen macht Aufzucht von Embryos als Organspender nötig http://www.aerztezeitung.de/docs/2000/08/21/145a1201x.asp


Potential Conclusions

The discussion in the United States about genetic engineering of the human being has escalated much more than in Germany, and much more than in Europe generally speaking. So has the reducing of the human being to his biological design. The perfect model of the contemporary biomedicine, that is the "genetic enhancement engineering" is not shamefully concealed as it is in Germany and in most of the European countries, but openly discussed. Whereas here in Germany the question of whether genetic engineering should be done is debated on, in the United States only the question of How and When is considered.

Another difference: In Germany biomedicine as well as bioethics is being criticised openly. More than 2.5 million signatures have been collected against the Bioethics Convention of the European Council, particularly against research for the benefit of others on people without the capacity to consent. Hereby the criticism relates explicitly to the historical experiences with medicine during the era of the National Socialism, particularly to the Nuremberg Code of 1947. This kind of criticism is exceptionally powerful. After all Germany has not signed the Convention on Human Rights and Biomedicine of the Council of Europe nor ratified it up to now. At the same time this historic relation of criticism is vehemently disapproved of by adherents of biomedicine.


On the one hand legal regulations must not contradict binding standards, but on the other they must be democratically legitimised. The controversial ethical aspects of PID require the setting of political and legal priorities. Such priority setting is already visible in current direct and indirect regulation of PID in connection with different national legal traditions:

1. An extensive guarantee of embryo protection in criminal law: Here, the basic prohibition of PID is valid because of the injunction against treating human life as an object (Germany).
2. The tolerant regulation: Here the individual option as well as the scientific progress option are given special attention. Legal regulation formulates limits on the development and application of PID: strict regulation of indications, binding to special centres or clinics, accompanying genetic counselling, examination by an ethics commission (France).
3. The liberal regulation: Here licensing for the development and application of PID is valid. Licensing is granted on the condition of strict adherence to medical goals (prohibition of basic research), procedural standards and quality control (United Kingdom).
4. Absence of any institutional regulation (Italy, Greece). Any efforts to standardise European regulation of PID (or more generally reproductive biomedicine) must take account of differing national legal traditions as well as binding normative standards and the ethical controversy. Also in connection with this goal, laws must grant points of ethical consensus a legally binding status. Furthermore, the integration of public debate and regulation regarding new developments in biomedicine (like PID) should be striven for on the European level. In order to name points of agreement and disagreement, the above mentioned points to consider must be thoroughly discussed throughout Europe.

Further reading: Legal and Ethical Aspects of Cloning


Winnacker, Ernst-Ludwig; Rentorff, Trutz; Hepp, Hermann; Hofschneider, Peter Hans; Korff, Wilhelm 1997: Gentechnik: Eingriffe am Menschen. Ein Eskalationsmodell zur ethischen Bewertung, München


References and further reading:

- A list of Think Tanks in Germany: [http://www.nira.go.jp/ice/tt-info/nwdtt99/id-eur.html#153](http://www.nira.go.jp/ice/tt-info/nwdtt99/id-eur.html#153)
- Further time series and statistics on the German research system:
  - National Accounts Data: [http://www.diw-berlin.de/diwwbe/eb98-06/n98jun_t.htm](http://www.diw-berlin.de/diwwbe/eb98-06/n98jun_t.htm)
  - German Research perspectives: [http://www.dfg-bonn.de/aktuell/eng_index/perspectives.txt](http://www.dfg-bonn.de/aktuell/eng_index/perspectives.txt)
  - Forschungslandkarte: [http://www.forschung.bmbf.de/](http://www.forschung.bmbf.de/)
- Germany in the citation index: [http://www.iwp.uni-linz.ac.at/LKU/97swn/97swn_c.html](http://www.iwp.uni-linz.ac.at/LKU/97swn/97swn_c.html)
- Literature:
  - EU, European Report on S&T Indicators, pages 107 – 130. (EUR 17639)

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19 The most complete inventory of scientific institutions in Germany can be found at the BMBF ([http://www.forschung.bmbf.de](http://www.forschung.bmbf.de)) since June 1998. The “Research Map of Germany” offers a broad overview of the research activity in Germany. More than 800 publicly sponsored institutions are introduced. The spectrum ranges from institutions of higher education, the Max Planck Institutes, the Fraunhofer Institutes and the Helmholtz Centres, up to specialist information centres and technology transfer centres.
Science and Governance: the Italian case

REPORT ON TWO CASE STUDIES: ELECTROMAGNETIC POLLUTION AND HUMAN CLONING

Andrea Pozzali *

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- The present report has been written by Andrea Pozzali, under the supervision of Riccardo Viale
1 Introduction: a general overview of the Italian structure for scientific advice

When it comes to analyse the relations between science and governance in Italy, and the way in which scientific knowledge is mobilized and used to support government decisions, it is necessary to start from a few preliminary considerations about the role that science plays nowadays in the Italian system as a whole.

It is well known that the Italian system for Science and Research displays, if compared to other European systems, some anomalies, that become quite evident by taking into consideration just a few indicators. The level of expenditure in R&S as a percentage of GDP is at 1,03%, while the average, for the EU, is at 1,9%. The number of researchers every 10000 people is well under the European average, and the difference is particularly strong if one comes to look at young researchers. In Italy, science has still to take the lead in driving the economic development, as it is demonstrated by looking at the low impact of the high-tech sectors in the Italian economy.

The weakness of the Italian system for Science and Research has finally come to the attention of the policy-makers, who have decided to start a rationalizing process. This reorganization has started in 1998, with D.L 204/98, and is currently reaching its conclusion with the final approval of the PNR (National Program for Research), which is due to come in a couple of months. This process will transform the way in which scientific advice enters into the governance process indeed, but in this phase it is difficult to assess the future consequences of the most recent changes.

In this brief overview, we start by taking a look at the way the system has functioned till now, and then we will describe the new bodies of scientific advice that were introduced by the reform.

Generally speaking, the scientific advice structure in Italy doesn’t show a high degree of formalization. We can isolate three different types of level: the governance level, the parliamentary level, and the research institutes level.

At the governance level the most important ministries (e.g. the ones that have to deal with the most technical matters, such as the Health Ministry or the Environment Ministry) have got their own permanent scientific committee, composed by experts nominated by the Ministry himself. These scientific committees have to provide obligatory advice over the regulatory activities, and they can also be invited at any moment to express their advice over relevant questions on the political
agenda. The technical secretariat of MURST (Ministry of University and S&T Research) is in charge of keeping the coordination among these scientific committees. Actually, it seems that the range of competencies of these committees is not very wide: when a specific problem arises, usually an ad hoc committee has to be created to deal with it.

An important moment of communication between the scientists and the government is represented by auditions periodically held at CIPE (Interdepartmental Committee for Economic Policy). As CIPE is responsible for the elaboration and discussion of the guidelines of the economic policy of the State, these auditions come to play a relevant role in the process of allocating funds to the scientific research, and establishing the scientific priority at the national level.

At the parliamentary level, auditions with scientific experts from Italy and from abroad can be held by the permanent parliamentary commissions on every specific matter which requires scientific investigation. Usually these auditions are held during the initial phase of the debate, when the information needed to support the decision-making process must be gathered, but they can be held also in subsequent stages. Also the special commissions, nominated to deal with specific problems, have a high degree of freedom in accessing to scientific expertise and advice in every phase of their activity.

An important source of scientific knowledge is represented by the research institutes. The large majority of these institutes operate under the vigilance of MURST: to name a few, one should mention CNR (Consiglio Nazionale Ricerche), INFM (Istituto Nazionale Fisica della Materia), ASI (Agenzia Spaziale Italiana). Besides them, there are other institutes such as ISS (Istituto Superiore Sanità) and ISPESL (Istituto per la Sicurezza E Protezione del Lavoro), which operate under the vigilance of the Health Ministry and deal with research in the field of public health, ENEA (Ente Nazionale Energie Alternative), which operate under the vigilance of the Ministry of Industry, Commerce and Handicraft, ISTAT (Istituto Nazionale Statistica) and ICRAM (Istituto Centrale Ricerca Applicata al Mare), which operate under the control of the Environment Ministry. All these institutes are independent under the scientific and organizational point of view. They carry on their own specific research, the results of which can be used as a source of information and advice for the policy-makers. They can also be required to provide advice on specific matters.

The picture we have provided is quite a static one: to get a deeper insight, it would be necessary to look at the ways in which scientific knowledge actually enters in the decision making process.
However, in doing so, it’s quite difficult to keep the analysis on a level of generality, because there are a lot of differences between the various Ministries. Seemingly, there’s no general principle of accessing to scientific knowledge, so one has to look at all the different structures and try to describe their operations. The lack of central organizations of advice makes this quite a difficult task, because of the presence of various offices and observatories, each one with a very focused range of competencies and with its own way of functioning. In fact, it seems that the most important sources of advice for the government system are to be found among research institutes such as CNR and ENEA, and not in the Ministerial departments.

Anyway, considering that not every Ministry has its own committee of advice, it would be possible to focus our attention only on the most important Ministries and to try to give a more detailed description of the functioning of the committees operating within them. For this purpose, we may take into consideration the Environment Ministry and the Health Ministry.

The Environment Ministry has got its own, permanent Technical-Scientific Commission. The Commission is made up of 36 experts and it is divided in 5 divisions. Each division is coordinated by a Division Responsible. The Commission gives obligatory advice on the regulatory activities of the Ministry and it can also be required to elaborate specific proposals by the Minister himself or by the Directors of the various Services. As it is required mainly to evaluate and control the Ministry initiatives, it doesn’t seem to have a really active role in shaping the decision making process. Its main range of competencies concern the elaboration of cost-benefit analysis and the ex-post control of the results achieved by the various projects. It also promotes various activities of technical-scientific advice on a wide range of subjects such as the transports policy, the protection of the sea, the protective measures for the Venice lagoon, but it seems that this function plays a minor role in the overall attributions of the Commission.

Within the Environment Ministry there are also other structures dealing with more specific issues: we can take as an example the Technical Secretariat for the Defence of the Soil, which is composed by 20 experts nominated by the Ministry himself and it’s in charge of collecting and analysing data on the hydro-geological situation of the national territory. Even if they are in charge of more specific matters, these structures are similar to the Technical-Scientific Commission since they mainly give obligatory advice an perform ex-post evaluations.
The Health Ministry has a more formal structure for accessing to scientific knowledge. The main sources of scientific advice are the Higher Council of Health and the Higher Institute of Health. The former is composed of fifty members of right (the General Directors of the departments and the services of the Ministry of Health, the Director of the Agency for the Regional Sanitary Services, the Director of the Higher Institute of Health and the Director of the Higher Institute for Worker Security and Protection), plus some members not of right, chosen by the Minister among university professors and other experts. External experts can be convened on occasion. The Higher Council of Health acts on input from the Minister, who can invite it to consider questions of specific interest, but it can also propose in first person the study of important problems and advance opinions concerning the formulation of guidelines for the protection of the public health. Moreover the Council expresses obligatory advice on the regulations predisposed from any central administration that concern public health and on international conventions regarding the same matter. The Council is articulated in five sections, that meet every month. The general assembly gathers every two months. The Minister has faculty to convene the general council, or one of its sections, at anytime.

The Higher Institute of Health (ISS) is the technical-scientific organ of the National Health Service. It is independent from a scientific and administrative point of view, but it operates under the vigilance of the Ministry. It carries out controls, experimentation and researches on every matter of public health in Italy. The Institute is composed from experts designated in part from the Health Minister and in part in representation of other Ministries (the Environment Ministry, the Ministry of University and Scientific and Technological Research, the Ministry of Industry, Commerce and Handicraft, the Ministry of Social Transactions). These experts work together with the Directors of the Laboratories of the Institute.

The Institute collaborates with the Health Minister in the elaboration of the National Sanitary Plan, it advises the government and the regions for the respective sanitary plans, it promotes programs of scientific research, and it promotes conventions and scientific debates at the national and international level.

Another technical-scientific organ of the National Health Service is the Higher Institute for Worker Security and Protection (ISPESL). Also this institutes operates under the vigilance of the Health Ministry, while being at the same time fully independent from a scientific and administrative point of view. ISPESL deals with every matter related with workers health. It carries out activity of advice for the elaboration of national and regional sanitary plans, supplies technical-scientific
standardization of methods and procedures of risk assessment on matters related to workers health and it carries out activity of certification and accreditation of laboratories and organisms of certification.

The technical-scientific committee of the ISPESL is named with decree of the Health Minister. It remains in charge for three years and it gathers at least four times every year. It is composed of experts chosen by some Ministries (Health Ministry, Ministry of Industry, Commerce and Handicraft, Ministry of Social Security, Ministry of University and S&T Research, Ministry of the Interior and Environment Ministry) and other experts chosen by research institutes such as the National Research Council (CNR) and the National Agency for Alternative Energy (ENEA). Within the Health Ministry there are also other important commissions in charge of dealing with specific topics: one should mention at least CUF (Commissione Unica Farmaco) which controls the introduction of medicines on the market, and their prices, and CON (Commissione Oncologica Nazionale) which deals with cancer therapy.

To rationalize the distributed and quite informal structure of scientific advice, D.L. 204/98 has introduced some unified committees that should represent the most important sources of knowledge and advice in the elaboration of the science and research policy. These committees operate within MURST and formulate their proposals to the Ministry himself and to the government. They are:

1. **CEPR (Committee of Experts for the Research Policy):** composed by 8 experts, it has to deal with the research policy and with the evaluation of the national priorities, on the basis of the current tendencies of the research at the international level. It helps the government in the elaboration and monitoring of the PNR. The Committee was nominated in 1999 and it has began to work six months ago, so it’s quite difficult to evaluate its activity at present.

2. **CSN (National Scientific Councils):** they are elected in representation of the national scientific community. They constitute the AST (Science and Technology Assembly), together with spokesmen of the public administrations and of the economic world. CSN and AST formulate observations and proposals for the elaboration of PNR. They also provide advice to CIPE and to other public administrations. The election of CSN and AST is due to come in a couple of months.

With D.L 204/98 and the introduction of central sources of scientific advice, science is likely to have a stronger role in the policy formulation process. However, this reform is at present reaching its end, and we have to wait to see if and how the new system works.
Moreover, the reform will likely affect the way in which the various scientific priorities are selected and evaluated, but it should not have any particular consequence on the way technical and scientific support is provided to the governance. In fact, the reform deals more with problems such as the elaboration of PNR and the evaluation of national priorities than with the restructuring of the present structure of scientific advice. The lack of a rational structure of scientific advice could be interpreted as a sign of weakness and in fact, in the past, scientific advice has been frequently used simply as a way to rationalize decisions taken mainly on a political base. However, changing the structure of scientific advice is not enough, because the question remains open: is scientific advice an important source of knowledge or just an *ex-post* way of legitimating the decisions of the policy makers?
2 The use of embryonic stem cells

2.1 Legislative background

At present, there is in Italy a lack of legislation on the issue of therapeutic human cloning.

It can be argued that human cloning represents the typical example of a complex problematic which raises major ethical and technical questions, and which has arisen too quickly, so that normative decisions in this field are produced with a certain delay.

The only operating dispositions of law are some ordinances emitted between 1997 and 1999 by the then Minister of Health Rosi Bindi. The first of these ordinances is the one of 5 March 1997, which was since then ten times renewed. This provision assumes all the characters of an emergency provision that aims at freezing a potentially dangerous situation, or at least one that could carry various types of consequences not already known.

The text of the provision is very short and it limits itself to prohibit “whichever type of experimentation and intervention, directly or indirectly finalized to animal or human cloning”. In the following decrees it was stated that “the prohibition is not applied to the cloning of transgenic animals used for the production of life-saving medicines or to the cloning of animals species in via of extinction, on condition that it is preventively notified to the Ministry of Health (…) and to the Higher Institute of Health”.

It doesn’t seem that the Minister had based his intervention on any particular kind of scientific advice supplied by the national scientific community. Rather, she took as a base of reference the recommendations provided by the European Community. In the introduction of the ordinances explicit reference was in fact made to directive 98/44/CE of the European Parliament and of the European Council on the legal protection of the biotechnological inventions, that prevented the patenting of any procedures of human cloning for ethical and legal reasons. Reference was made also to the conclusions of the additional Protocol of the Convention of Oviedo, signed from Italy in 1998, which also prohibited the cloning of human beings.
To sum up, the intention of the Minister Rosi Bindi was to prevent any kind of possible private action on the issue of human cloning, so that the Parliament could start an organic reflection on the topic. Unfortunately, the legislative process did not start: currently the Senate is discussing a bill of law, already approved from the Chamber of Deputies, on the matter of assisted procreation. This bill contains an article that prohibits human cloning, but it has to be kept in mind that the main purpose of the bill is to regulate assisted procreation and not human cloning indeed.

From a preliminary analysis of these provisions it appears quite obvious that, in the field of the human cloning, ethics carries out a pre-eminent role in shaping the decisions of the government, and this impression is in some way strengthened if the current developments of the situation are observed with attention.

The decrees of the Minister Bindi are not indeed adequate to regulate such a complex field as human cloning. It has also to be remarked that, as they lack the formal approval of the Parliament, they could not have a strong regulatory power. In fact, this lack of cogency was clearly fixed by the judge in 1999, when Italian researchers succeeded in cloning a calf and the judge did not proceed against them. Moreover, these provisions seem substantially inadequate to cope with the developments that the scientific research on human cloning is currently achieving. It is quite meaningful that the first bank in the world of cerebral stem cells was instituted in these months in Italy, at the Neurological Institute Besta of Milan. The bank is intended to preserve material coming from dead foetuses deriving from abortions and that can be used for future therapies against neurological diseases. The event is of great importance also because it constitutes one of the applications in the European field of the proposals contained in the so-called Donaldson Report, fruit of the job of a group of study that has worked on these topics for two years and was constituted by the English Government.

Also among the European Community the necessity is more and more perceived to start a deeper reflection on the topic of human cloning, that holds account of the developments of the scientific research and that allows to pass from a total ban to a more detailed regulation. It has in fact to be remarked that human cloning could have many useful therapeutic applications, such as the possibility to provide organs for transplantations or to develop new therapies for the cure of cancer.

2.2 Advice structures
Finally, also in Italy the Government approached the issue of human cloning from a new perspective. The competence to arrange provisions in this topic is up to the Ministry of Health, whose structure of scientific advice has been already partially described in analysing the case of electromagnetic pollution. In that case, we have looked at the role played by ISS and ISPESL, that represent two permanent structure of scientific advice.

In the case of human cloning, the current Minister of Health Umberto Veronesi (who has replaced the former Minister Rosi Bindi) has decided to nominate an ad hoc commission with the exclusive competence to supply scientific and ethical advice to the Ministry of Health and to the Government. The Commission of study on the use of stem cells had the specific task to answer to two very precise questions:

- the first question regards the actual possibility of using stem cells to replace damaged ones and therefore contribute to the cure of degenerative diseases;
- the second question concerns which type of cells could represent the best source for the stem cells: fertilized oocytes, foetuses of abortions, blood of the umbilical cord, spinal marrow, adult cells to be reprogrammed.

After having answered to these scientific problems, the Commission had also the task to give answer to some ethical problems raised by therapeutic human cloning, such as which are the limits and the acceptable borders in the utilizations of fertilized oocytes or foetuses of abortions.

The Commission was given three months of time to come up with an answer to the scientific and ethical questions made by the Minister: it was appointed on 20th of September and it finally closed its work by the end of December. The activity of the Commission was aimed more at risk management than at risk assessment: the Commission was called to supply clear indications of policy in order to manage the scientific and ethical problems raised by human cloning. The Commission was made up of 24 experts named directly from the Minister of the Health, and was presided from the Nobel Prize for Medicine Renato Dulbecco.

As it had to answer both to scientific and ethical-juridical questions, the Commission had one mixed composition. Actually half of its members were scientists (among them there was the other Italian Nobel Prize for Medicine, Rita Levi Montalcini, and other experts coming from the greatest Italian research centres) while the other half was made up of lawyers, experts of bioethics, philosophers and theologians.
Another source of advice in matter of human cloning could be represented by the National Committee of Bioethics (Comitato Nazionale di Bioetica, CNB), which was instituted in 1990. However, a few qualifications are needed. If compared to the Commission, CNB has a more permanent character and it also has a broader remit, as it deals with all matters of ethical relevance, linked to scientific and technological progress (obviously, human cloning is just one among these kind of issues). Moreover, CNB does not provide strictly scientific advice: actually, it gives greater attention to ethical and juridical problems than to the assessment of risk done on a strict scientific base. The main functions of CNB are:

- to elaborate summaries regarding the present state of research and experimentations in the fields of biotechnology and healthcare;
- to formulate policy proposals to deal with ethical and juridical problems arising from the current developments of scientific research;
- to promote the wording of codes of conduct aiming at guarantying that correct information is supplied to the public opinion.

The members of CNB are nominated directly by the Prime Minister. At present, CNB is made up of 42 members, for the larger part experts of bioethics and lawyers, but there are also scientists (mainly experts of genetics) and sociologists.

Given the present situation, it seems that CNB could not be considered properly as a source of scientific advice for the problem of human cloning for at least two reasons. First of all, CNB does not deal specifically with human cloning, but it gives generic advice on a variety of problems. Secondly, CNB should be considered mainly as a source of ethical advice, as it’s demonstrated by the fact that, actually, scientists come to play a minor role in it.

Considering this, we have decided to focus our attention on the Commission of study on the use of stem cells, which could be considered the only source of scientific advice for the Government in matter of human cloning.

2.3 The operation of the advice bodies

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1 Also the CNB has prepared by December a report on the therapeutic use of stem cells. This report was anyway dedicated more to ethical than to strictly scientific problems
As the purpose of our study is to analyse and typify the advisory structures in the science-related policy, the case of human cloning in Italy offers some advantages: in this case, in fact, we have a well identified source of advice, which moreover has got a specific remit and a limited time span. For this reason, we can easily draw some general reflections concerning the operation of the Commission.

First of all, it seems that the Italian Government has moved with a certain delay, if one comes to look at what has happened in countries such as UK or the USA, where the reflection on human cloning started a couple of years ago. One of the role of the Commission was in fact to look at what had already been done abroad as a reference base for its conclusions. The possibility to start from the results of the work made by similar group of study, which have worked in UK and in the USA, accounted also for the limited amount of time allowed for the work of the Commissions. The Commission in fact did not have to carry on its own research, nor it had the power to commission specific research (this is also due to the limited time allowed), but it had only to examine the existing literature and comment on it. Maybe another reason that accounted for the limited time allowed was the intention of the Minister of Health not to accumulate further delay on the issue of regulation of human cloning, too.

Finally, it had to be considered that the Commission of study on the use of stem cells cannot be considered as an organ of “scientific advice” in a tight sense, but rather as an organ of “scientific and ethical advice”. The Commission did not in fact incorporate the point of view of the scientific community only, and it was not called to express appraisals of exclusively technical type. The Commission was instead a place in which the different points of view of scientists, philosophers, lawyers and theologians could converge and result in the elaboration of a final output that accounted for all the many sides of the problem in the same time. The questions explicitly placed from the Minister to the Commission were in part of scientific nature and in part of ethical-legal nature. We can say that the work of the Commission could be divided in two phases: the first concerned the answer to scientific problems, the second concerned the answer to ethical ones. If we take a deeper look at the composition of the Commission it seems that, in choosing its members,

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2 If we take a look at the final document prepared by the Commission, this division is confirmed. In the final synthesis we can in fact find the various answers to the questions made by the Minister. Each answer is divided in two well defined parts: a scientific advice and a ethical advice. While there was unanimous agreement on all scientific matters, there was also a division on ethical problems concerning research on embryonic cells that resulted from an over production of embryos for assisted procreation. This type of research was considered acceptable by the majority of the members of the Commission (18 on 25) that refers to the principle of beneficality to justify its decisions. The catholic members of the Commission expressed their negative advice on this kind of research on the basis of the principle of inviolability of the embryo.
the Minister had meant to represent all the possible voices, those in favour of science and those mainly critical in its confronts. It’s quite meaningful that among the members of the Commission were also some of the most critical voices against the dissemination of scientific applications in technological field, such as the Archbishop of Ravenna Monsignor Ersilio Tonini, or the philosopher Umberto Galimberti.

It seems obvious that the problem of human cloning cannot be resolved by science only, as it raises important ethical questions too. But maybe it would have been better to separate in a clearer way the two phases of the reflection on human cloning, by creating a scientific technical group with the task to summarize the point of view of the scientific community on the problem, and then by starting an open comparison between the positions of the scientists and those of the other experts more inclined to pay attention to ethical problems. In this way the dialectic and the debate between science and ethics would have been carried in evidence, concurring perhaps to a clearer definition of the various points of view and a clearer division of the decisional process in distinguished phases. It has been already remarked, while looking at the case of the electromagnetic pollution, that in Italy the scientific advice structures (or at least some between them) cannot be considered as an expression of the simple point of view of science, but that they tend to include in the formulation of their opinions to the executive organs also other considerations of extra-scientific character. The case of human cloning seems in some way to support this affirmation.

As a consequence, as the scientific point of view comes to be more and more confused with a series of other points of view in the centres of institutional advice, the effectiveness of science in orienting the action of government is strongly weakened. Mixed with a series of contrasting voices, which often carry out non scientific values, the voice of the scientists runs the risk to remain (in all or in part) unheeded.

2.4 The interaction between the advisory bodies and decision-makers

The work of the Commission was strictly delimited by the Minister of Health who defined in a clear cut way the questions that the Commission had to answer. This was particularly true for what concerned the scientific problems raised by human cloning. For what concerned the ethical side of the problems, it seems that the Commission had more degrees of freedom: it did not have to provide answer to specific questions, but it could choose the
problem to address. Even in this case, however, the Minister provided a framework to guide the work of the experts.

The Commission operated independently from the Ministry of Health and it only had to present the Minister with a final document, that should represent the basis for the further political process. It should be remarked, however, that some elements of dialogue between the work of the Commission and inputs coming from the Minister or from the Government could be favoured by the presence of a high-level functionary of the Ministry of Health, who was actually the secretary of the Commission. However, this fact was not perceived as introducing any limits to the freedom of work of the Commission.

2.5 The incorporation of advice into policy

At present it’s not possible to evaluate how scientific advice is incorporated into policy: The Commission closed its work by the end of December, and the final report was presented to the public on the 28th of December. The report could represent in the future the starting point for reflections by the Parliament on the matter of human cloning (at least, this is what the Health Minister declared to the newspapers). However, as the period of office of the legislature reached its end, the whole question of therapeutic human cloning will have to be reconsidered by the new Parliament and the new Government.

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3 The report, together with further information concerning the composition of the Commission, is currently available on the web, at the site of the Health Ministry: [www.sanita.it/sanita/bacheca/cellstami](http://www.sanita.it/sanita/bacheca/cellstami).

4 Actually, by looking at the programs presented by the different parties during the electoral campaign, it doesn’t seem that this issue is perceived as having a high priority.
3 Electromagnetic pollution

3.1 Legislative background

In the last twenty years scientific research has become more and more involved in assessing the biological effects that electromagnetic fields can exercise on human organism and the possible consequences on human health. This growing interest has produced on one side an increment in the number of scientific studies aimed at deepening the knowledge of the mechanisms involved in the biological action of electromagnetic fields. On the other side, it has promoted the adoption of norms and regulations which establish limits of exposure to electromagnetic fields for the population and for the workers.

In Italy electromagnetic pollution is restricted by D.P.C.M. n.104 of the 23/04/1992 (for what concerns the low frequency fields) and D.L. n.381 of the 10/9/1998 (for high frequency fields). These norms fix threshold values of exposure for the population, but they are not applied to workers. On the 14th of February 2001, the Parliament finally approved a general policy law that is intended to cover all the different sides of the matter. This law does not fix any kind of threshold value, but it contains a series of general dispositions that are to be specified and implemented by a following decree that is due to come in a couple of months.

Before proceeding in the analysis of the process that ended in the formulation of these norms, some preliminary definitions are needed.

Electromagnetic fields can be classified according to various criteria. The first distinction concerns the frequency of the electromagnetic field. Electromagnetic waves of very high frequencies are called “ionising”, since they can provoke modifications in the structure of DNA. The value of frequency above which ionising effects can be produced is perfectly defined and it is “discreet”, in as much it divides in a clear cut way ionising and non-ionising waves. Electromagnetic waves whit a frequency inferior to 10,000 THz (ten million billions of Hertz) cannot provoke modifications in the structure of DNA.

A further distinction is possible within non-ionising waves. It is the distinction between ELF (Extremely Low Frequency) fields on one side and high frequency fields on the other.
ELF fields (50-60 Hz) are generated mainly by systems of distribution and transmission of electric power and from any kind of electric household appliances, while high frequency fields are generated by systems of radio transmission and by transmitting stations used for mobile telephony.

When it comes to analyse the consequences that electromagnetic fields can have on human health, another distinction is introduced, between acute effects (that arise in a short term) and long-term effects.

The scientific literature reports some possible acute effects connected to cases of exposure to ELF of elevated intensity: in some cases the subjects have perceived feelings of cutaneous tingling and annoyance, in others the vibration of cutaneous hairs has been observed. These effects, produced in particular circumstances of elevated exposure, vary from subject to subject and they do not cause serious sanitary consequences in any case. The analysis of the possible long-term effects of exposure to ELF fields is for many reasons more complicated. In the last twenty years numerous studies aiming at detecting these kind of effects have been produced, but complete knowledge on this topic has still to be reached. The main problem is represented by the fact that the causal mechanism of action of electromagnetic fields has still to be discovered. Knowledge on the long term effects of these fields must for this reason be derived from isolated laboratory experiments on animals or on human tissues, and from epidemiological studies on human subjects. This last type of studies in particular is exposed to all the difficulties and problems that are well accounted for in scientific literature when it has to cope with “injurious agents” that interest only particular groups of population, have extended times of latency (years) and not well defined times of exposure. For these reasons the differences that emerge from epidemiological studies are often of small-medium size and it’s difficult to separate the risk attributable to electromagnetic fields from risks deriving from other confusing factors.

Anyway, the scientific evidence presented by these studies, considered in its complex, does not allow to attribute with certainty long-term harmful effects to the action of ELF fields, even if the possibility that this kind of exposure can increase the risk of leukaemia in small children could not be completely excluded. However, even if it’s quite difficult to assess with precision this increase in risk, it seems that it is of modest entity.

As far as high frequency fields are concerned, the conclusions that one can draw by looking at the scientific literature are substantially similar to the ones reported in the case of ELF.
The evidence in support of possible long-term effects is in this case even weaker, while acute effects are mainly of thermic nature. Electromagnetic waves gradually loose energy as they penetrate inside of the human body, and this lost energy cause an increase of heat. Anyway, this increase of temperature is usually of light entity and it is controlled by the normal mechanisms of thermoregulation.

At the international level an important normative point of reference for the protection from electromagnetic fields is represented by the recommendations of the International Non-Ionising Radiation Committee (INIRC) of the International Radiation Protection Agency (IRPA), that introduce guidelines based on the totality of scientific and research works collected by the World Health Organization. Such limits are based mainly on the consideration of the acute sanitary effects, as the evidence concerning long-term effects is quite controversial, as we have already mentioned. The indications of IRPA/INIRC (and of ICNIRP since 1992) have been taken into consideration by the Council of the European Union in its recommendations on the limit of exposure to electromagnetic fields and are applied in many European countries.

When it comes to look at Italian norms, one has to consider separately ELF and high frequency fields. ELF are in fact restricted by D.P.C.M. n.104 of the 23/04/1992, that has substantially applied the indications expressed from INIRC/IRPA. High frequency fields are on the contrary regulated by D.L. n.381 of the 10/9/1998 which fix threshold values much more restrictive than those fixed at the European level.

The decree establishes in fact that the limit of exposure for the electromagnetic fields with frequency comprised between 100KHz and 300GHz is of 20 V/m. In case of prolonged exposure (more than 4 hours daily), the limit has been further lowered to 6 V/m, that corresponds to a value of density for the electromagnetic field that is between 45 and 90 times lower than the European level. It is quite clear that the diversities between the Communitarian and the Italian regulation are due to the presence of two different approaches to the same problem. While the European Community has chosen in fact to follow the principle of efficiency, concerning itself in the regulation only of the effects for which scientific evidence is available, Italy has based itself on a precaution principle, trying to pursue the maximal reduction of the exposure attainable. The presence of this precautionary principle can be explicitly found in the text of D.L. n.381 itself.
D.L. n.381 has been adopted by the Environment Ministry in conjunction with the Health Ministry and the Ministry of Telecommunications. As this decree applies only to the population but not to professional workers, these same Ministries have prepared a bill of law to come to a global regulation and this is the bill that the Parliament finally approved on the 14th of February. The description of the scientific advice structures that supported the decision-making process at the executive level is contained in the following paragraph.

3.2 Advice structures

The structures of scientific advice consulted by the Government to regulate electromagnetic pollution are the Higher Institute of Health (ISS) and the Higher Institute for Worker Security and Protection (ISPESL). Both of them are permanent organ of technical-scientific advice, operating under the vigilance of the Health Ministry, but with full autonomy from a scientific, economical and administrative point of view.

The advice supplied by these institutes is mainly of a formal character, and it is addressed to executive organs at the national or regional level. It has to be remarked that, as in Italy a clear distinction between risk assessment and risk management is not present, ISS and ISPESL can carry out a general appraisal of the risk, but they can also formulate guidelines for the management of such a risk.

The range of competences of ISS and ISPESL is quite an ample one, as they carry out activities that go from research to professional training, from certification to the organization of conventions and conferences. The activity of scientific advice is therefore only one among the many competences that these institutes carry out. In particular, ISS can be considered as the main source of advice for all issues concerning public health in Italy.

The Institute:

- collaborates with the Health Minister in sanitary and scientific programming;
- promotes programs of national interest for the protection of public health;
- carries out activity of advice for the government and the regions;

\(^3\) Since 1992, the place of this committee was taken by ICNIRP (International Commission on Non-Ionising Radiation Protection).
• promotes programs of scientific research on the relationships between health and environment;
• proposes programs and clinical experimentations of national interest;
• carries out, in collaboration with the Higher Institute for Worker Security and Protection and with other agencies or administrations that take care of the production and employment of the thermoelectrical and nuclear energy, activity of advice for the protection of public health;
• participates to international activities finalized to the protection of public health;
• carries out functions of accreditation of laboratories and organisms of certification;
• stipulates national and international agreements of collaboration with administrations, agencies and associations for the development of particular researches relating to its institutional tasks;
• assumes initiatives of professional training of the National Health Service staff;
• promotes conventions and scientific meetings at the national and international level and participates with its own experts to national and international conventions;
• spreads the result of its activity of research.

ISPESL has got a more specific remit, as it deals mainly with issues that can carry consequences for the health of workers, but its range of competencies is in any case quite ample.

The Institute:
• carries out activity of advice for the elaboration of national and regional sanitary plans;
• supplies technical-scientific standardization of methods and procedures of risk assessment on matters related to workers health;
• carries out activity of certification and accreditation of laboratories and organisms of certification;
• supplies technical-scientific advice to the Ministry of Industry, Commerce and Handicraft for the vigilance of the conformity of products to safety requirements;
• carries out research activity and professional training for the National Health Service staff in fields related to worker health.

The composition of the institutes of scientific advice mirrors the scientific competences and the levels of expertise present on the national territory as scientists and researchers of proven experience work in both ISS and ISPESL. The scientific committees of ISS and ISPESL are formed from experts named in large part by the Health Ministry and in smaller measure from other
Ministries potentially interested in the activities of these institutes. The scientific Committee of the ISS is made up of 15 experts designated directly from the Health Minister, 1 expert in representation of the same Health Ministry, 1 expert in representation of the Ministry of University and S&T Research, 1 expert in representation of the Environment Ministry, 1 expert in representation of the Ministry of Industry, Commerce and Handicraft, 1 expert in representation of the Ministry for Social Affairs, the Directors of the Laboratories of the Higher Institute of Health and some elected representatives for the biological and technological disciplines.

As far as electromagnetic pollution is concerned, it has to be remarked that experts from ISS have been (and are still) involved in the work of both INIRC/IRPA and ICNIRP.

The technical-scientific committee of the ISPESL is named with decree of the Health Minister. It remains in charge for three years and it gathers at least four times every year. It is composed of six experts chosen by the Health Minister, six experts designated by the Permanent Conference for the Relationships between the State and the Regions, the director of the Higher Institute of Health, an expert designated by the National Research Council, an expert designated by the National Agency for Alternative Energy, an expert designated by the National Institute of Assurances for Industrial Accidents, an expert designated by the directors of the central departments of ISPESL, and other experts designated by the following Ministries: Ministry of Industry, Commerce and Handicraft, Ministry of Social Security, Ministry of University and S&T Research, Ministry of the Interior and Environment Ministry.

3.3 The interaction between the advisory bodies and decision-makers

We have already seen that Italian norms on electromagnetic high frequency fields fix threshold values that are far more restrictive than the ones recommended by the European Community, and this “anomaly” could be explained by the different approaches to the electromagnetic pollution problem. While UE operated on the basis of an efficiency principle that take into account only unquestionable scientific evidence, Italy has followed a precautionary principle, according to which the lack of sure scientific data does not represent a sufficient guarantee against possible long-term risks still unknown, given the present state of knowledge. The diversity of the two approaches appears with particular evidence in relation to the problem of long-term effects of electromagnetic high-frequency fields. As the scientific knowledge does not allow to attribute to these kind of fields any type of long-term effects, the European Community has decided to concentrate only on acute
effects. For this type of effects incontrovertible scientific data are indeed available, and are represented from the indications of INIRC/IRPA and of ICNIRP. It has to be remarked that Italy was the only country of the UE to vote against the recommendations of the Council of the European Union, on the basis that these recommendations did not take into considerations long-term effects of electromagnetic high frequency fields.

The precautionary approach of the Italian Government has not only led to the adoption of limits far more higher than those suggested by a scientific approach. It has had also important consequences in the framing of the whole problem of electromagnetic pollution. Glares of that can be found in the text of the general policy law approved in these last few days by the Parliament. This law is not aimed at fixing explicitly the threshold levels of exposure, as this task has to be taken by following implementing provisions, but it introduces some key concepts that would have to guide the action of the legislator. The first concept is the “limit of exposure”, defined as the “value of field (…) that does not have to be exceeded in any condition of exposure, for the protection of health from acute effects”. This concept is not a novelty, since it is contained also in European recommendations, but the law introduces also two terms that are peculiar of the Italian situation. The first term is the “attention value”, defined as the value of field not to be exceeded for the protection from possible long term effects. The second term is the “quality objective”, defined as the value to be achieved through the use of available technologies and methods of reorganization, and aimed at minimizing the exposure of the population and of the workers as far as it’s technically possible.

The introduction of this terminology establishes a clear separation between the limits aiming at the protection from acute effects (based on sure scientific data) and the measures aiming at the minimization of the possible long-term effects (based on a precautionary principle and aiming at reducing the exposure of the population at the lowest level technically possible, without paying attention to scientific data).

Looking with greater detail at the phases of the decisional process that led to this provisions we can see on one side that a kind of divergence has been produced inside of the structure of scientific advice itself; on the other side we can detect how the final decisions were strongly influenced by factors of political convenience.
The presence of a possibilist attitude relative to the presence of risks due to long term action of electromagnetic fields can be found in many relations of the Higher Institute of Health\[6\]. In these studies explicit reference was made to the necessity to find an equilibrium between the criterion of efficacy and the precautionary principle, and to refer preventive actions to the certainties available on the scientific plan. For this reason, even if the possible existence of health damages from chronic exposure was recognised, ISS researchers thought that it would have been somehow premature to fix new limits based on the result of the epidemiological available studies. The evidence presented by these studies did not allow in fact “to optimise the intervention on the basis of an efficiency principle”. The Higher Institute of Health, after having recognized that further knowledge on the biological mechanisms of electromagnetic fields was needed in order to fix a limit for the protection from long-term effects, invited however to take into consideration solutions to contain and to reduce the exposures of the population, with particular attentions to situations where small children were involved.

The position of ISS appears therefore imprinted to the attainment of a fair compromise between the requirements of efficiency, that impose to take into consideration only scientific evidence, and the requirements of caution, with particular reference to the exposure of the most sensible subjects.

ISPESL has instead adopted a different approach, that we can define a “pragmatic-technological” one. In this approach the emphasis has been placed almost exclusively on the precautionary principle. Following this general principle, the main objective of normative action is to fix the threshold values that allow to minimize the exposure of the population, holding in account current technological ties. It clearly appears that in this type of approach the reasons of scientific research assume a secondary role.

It has to be remarked that ISS and ISPESL, in January 1998, have presented to the Government a joint document which explicitly recognize that cognitive uncertainty cannot be invoked as a justification for non intervention. The document also remembered that, in environmental matters, situations in which scientific data are insufficient in order to assume definitive decisions are almost the norm, and anyway even in these situations a decision must be taken. The document contained in addiction references to the recommendations of ICNIRP for what concerns the protection from acute effects.

What is quite interesting to underscore is that following this document ISPESL has decided to present on its own a proposal for the protection of the population from long term effects, and it’s precisely in this proposal that we can find the threshold value of 6 V/m that was then adopted by D.L. n.381. On the contrary ISS, remaining coherent with its own position, did not think opportune to fix threshold values for the protection of population from long term effects as long as scientific evidence on these effects is lacking.

In the case of electromagnetic pollution a particular situation has therefore arisen. In fact the uncertainty on the role that scientific knowledge ought to play in the decisional process was produced not in the dialectic between government bodies and structures of scientific advice, but inside of the structures of scientific advice themselves. This fact can perhaps be a consequence of the fact that in Italy we can’t speak of “pure” structures of scientific advice in a strict sense. The existing structures of scientific advice carry out in fact a wide range of functions and they do not have the exclusive competence of scientific advice. Moreover these structures are not limited to supply data and scenarios for the risk assessment, but they can also formulate their own policy proposals and in doing so they can also take into consideration principles which are not, closely speaking, scientific. In a certain sense, it can be asserted that a certain degree of “political compensation” between scientific interests and extra-scientific values (such as economic, ethical or political influences) takes place inside of the structures of scientific advice themselves. In other words, what often comes out from documents and notes of the structures of scientific advice cannot be considered simply as the point of view of the scientific community, but as a policy proposal that already contains a certain degree of mediation between the point of view of the scientific community and other points of view.

If this is the situation, it does not come to a surprise that the final result was the production of a normative that does not rest on sure scientific evidences, but is the fruit of many different influences.

In conclusion it has to be remembered that, after the adoption of the D.P.C.M of April 1992, which fixed the limits of exposure to ELF fields in full agreement with the indications of the INIRC (adopting therefore the point of view of the international scientific community), many Italian Regions have reacted by proposing more restrictive regional laws. The first to take the lead was Veneto Region, that in 1993, on initiative of the Green regional group, adopted a provision that lowered the levels of exposure by a factor of 500. Considering the possible consequences that a
similar provision could have had for the activities of distribution of the electric power, voices against the law, with ENEL in front line, at first succeeded in freezing and then in indefinitely suspending the provision. Anyway this fact was by itself enough to generate an intense debate on electromagnetic pollution, and the example of the Veneto Region was followed from other Regions that proposed similar legislative provisions to assure the maximum level of protection compatible with technological and productive requirements. The presence of these laws has heavily influenced the following interventions of the government. When the moment has arrived in fact to fix with D.L. n.381 the threshold values to be applied on all of the Italian territory, one of the preoccupations that have surely guided the decisional process was the will “not to mark a step behind”, by fixing limits that could be less restrictive than those already fixed from some Regions. This was done in part in order to avoid disparity between various zones of the country, and in part in order to impede possible political controversy eventually fuelled by those political parties that are particularly involved in environmental protection.

3.4 The incorporation of advice into policy

As a conclusion, we can draw a brief summary of how scientific advice relative to electromagnetic pollution was incorporated into policy. In order to do this we must make a separation between the positions expressed by ISS and those expressed by ISPESL. There is in fact enough evidence to support the conclusions that these two institutes have chosen different lines of actions. Having to deal with a problem of “scientific uncertainty”, ISPESL has decided to rely almost exclusively on the precautionary principle, and this position had a clear impact on decisions made at the political level. In contrast the position of ISS, which tried to balance the necessary precautionary needs with a greater attention to the available scientific evidence and to recommendations made by international bodies of advice, did not succeed in orienting the decision-making process. The final outcome of the decision-making process was also heavily influenced by extra-scientific factors, and particularly by pressures made by political forces strongly involved in environmental protection (Green Party) and by other organizations of consumer and labour protection. It has to be remarked that the Government had also to take into considerations the various regulatory policies of Italian Regions. Looking at the positions held by some of these Regions, it appears quite evidently that different political orientations led to different decisions and only the most restrictive regional laws were able to drive the decisions at the national level.
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Science and Governance: the Swedish Case  
Göran Andersson

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1 An Overview of the advisory process

1.1 Some Swedish governance basics

The Parliament appoints the Prime minister who gets the mission to form the Government. The Prime Minister appoints all other ministers by himself. The government appoints committees, decides on committee instructions, bills and regulations. All government decisions are made collectively. This means that even though all matters are prepared in concerned ministry and signed by concerned minister, the minister first has to present the matter in a government meeting were the other ministers are present and agrees with the proposed decision. Thereafter the concerned minister signs the decision, and thereby makes it official.

An important government bill is the yearly budget bill, where all allocations of the states financial resources are presented for all areas. The government often uses the budget bill as an opportunity to launch new ventures and in the cases where new or changed law-text are needed it is presented here.

Beside the budget bill there is of course a number of government bills proposed to the Parliament throughout the year with different levels of policy significance.

In Sweden the organisation of the government office differs from many other European countries in a way that might create special conditions and structures for how scientific, as well as other, advice is processed. The Government Office consists of ten rather small ministries plus the Prime Minister’s Office. In addition, the Government Office also has a number of public authorities (national boards and agencies), whose main purpose is to implement the Government’s policies. These authorities work rather independently and several of them have the right to decide on regulation in their area. Even though the main purpose of these agencies is to implement and administrate Government policies, they are important actors in the policymaking process as well. Many of them employ a number of researchers and/or have their own research departments. Therefore they can utilise networks of researchers nationally as well as internationally. Since the government offices is relatively small the ministries (the politicians as well as the civil servants) have to rely on these sources as an important source of information.

One example on such an agency is The Swedish Gene Technology Advisory Board. This board was established in 1994 with the task of following the international and national development in the gene technology area, cover ethical matters and through counselling promote a safe and ethical use of gene technology. The members of the board are appointed for three years and consist of a chairman and a vice-chairman, both experienced judges, and fourteen other commissioners. Seven of these are members of the Parliament and the rest are researchers nominated by different research councils.

Besides national agencies and boards, civil servants in the government office have to build and use their own networks of reliable informants. An important part of this are scientists at universities, institutes and other organisations. The networks are used in different phases of a policy making process and they might also work as a way for scientists to initiate or promote action by the government office.
1.2 How does scientific advice finds its way into policy decisions?

In order to understand how scientific advice is used in the policy making process, a short description of this process will follow. In the end there will be a concluding text that tries to focus some important aspects of the process.

In this context policy decisions can be divided into two groups, parliament decisions and government decisions.

A large number of government decisions are made every year. Most of them are not policy relevant but a number of them are. It concerns matters like instructions to committees, appointing members of committees, etc. These decisions are mainly part of preparing government bills for parliament decisions and will therefore be described under relevant headline in the following text and not further discussed here.

All parliament decisions are prepared according to a rather strict procedure/formalised process created to ensure that relevant competence and all different aspects and viewpoints concerning an issue will be taken in consideration before the final decision is made by the parliament. Of course in reality there is always room for criticism of how the system really works.

This formal procedure can be broken down into a number of steps where scientific (and other) advice may be influencing or affecting the process.

1. An issue arise
2. Instructions (for a committee) are written
3. A commissioner is nominated and a (temporary) committee is formed
4. The work of the committee/The report
5. The matter is being referred for consideration
6. The government bill
7. The standing committees work
8. Final proposition to the parliament

1. An issue arise
The origins of what finally is made into a new law or other policy decision may of course be of very different nature. It may be part of the political ambition/program of the government, an initiative taken by a civil servant responsible for an area (and of course supported by the minister of the ministry). Sometimes it is science and technology that put an issue on the political agenda as in the case of research on human embryos and stem cells. Another common motive is ”Firefighting” – more or less ad hoc, emergency issues that has to be dealt with, often with a lot of media attention.

Issues that are judged important enough are normally dealt with by appointing a committee. The first step in that process is to write the committee instructions.

2. Instructions (for a committee) are written
There are some general formal guidelines for how committee instructions should be written, but they do not say anything about the use of science or scientific advice. A civil servant or group of civil servants within the concerned ministry/-ies carries out the major work. At this stage the knowledge and the contacts/network in science-
community of those civil servants will have an effect on the formulation of the instructions. It is also common for there to be a lot of negotiation between different ministries about formulations. Finally when everybody agrees to the formulations, the instructions are made official through a government decision. In the decision the time limits for the committee are also fixed. Over the last years there has been some criticism towards government not giving committees enough time to do a proper job. As a contrast it might be mentioned that not to long ago, quite a lot of criticism was put on government for setting up to long investigating committees as a way of postponing important decisions.

The next step is then to appoint the committee who is supposed to fulfil these instructions. Where issues are judged especially important, the government appoints a parliamentary committee, with members of the parliament from all political parties.

3. **A commissioner is nominated and a committee formed**

There are no formal guidelines for how commissioners should be appointed other than general regulation for work in government committees (SFS 1998:1474). How the nomination process is handled seems to differ from ministry to ministry and from issue to issue. The government also nominates experts for the committee and decides on how large the committee should be. A common way to compose a committee is to have a dialogue between the nominated chairman of the committee and the ministry about what other persons that should be part of the committee, but the final decision is always made by the government.

Since there are no formal guidelines or criteria that can be referred to, this phase of the process is handled in different ways. The minister may use his staff of civil servants to screen the field for competent persons, discussing important criteria, and after that make the official decision. But the opposite could also be the case – closed processes where the minister (and his closest advisors) appoints people. Both ways it is rather informal and not that open to public scrutiny. This uncertainty might be seen as a democratic problem, but it is supposed to be regulated mainly when the committee report is being referred for consideration (see step 4). If a committee has done an inadequate job it is expected to be discovered during the referral process and strongly criticised.

4. **The work of the committee/The report**

The instructions decided on by the government set the framework for the committee’s work. The committee works independently even though it formally is a part of the Government Office. It is free to call in experts, arrange hearings and in other ways collect knowledge and viewpoints from stakeholders. It is also common that stakeholders approach the committee with suggestions and information in order to ensure that their interests not are overlooked. So there are meny possibilities for scientific advice to be counted in this stage of the process. To what extent it is actually done does probably differ from committee to committee.

An example of a committee is the Government Committee on Bio-Technology under the Ministry of Education and Science. The committee was formed in October 1997 as a Parliamentary Committee, with members of the Parliament, representing all parties in the parliament, as commissioners. There are no scientists in this committee. The overall task for the committee is to investigate the possibilities and risks of modern Bio-Technology. More specific tasks are specified in the instruction [http://www.bioteknik.gov.se/index.html](http://www.bioteknik.gov.se/index.html). The committee will end their work in December 2000. So far the committee has collected material from a number of relevant
areas (such as agriculture, forestry, health and industry). This material is based on scientific material as well as discussions with different interest groups. The committee has also produced some preliminary concluding texts. All of the material is available on Internet or as paper documents and the committee is asking for comments from anyone that is interested.

A committee’s conclusions and propositions are normally presented as a report published in the "Statens Offentliga Utredningar (SOU)"-series (The States Public inquiries).

When the committee report is presented, the Government is basically faced with two alternatives. Either they put the report on the shelf (and the reasons for that may vary), or they proceed with the propositions in the report in order to get them to the Parliament. Then, according to the constitution, the report has to be referred for consideration.

The government can however chose to instigate a new investigation if, for example, the problem at hand has shifted in some direction during the committees work or if the government thinks that some part/aspect of the problem not is satisfyingly dealt with. Sooner or later the government has to decide whether to go on or drop the subject.

5. The matter is being referred for consideration
Before the Government takes a stand based on the committee report the matter has to be referred for consideration. In order to get opinions on consequences of the propositions from all relevant stakeholders the report is sent out to all concerned authorities, organisations and communities. Who is considered a stakeholder and thereby gets on the mailing list, is based on the selection made of concerned ministry. The mailing list is discussed and negotiated within the government offices. Normally the stakeholders should have at least three months to answer. The referral is compulsory for public agencies and must be in written form, even if it is just to say that there are no remarks or opinion. All other organisations, authorities, communities and single citizens are free to criticise the committee report if they want.

This step in the process also provides good opportunities for different scientific advise/advisers to be heard. Many government agencies have their own research departments and/or links to scientists/scientific expertise. Often quite contradictory opinions between different organisations and agencies are revealed in this process. All these documents are official and they are often referred in media, especially if some organisation is very critical to the committee’s suggestions.

This part of the formal process is seen as important in order to safeguard the democratic process. In many ways this really is a very open process. Concerned stakeholders put effort in criticising the outcomes of reports and sometimes propose alternatives.

The different referrals are compiled by a civil servant and used as an input in the Government bill.

6. The Government bill
Civil servants in the concerned ministry/ies write a draft text that is processed and reviewed with other civil servants and politicians in an internal process. It finally ends up in the Government Bill proposed to the Parliament.
When the Bill is put on the Parliament’s table each and every one of its 349 members has the right to make a counter proposition within three weeks. At the same time the bill is examined by concerned standing committee/s in the parliament. There are 16 standing committees covering different areas such as education, foreign affairs, defence, etc. Every committee consists of 17 Members of Parliament distributed in proportion to the party’s relative size in the chamber.

7. The parliamentary standing committees work
Every committee has its own staff of civil servants that prepares the matter by putting together the government bill with counter propositions, gathering complementary information and viewpoints from various sources. The responsible staff member then presents the matter for the committee. In order to get the best possible basis for their committee-report they may arrange hearings, interview experts or representatives for different interests or organisations.

This means that again there is an opening for scientific advice (and of course a lot of other influences as well) to influence the final outcome of the parliament decision.

8. Final proposition to the parliament
When the standing committee-report has reached the chamber the matter is settled in a plenary session. In some cases there is a debate before voting. But at this stage nothing really influences the final decision.

When the voting is over and the decision made it is the government who is responsible for carrying it out.

1.3 Some short conclusions
Policy decisions are prepared according to a rather formalised process that utilises scientific advice as well as other sorts of advice. This process is quite open and transparent with some self-regulating elements.

Important structures are also the personal networks of the civil servants, the political staff and the minister and the scientists that are part of those networks. These resources may be used to raise an issue, formulate committee instructions and appoint committee members and in the process of writing government bills. These inputs are not that transparent and easy to see. They are informal and more ad-hoc.

The national agencies and boards are important providers of scientific advice to the Government and the Parliament. Since they employ a number of scientists they can utilise large networks of scientific knowledge, digest it and provide the government office with it – either as a part of the agency’s mission, as part of a Government investigation, or at a personal level.

Government committees and Parliament standing committees have good access to scientific advice. How, when and to what extent they use it are questions that needs further investigation.
2 Advisory bodies on Stem-cells

2.1 Introduction

The case of stem cells is a poor case in showing how science is a part of the policy making process as, in Sweden, no policy decisions have been taken so far. There is no legislation directly concerned with stem-cells. There is one Act, established in 1991, concerning operations on fertilised eggs from humans, for the purpose of research or treatment (SFS 1991:115). This act basically states that research and treatment experiments on fertilised eggs are only allowed until the fourteenth day after fertilisation, after which they must be destroyed. There is widespread agreement that this law must be modernised since it was constructed before the stem cell technique was known but so far nothing has been done.

A more extensive legislation is the Environmental Code. The thirteenth chapter in this act is concerned with gene-technology. Stem cells are not explicitly mentioned but are implicitly part of the wider concept of GMO:s. This act is not very detailed, rather the opposite. There are general rules of consideration under the Environmental Code which also apply to gene technology activities. The fundamental rule of consideration means that anyone initiating an activity must perform the protective measures, observe the limitations, if any, and take the precautionary measures that are required in order that the activity do not harm human health or the environment.

2.2 Legislative background

As has been mentioned, there is no legislation directly concerning stem-cells. Only the Environmental Code that regulates how GMO:s should be treated.

Extensive work has been laid down to reform Swedish environmental law. This has resulted in the Environmental Code which came into force 1 January 1999. 16 acts have now been amalgamated in the Environmental Code among them the Genetically Modified Organisms Act. The main environmental statutes have been amalgamated into the Environmental Code. The provisions of the Environmental Code are aimed at promoting sustainable development whereby present and future generations will be guaranteed a healthy and acceptable environment. Sustainable development is based on the insight that nature is worthy of protection and that the right of humans to alter and utilise nature is linked to a responsibility to manage nature well. There are general rules of consideration under the Environmental Code which also apply to gene technology activities. The fundamental rule of consideration means that anyone initiating an activity must perform the protective measures, observe the limitations, if any, and take the precautionary measures that are required in order that the activity do not harm human health or the environment. The responsible authorities have issued Regulations on genetically modified organisms within their respective areas.

The main amendment to the GMO Act when incorporating it into the Environmental Code was to require clear GMO-labelling. The competent authority (CA) shall in its decision require that a clear labelling of the product be made.

An investigation is ongoing to analyse the existing structure and division of responsibilities between competent authorities. It is carried out by a Parliamentary Committe on Biotechnology, which was established with the aim of analysing the
possibilities and risks of modern biotechnology to society. The Committee shall report on its conclusions in the beginning of December 2000.

Other important pieces of legislation regulating GMOs are the Novel Foods Regulation (258/97) that has been implemented in the Swedish Food Act as well as transport requirements in the Transport Act and health aspects of medicinal products in the Medicinal Products Act.

The objectives of the Swedish GMO legislation, which covers contained use as well as deliberate release and placing on the market of all types of GMOs, are to protect human and animal health and the environment, including taking into account the ethical aspects of any activity.

2.2.1 Contained use
In the new Directive 98/81/EC four classes are recognized. This is in line with the Swedish procedures. The Swedish legislation differs from 90/219/EEC in the sense that it classifies GMMs into four categories instead of only two. Category 1 in the Swedish legislation is equivalent to that of Directive 90/219/EEC, whereas GMMs classified into category 2 in the directive has been classified according to category 2, 3 and 4 in Directive 90/679/EEC on biological agents. The safety measures needed for these categories are thus also valid for GMMs.

As contained use of other GMOs than GMMs is regulated on a national basis Sweden has adopted its own rules. In order to use GMOs in a facility, such as a laboratory, greenhouse, growth chamber etc. where a GMO never before has been used, the facility must be approved by the CA. Prior to any use of a facility previously not used for GMOs, users shall report to the CA about their intention. The report shall contain information on the user(s), location of the facility, description of the facility and technical arrangements which are relevant to safety, the organism(s) to be used including introduced or modified traits and waste management. Unless the CA has not responded negatively within 90 days from receiving the report, the facility can be used for GMOs. It is to be noted that the legislation does not require a report on facilities used for GMOs before 1 January 1995 when the legislation came into force. Such facilities are regulated through inspections.

A user must also report to the CA prior to any contained use that it is of a commercial, industrial or large-scale nature. In this case the report shall contain information about the genetically modified organism(s), source and purpose of the introduced genetic material, the purpose and scale of the contained use and an environmental risk assessment. If the CA has not within 60 days opposed to such an activity, the user can proceed.

In both the above cases the CA is entitled to ask for additional information that might be necessary for assessing the safety of the contained use. If, during inspection, the CA finds any facility inadequate with regard to safety measures, additional safety measures can be required or the operation stopped.

2.2.2 Deliberate release and placing on the market
For deliberate release into the environment and placing on the market of GMOs the Swedish legislation is more or less identical to Directive 90/220/EEC regarding
notification procedures. Consequently, no deliberate release and placing on the market of GMOs can take place without an explicit consent. It is, however, stated in the Swedish legislation that a consent is valid for five years unless otherwise stated in the consent.

2.2.3 Ethical aspects

Sweden has unlike most other member states a clause saying that ethical aspects must be considered before issuing a consent. One of the primary tasks of the Gene Technology Advisory Board is to ensure that such ethical concerns are taken. The discussion on ethics and gene technology in Sweden has mainly focused on transgenic animals and the use of human and/or animal genes in food crops. Ethical considerations have recently also been brought up in relation to the use of antibiotic resistant marker genes, particularly in food and feed plants. So far no notifications have been rejected for ethical reasons in Sweden.

2.2.4 Authorities concerned

- Arbetarskyddsstyrelsen (the National Board of Occupational Health)
- Fiskeriverket (the National Board of Fisheries)
- Gentekniknämnden (The Swedish Gene Technology Advisory Board)
- Jordbruksverket (The Swedish Board of Agriculture)
- Kemikalieinspektionen (the National Chemicals Inspectorate)
- Livsmedelsverket (The National Food Administration)
- Läkemedelsverket (The Medical Products Agency)
- Naturvårdsverket (The Swedish Environmental Protection Agency)
- Skogsstyrelsen (The National Board of Forestry)
- Bio-Teknikkommittén (The Parliamentary Committee on Bio-Technology)
- Statens Medicinsk-Etiska råd (The Medical-Ethical Advisory Board)

The Swedish Environmental Protection Agency and the Swedish Gene Technology Advisory Board have consultative and co-ordinating roles. The prescribing authorities have an obligation to consult these co-ordinating authorities regarding new GMOs and before issuing regulations. The Environmental Protection Agency shall report yearly to the European Commission on the control of the use of products placed on the market and on consents given for contained use of genetically modified microorganisms. The Gene Technology Advisory Board shall support a justifiable use of GMOs from an ethical point of view.

The only agencies/committees worth mentioning when it comes to stem-cells are: The Medical-Ethical Advisory Board (MER), The Swedish Gene Technology Advisory Board (GTN), and The Parliamentary Committee on Bio-Technology. GTN and MER are two somewhat overlapping but mostly complementary bodies.

2.3 The Advice structures concerned with stem cells

2.3.1 The Medical-Ethical Advisory Board (MER)

MER was formed in 1985 as respons on a parlimentary debate on ethics concerning transplantations from dead humans. The Parliament thought they did not have have the
compete to make good judgements. So they wanted a body that could discuss difficult ethical issues and give advice to the Parliament. It was formed with inspiration from Denmark and France. Nowadays most European countries have something similar, but Sweden is unique by having Members of Parliament on the advisory board. The motivation is that they represent the general public. Besides them there are representatives from concerned ministries, scientific expertise from different areas, including ethics. In total the group consist of approximately 20 people that meet 10 times a year.

The role of this advisory body has so far just been to keep itself informed on what is going on internationally and nationally, concerning stem-cells.

2.3.2 The Gene Technology Advisory Board

The Gene Technology Advisory Board that was formed in July 1994 is a governmental authority with an obligation to follow the national and international development in the gene-technology area, survey ethical issues and through advice promote an ethically defendable and safe use of gene-technology in order to protect the health of humans and animals.

Another duty of The Board is to spread knowledge about developments in the gene-technology area. The Board shall notify the Government if any area of application or any planned use of gene-technology may be questioned for ethical or humanitarian reasons.

The full directives for the board is to be found in The Instruction for The Gene Technology Advisory Board (Förordning (1994:902) med instruktion för Gentekniknämnden)

The Gene Technology Advisory Board produces a yearly survey of the developments in the gene-technology area and this should contain information on how research and development has been affected by the Environmental Code.

The Gene Technology Advisory Board is made up by a chairman, a vice chairman, both lawyers and experienced judges. There are fourteen other members of the Board. Seven of these are MPs representing all parties in the Government. The other seven are scientists, nominated by different research councils. One of them is an expert in ethics. The Board also has a small office with one administrative director who is scientist himself and has a large network of contacts in research in the area.

2.3.3 The Parliamentary Committee on Bio-Technology

The Parliamentary Committee on Bio-technology was formed with the task of:

- analysing the possibilities and dangers of modern bio-technology;
- judging the long term effects of possibly changes due to modern bio-technology;
• framing propositions for an overall policy for the area in an international perspective;
• promoting debate and discussion concerning bio-technology and its consequences for the individual as a patient, employee, employer, etc.;
• analysing how knowledge, values, and other factors form attitudes towards bio-technology;
• identifying the issues that may need an extended judgement of consequences and a deeper ethical discussion;
• judging the need of education to raise the level of knowledge on bio-tech. in different sectors of society;
• judging opportunities and identifying obstacles for Swedish industrial development in bio-tech; and finally
• reviewing the present organisation of public authorities for permits, auditing and information in order to propose new work forms.

The committee was formed, under the Ministry of Education, after a promise made in the Parliament by the former Minister of Education, Carl Tham, as a response to a debate on bio-technology. The directives (above) given were not very specific and the committee has therefore had to judge where to focus their work.

The committee has been made up by a chairman from the Ministry of Justice and nine MPs, three social-democrats and one from all the other parties of the parliament. There were no experts appointed to the committee, which is quite rare, but the reason was that, given the broad task of the committee, too many experts would have been necessary over the long-term. Instead experts have been called in when the committee has judged it relevant.

The committee also has a few committee secretaries, performing all the writing and administration of the committee. They are people with a good knowledge on the issue and personal networks giving access to experts. They have, for example, been searching for recent articles in scientific publications and summarising them for the MPs on the committee.

2.4 The operation of the (different) advice bodies

Both the Medical-Ethical Advisory Board and The Swedish Gene Technology Advisory Board are permanent advisory committees. The Parliamentary Committee on Bio-Technology has been working since the autumn 1997 and dissolved in December after presenting their report. That report will contain propositions on how the public authorities concerned with bio-technology will be organised in the future. All of the bodies are formal sources of advice. Their audience is not just restricted to the Government – they are seen as a source of advice for the executive, the legislature and the general public.

MPs that sit on the committees are nominated by their party group while other members are nominated by the concerned ministries. In general the civil servants of the unit responsible for the issue are asked by the Minister to propose names of suitable candidates. It is then down to the personal networks of the civil servants to produce the necessary committee members.
All three of the committees/boards discussed tend to look around at the available scientific evidence and then summarise it. They do not commission new research themselves. If the expertise on the committee is deemed as insufficient then further experts can be called in to answer the committees questions.

The operations of the committees are transparent. The openness of public authorities in Sweden is very large and quite unique in Europe. Transparency is a key word and the Swedish Act on Secrecy states that everything is public unless otherwise claimed. Reasons for not releasing information could either be that it is classified as confidential business information (CBI) or that its release could harm intergovernmental relations.

2.5 The interaction between the advisory bodies and decision-makers

Although all three committees do have particular remits these are rather broad and within this they have had a large amount of freedom regarding the selection of issues that they examine. This reflects the Swedish tradition where public authorities tend to have a great deal of independence from the Government Office. There are differences between Ministries with regard to how they interact with "their" committees and authorities but this relative independence is always maintained. Since the Swedish Ministries are quite small in European comparison, the number and the size of different agencies/boards and committees are quite large and employ a lot of professionals/highly educated people. Therefore these bodies are frequently asked to comment on different relevant policy options. This is seen as a very important part of the policy making process in Sweden.

2.6 The incorporation of advice into policy

As no policy decisions regarding stem cells have been taken so far in Sweden, it is difficult to comment on what the impacts of advice will be. However all three described committees seems to have been able to incorporate scientific knowledge and advice quite well and balance it with the more ethical concerns of the general public. The mix of politicians and scientists in two of the committees has been seen as a learning experience for both parties.

Although the position of the scientific advice is perceived as quite strong it is impossible to untangle this from many of the ethical concerns. As such, the three committees provide an example of how politicians handle uncertainty. The two permanent committees are there to handle ethical questions and to notify the government of new issues on an early stage by collecting information on science and development. The Bio-Tech committee was formed as a direct consequence of a parliamentary debate on the issue and many of its tasks are aimed at reducing uncertainty (see above).
3 The EMF case

3.1 Background Legislation

As in the case of stem-cells there is no particular legislation in Sweden regarding the health effects of EMFs. The reason for this is that the politicians have not yet found any reasons or it. The government has for many years let investigations keep them updated on research, but so far no facts has been judged serious enough to motivate legislation. The Environmental Code could be used as a general legislation as it is stating that it should be applied in such a way that the health and environment of humans should be protected against damages and accidents whether they are caused by pollution or otherwise.

3.2 Important advice structures

The Swedish parliament recognised the issue of hypersensitivity to electricity and electric fields in a couple of parliament reports in 1993 and 1994 (1993/94:BoU17 EL-överkänslighet and 1994/95:BoU18 Byggnaders inomhusmiljö m.m.) They also pointed at the importance of more research in hypersensitivity to electricity. The Standing Committee on Housing declared that powerful and efficient measures had to be taken to deal with the issue. At the same time they stated that no generally accepted explanation of its causes was at hand. The conclusions the Standing Committee drew were first that the knowledge about the factors behind hypersensitivity to electric fields must improve. Second, they stated that the knowledge and practical experience gained so far had to be systemised and transferred to concerned organisations.

Against that background, the Government, in November 1995, commissioned The Swedish Council for Work Life Research (RALF) to follow up and gather the results from research in the area, present ongoing as well as planned research projects and present the amount of money allocated to research on this topic.

The Council presented its results in the autumn of 1996 stating that it is very difficult to define hypersensitivity to electric fields and that it was therefore not possible to get a realistic opinion of the size of the problem. The report contains a discussion of how well different factors are validated and what different research areas should be further developed in the future.

In the Government Bill on Research and Society (Regeringens proposition Forskning och samhälle 1996/97:5, september 1996) The Government concludes that in spite of the relatively large amount of resources spent on research on EMF, no consensus in interpreting the results has been reached.

As a consequence, the government in the same bill proposes that RALF is again commissioned to present a research overview and to evaluate Swedish as well as international research results. With that evaluation as a base, a ”consensus conference” should be arranged. This mission was, in November 1997, prolonged until 1 December 2000, after a proposition from RALF to the government. The reason was that they had learned that WHO was working with the same mission and RALF wanted to await the WHO-report. The mission was also complemented with the mission to write interim-reports to the government in March every year 1998-2000.
In a recent Government Bill on research call "Research and Renewal" (Forskning och Förnyelse, Regeringens proposition 2000/01:3) the government proposes a new organisation and structure of public funding of research. In this reorganisation RALF will be split in two halves that merges with two other new research funding agencies. In the Bill the government states that the new “Research-council for Working-life and Social Sciences (my unofficial translation of the name. No official English name yet decided) takes over the responsibility to judge the remaining need for research on risk to human health from EMF.” In other words, this means that the government leaves it to the new research council to decide if there will be any more money spent on this type of research program. The basis for their judgement should to a great degree be based on the upcoming RALF report as well as the WHO report.

The text above pinpoints RALF as the most important advice structure in the Swedish system even though there are some other public bodies are concerned with special aspects of EMF. That is mainly The Occupational Safety and Health Administration in Sweden (Arbetarskyddsstyrelsen) and The Swedish Radiation Protection Institute (SSI).

The National Board of Occupational Safety and Health is a central administrative authority with the general duty of observing developments in the work environment sector. It is the supervisory authority of the Labour Inspectorate. The main tasks include the following:

- issuing Provisions and/or General Recommendations by authority of the Work Environment Ordinance, and transposing EC Directives to the body of Swedish regulations, which together with the Work Environment Act forms the basis of the Administration’s supervisory activities;
- deciding appeals, complaints and working questions;
- carrying out supervision in keeping with the priority targets;
- taking part in and influencing EU regulatory activities in the work environment sector (drafting of Directives and standards);
- carrying out product-oriented supervision, market control included;
- taking part in Government consultation procedures and responding to enquiries;
- supporting the Labour Inspectorate in its supervisory activities, e.g. through measures for the development of knowledge and methods
- carrying out information and training measures;
- taking charge of the official statistics concerning the working environment and the Occupational Injury Information System (ISA) compiling input data for the Government; and
- transmitting Swedish work environment know-how to countries where work environment standards are lower.

EMF is right now taken under consideration by the Board and the EC directives\(^1\), will be used in Sweden without any further restrictions together with a “recommendation of carefulness”.

The Swedish Radiation Protection Institute, SSI, is another government authority with the task of protecting people and the environment from the harmful effects of radiation. SSI ensures that the risks and benefits inherent to radiation and its use are compared and evaluated. SSI also develops competence on radiation to minimise the risk involved for

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\(^1\) Council Recommendations on the limitation of exposure of the general public to electromagnetic fields (0-300GHz), Document 8550/99 DG I, 5 july 1999.
the individual. SSI decides the dose limits for the general public and for workers exposed to radiation and also issue regulations which, through inspections, it ensures are being followed. SSI provides information, education, and advice, carries out research and also administers external research projects. The research carried out has so far been on ionising radiation from nuclear plants, radon, etc.

SSI keep contact with the National Board for Worker Safety on the issue. Both authorities normally use and rely quite heavily on different scientific resources in their work.

Returning to RALF as the most important “advice structure” in the case of EMF in Sweden, we need to go into some more detail of how they have worked with the EMF-issue, in order to be able to use our typology.

RALF has basically had two different but interrelated lines of action on the issue of EMF. The first is allocating research funding in a program for EMF research. The second is the specific action taken to handle the mission the government gave them in 1996.

Starting with the first, there is approximately 8 Million SEK per year allocated to RALFs research program on EMF. There are approximately 20 to 25 different research projects running on a continuing basis. The projects normally last one to three years. This program was up and running before they got the mission from the government and according to the interview person (IP) the mission has so far affected the program quite little, and it will probably go on in the new.

The second line of action is the activities taken to fulfil the government mission. RALF appointed two experts who have formed a work-group together with the responsible for EMF research program. In order to prepare for the prescribed ”consensus conference” three workshops were arranged. A limited number of experts were invited to each workshop (6-10 people). Additionally, the association for Electricity or Monitor damaged participated with one representative and one expert of their choice.

Every workshop was aimed at giving answers to limited number of questions. The experts were asked to prepare written as well as oral answers on the questions specified for each workshop. Each workshop resulted in a documentation consisting of referrals of the discussion as well as the written answers on the work-shop specific questions.

The workshops were concluded with a public hearing. It was advertised in the six major newspapers in the country. Anyone who wanted to contribute with his/her experiences was welcome to make an oral statement at maximum ten minutes or write the statement down on maximum two pages. The hearing resulted in 30 oral statements and over 400 written statements. Together with the documentation from the tree workshops this formed a base for the concluding consensus conference in april 2000.

The aim of such a conference is to map out which different statements on an issue where there is consensus among the participants. The result is of course depending on the choice of participants. In this case all participants from the workshops were invited. Also RALFs reference-group and priority-group for the research programme EMF

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2 Consists mainly of representatives from employer and employee organisations.

3 Consists of a number of EMF-researchers that evaluates applications for research funding.
were invited, as well as representatives from the ministries of Industry, Social welfare and Environment. The conference resulted in 11 statements all participants agreed upon. They concern; areas of hypersensitivity to EMF (definition, lack of scientific knowledge, treatment, etc), information and risk-communication, continued research. A lot of the documentation made is also available on Internet, which makes it easy accessible for a large part of the Swedish general public as well.

RALF has also made three interim-reports, in the last three years. They have been sent to the Government office and have probably contributed to keeping the question alive in the latest government Bill on research.

RALF is now in the final stage of writing the final report, which will be an important input into the new research council’s work with this issue.

An experience both RALF and the government office have is that people who claim that they are hurt by EMF do not feel that they are taken seriously and they see the unsupportive or mixed results from research with great scepticism. Sometimes accusing government for using biased experts, etc.

3.3 General points

The advice structures dealing with EMF must be seen as very permanent. RALF was formed in 1995 through mergers and splits of older public research funding councils and it will disappear again in 2001 through a split. But the issue of EMF was started before RALF was formed, and as the latest government Bill proposes, the issue will live in the new organisational structure.

The research RALF support is to a relatively large degree basic research (as opposed to applied) in order to fill a gap of basic knowledge. That research could be used for different purposes, but will probably need to be more application oriented to be useful for either politicians or public authorities in the short run. The aim is not to provide the politicians with solutions but to produce a platform most stakeholders agree upon, and hopefully give some kind of direction as to reasonable lines of action. As such, RALF, through the workshops, the hearing and the final consensus conference, has undertaken both risk assessment and risk management. By highlighting basic research a lot of risk assessment has been done and by creating a number of meetings with important stakeholders and experts, the knowledge on how to manage risk is spread, at least to some degree.

Generally speaking, RALF, as well as other concerned authorities, employ people with good own knowledge on the issue. They also build up personal networks of contacts with researchers and other experts they judge as trustworthy and reliable that they can utilise when necessary. And of course in the cases when they commission research, the results are in some way incorporated in their knowledge. In this case, where RALF was commissioned by the Government, there were two external experts nominated to work with RALF. They have been criticised by interest groups as they have also performed for a large Swedish mobile phone company. This has actually made the upcoming report less useful for the Government office.
3.4 Operation of the advisory bodies

As already expressed in the text above, the Government commissioned RALF to summarise national and international research. However, their normal operation is to commission research on working life. In order address the task given to them by the Government, RALF has used a number of experts as well as listening to the concerns of other stakeholders, with, for example, the strongest interest group being able to appoint an expert of their own.

The EMF case has seen uncertainty due to a lack of knowledge and lack of consensus around the present results from research. This has created two complementary lines of action. First the Government and RALF have called for more (basic) research. Second, while waiting for results from that research, Sweden has followed EU guidelines. A number of national agencies have agreed on and proposed a “principle of caution”, a set of guidelines for decision makers dealing with issues that may expose the general public to EMF.

The transparency of all national agencies in Sweden is quite high where very far reaching legislation obligates all public authorities to make all decisions and the material used, background material, reports, letters, etc, public. Many boards and agencies are also commissioned to mediate their specific knowledge to different target groups. Many agencies use the internet as an important information platform and the general public is able to gather quite a lot of information from the agencies homepages. EMF is no exception. One example is the yearly reports (and the upcoming final report) RALF was commissioned to produce. They are all available on internet as well as on paper (to order from RALF). A further example is The Swedish Radiation Protection Institute, SSI, who supply information on what EMF is, and reports on research on basestations, etc.

3.5 The interaction between the advisory bodies and decision-makers?

As described earlier, Swedish National agencies and boards normally work quite independent of the government. There is a strong tradition and policy that the Minister or the Ministry should not interfere in day to day business or single cases. The Ministries draw up framework regulations and targets for the agencies. In return the agencies have to describe what they have achieved according to these targets in their yearly reports. Sometimes the Government commissions an agency to do a special investigation in addition to their standard operations. A good example of this is the commission to RALF to summarise research on EMF. Within the framework set by the government, the agency is quite free to choose what they want to investigate.

The quality and quantity of the interaction between the government and the advisory body differs considerably from case to case. As an example, RALF experience a very low interest from the government office for the investigation on EMF. They have not received any feedback on their reports so far and the Ministries have not participated in conferences and hearings in a way RALF expected. On the other hand, on a more general level, national agencies and boards are frequently used as important bodies to
which a proposed measure is referred for consideration. That is also a mandatory step in the process of writing a government bill and it is very important as a “Quality control” of the propositions the government wants to propose.

One interviewee claims to have experienced deliberate incorrect use of the referral system. By letting a large number of boards, agencies and interest groups take part in the referral, the government ended up with a situation where they could state that a (large) majority of the organisations where supportive, or did not object, to the propositions. Thus hiding or neglecting that a few but very important agencies opposed to the propositions.

3.6 How is scientific advice incorporated into the policy process?

When it comes to EMF it is quite obvious that uncertainty surrounding the issue has led the Government to ask for more information. They have not been willing to make any decisions, either for or against the different technologies causing EMF, based on the present state of knowledge. By commissioning RALF to summarise research, using a three-year period, it may of course be interpreted as a way of buying time, hoping that the public interest fades away.

One IP points out that in general, the government propositions on this type of issue do not have the characteristics that requires that much of scientific advice. There are normally more legal and ethical matters at stake, but since there has been no propositions presented yet it is hard to say how scientific advice or knowledge is going to be handled in the EMF case. Overall the interviewees agree that science and scientific advise receive high importance in policymaking, but as one interviewee express it, “the more politicised an issue gets, the lighter is the weight of scientific advice”.
# Science and Governance: the UK Case

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1 An overview of scientific advisory structures in the UK

1.1 Introduction

Scientific advice is playing an increasingly important role in the formulation of policy at both the national and international level. The UK has seen much reflection on the use of scientific advice in policy making in recent years, partly due to this increase in importance, and partly due to the loss of public confidence in the Government’s use of scientific advice resulting from the BSE issue.

One response to the issues surrounding scientific advice was the publication in 1997 of “The use of scientific advice in policy making” by the Office of Science and Technology (OST) (OST, 1997). The implementation of these guidelines was reviewed in 1998 (OST, 1998) and 1999 (OST, 1999) and an updated version, “Guidelines 2000” was published in July of this year (OST, 2000a). The Guidelines “sets out key principles applying to the development and presentation of scientific advice for policy making” (ibid., p.1) and covers the processes of:

- identifying issues requiring scientific advice;
- obtaining the best possible advice from a wide variety of sources; and
- handling of advice by departments

The Guidelines apply to all areas where scientific advice is required, whatever the source of the advice, but it is seen as particularly important that they are followed when there is significant scientific uncertainty, a range of scientific opinion, or where there are potentially significant implications for sensitive areas of public policy (ibid., p.2).

The implementation of the Guidelines is seen as a priority of the Ministerial Science Group, which was established by the current Minister for Science, Lord Sainsbury. The establishment of this informal ministerial committee, which includes members from all Government departments with an interest in science, engineering and technology, is seen as a reflection of Lord Sainsbury’s commitment to restoring the public’s confidence in the Government’s use of scientific advice (OST, 1999).

In addition to the Guidelines on the use of scientific advice, the Government recently began a consultation exercise on a proposed code of practice for scientific advisory committees. The aim of this Code of Practice is to “encourage good practice across all scientific advisory committees and ensure that the minimum standards are followed in certain key areas of these committees’ operation” and “should help committees translate into day to day practice, the principles behind the Guidelines” (OST, 2000b, p.2-3).

As well as these cross Government initiatives, the public concern over biotechnology prompted a review of the advisory and regulatory framework specifically for biotechnology. This has resulted in a number of changes to the advisory structures in this area (Cabinet Office and OST, 1999) and will be discussed in more detail later. The Government has also commissioned a “Review of the risk procedures used by the

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1 The exercise is due to end on 1 December 2000 (OST, 2000b)
government’s advisory committees dealing with food safety” (May, 2000) that provides interesting insights into how risk is dealt with by advisory committees.

This interest in the area of scientific advice is taking place in the context of wider changes in Government. The White Paper on Modernising Government laid out the Government’s view on the operation of public services, focusing on three main aims: to ensure that policy making is more joined up and strategic; to make sure that public service users, not providers, are the focus, by matching services more closely to peoples lives; and to deliver public services that are high quality and efficient (Cabinet Office, 1999). The ‘Better Regulation Guide’ is another area that may have an influence the scientific advisory structures. The guide is aimed at policy makers and emphasises the importance of; transparency, accountability, targeting, consistency, and proportionality.

1.2 Sources of advice

1.2.1 Across Government

Looking across Government the UK has what could be described as a devolved structure of responsibility for science matters. Individual departments have their own R&D programmes and when there is a need to seek external scientific advice it is the departments who take the lead. There are differences between departments in how this is handled. For example, the Ministry for Agriculture, Fisheries and Food (MAFF) has a centralised research programme managed by a central unit. When money is spent on scientific advice there will usually be an interaction with this central unit. By contrast, in the Department of Environment, Transport and the Regions, R&D responsibilities are devolved to individual programmes within the Department and the programme managers usually take decisions regarding the need for external advice. Within most departments there is someone in the position of Chief Scientist (or equivalent). However, it is arguable whether this means any more than that the position exists.

At the highest level, The Chief Scientific Adviser (CSA), who is as head of the Office of Science and Technology, provides advice to the Prime Minister, Cabinet, the Secretary of State for Trade and Industry, and the Minister for Science on science, engineering and technology matters. He his supported in this by the Transdepartmental Science and Technology Group. In their function of ensuring that transdepartmental scientific issues are being properly handled, the CSA has regular meeting with the chief scientists. However, he does not have line management responsibility for the network of chief scientists – the CSA is not the head of profession in the same way as other heads of professional specialisms such as law or economics. Hence, while there are mechanisms for dealing with cross-departmental issues, this falls short of a formal, controlling superstructure.

In addition there is the Chief Medical Officer (CMO), the Government’s principal adviser on medical issues. While this appointment is located in the Department of Health, the CMO has direct access to Ministers in all departments.
1.2.2 Range of sources of external advice

Many cases where a scientific input is needed in the policy process are relatively humdrum and can be dealt with in-house by a department’s own staff. However, if issues are particularly contentious or there is just not the required in-house expertise then departments will rely on external experts. There is a huge diversity in way external advice can be sought and departments will decide on the best approach depending on the issue to be dealt with.

In describing the scope of “Guidelines 2000”, the range of possible sources of scientific advice used by departments is reflected (see Box 1 for further details), “The Guidelines apply to all areas in which scientific advice is ought and whatever the sources of scientific advice to Government: whether in-house or from sole external experts; standing or ad-hoc advisory committees; contract research from academia, industry or commerce; independent research or elsewhere” (OST, 2000a, p.2).

Such a range of sources for advice is seen as desirable as it allows information to “be drawn from a variety of sources and monitored by those responsible in the department concerned, as an ‘intelligent customer’ for science, engineering and technology” (ibid.)

The multifarious sources of scientific advice within, and used by different departments are reflected in the second annual report into the implementation of the guidelines on scientific advice (OST, 1999). Examples include:

- Ministry of Agriculture, Fisheries and Food (MAFF) – “the advisory committee system plays an important and integral part in building science into policy. Most scientific advice and the results of MAFF funded research are considered through the advisory committee system before recommendations are put to Ministers”. In addition to this MAFF procedures include, “regular dialogue with other scientific advisers and interested groups in the UK” and the Foresight initiative is used to help identify possible problems. MAFF policy divisions are staffed, in certain areas, with specialist scientists who carry joint responsibility for policy and scientific activities. All this is overseen by the Chief Scientists Group (CSG)

- Ministry of Defence (MOD) – The MOD Chief Scientific Adviser (CSA) is “a full member of the top decision making bodies in MOD”. MOD procedures include “close day to day contact between scientists and policy staff on many wider matters as well as defence research programmes and through the use of advisory committees”. The principle sources for MOD of information on the latest developments in science and technology is the Defence Evaluation and Research Agency (DERA) and the Atomic Weapons Establishment.

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2 DERA (Defence Evaluation and Research Agency) is an agency of the UK Ministry of Defence, incorporating the bulk of the UK Ministry of Defence’s non-nuclear research, technology and test and evaluation establishments. DERA is one of Europe’s largest research organisations with a turnover of approximately £1 billion.

3 Atomic Weapons Establishment (AWE) is managed and operated on behalf of the Secretary of State for Defence by AWE plc. The shares in AWE plc are held by AWE Management Limited (AWEML), a joint venture company created with the specific purpose of performing the management and operations contract for AWE. AWEML is jointly owned by British Nuclear Fuels plc (BNFL), Lockheed Martin UK Limited and Serco Group plc (Serco).
• Department of Environment, Transport and the Regions (DETR) – DETR has an annual research budget of around £150 million and nearly all research is commissioned through open competitive tendering procedures. Other sources of advice for DETR include their Non Departmental Public Bodies (NDPBs), other Government departments and the voluntary sector. “DETR also places emphasis on utilising international research”.

• Department of Health (DH) – The DH’s policy directorates are increasingly making us of the Department’s own research programmes to bring together national and international research findings. DH has a considerable number of scientific advisory committees that advise on new scientific developments and present recommendations for further work. DH keeps abreast of international developments through networking and more formal arrangements such as participation in working groups set up by international bodies. The Medical Research Council also supplies Independent advice on medical issues of concern.

1.3 Purpose of advice structures

The review of the advisory and regulatory framework for biotechnology (Cabinet Office and OST, 1999) identifies two distinct functions for the regulatory and advisory system. Firstly, it considers approvals for individual products or processes, for example, assessing the environmental or health implications of a specific food to be licensed. Secondly “it sets a strategic framework for the development of the technology in this country” (p.4). The review concludes that a new approach is needed for this second function and as a result two new biotechnology-specific bodies have been established that will work alongside the Food Standards Agency. These new bodies, the Human Genetics Commission and the Agriculture and Environment Biotechnology Commission, have much wide ranging remits. This includes,

“strategic analysis of biotechnological developments, addressing broader issues including ethical considerations regarding the acceptability of genetic modification, identifying gaps in the regulatory and advisory framework, and building up a picture from the lessons learned from individual areas.” (p.ii)

While these new bodies will stay in close touch with the regulatory/technical bodies they will not control the individual committees work.

The advisory bodies can take a number of forms. They may have a statutory function, where they have been established by specific pieces of legislation and are expected to advise Ministers on the exercise of their powers under that legislation. Alternatively they may be non-statutory and offer advice on specific matters of interest, or when there is need to consider wider issues. Another distinction, within DETR for instance, is that between advisory NDPBs, which have a purely advisory role, and executive NDPBs (e.g. English Nature), which, in addition to an advisory role, are also involved in the implementation of policy. There is diversity between advisory committees in terms of the formality of their rules of procedure, the clarity of their terms of reference, and their freedom to interpret their role. The role, as opposed to the formal remit that may be set in legislation, of committees can evolve. In an uncertain world, there needs to be a degree of flexibility so that if a problem evolves the committees’ role can evolve in order that it can be discussed.
In the review of risk procedures used by Government advisory committees dealing with food safety (May, 2000), a distinction was made between committees that were concerned solely with risk assessment and those that also dealt with risk management. Risk assessment was defined as a “scientifically based process consisting of: hazard identification; hazard characterisation; exposure assessment; and risk characteristics” (p.18). Different committees did this in different ways, with some carrying out formal risk assessments, while others tended to rely on expert judgement. The process of risk management is seen as distinct from that of risk assessment and involves, “weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other [relevant] factors… and, if needed selecting appropriate prevention and control options” (p.18). It is recognised in the review that “historically it has not always been clear where the responsibility of the advisory committees’ end and those of Government begin. Sponsoring departments have not always been sufficiently precise about exactly what risks they were asking Committees to assess or the scope of the risk management work commissioned” (p.4)

The idea of risk management by committees can be contentious. One of the criticisms around the BSE affair was that, by asking the question ‘is beef safe’, the Government of the day abdicated a policy decision to the scientific advisors. However there is the point of view that the scientific advisors should be asked to have more involvement in the policy side. They could be presented with a number of policy options and asked to comment on what they would mean from the point of view of the science, or they could be asked to draw up policy options regarding what they see as necessary from the scientific point of view. Another area where the advisors should perhaps have more involvement is in the interpretation of the scientific advice, as it may be the case that it is not fully understood by officials. There is the issue here of why science should be ring-fenced and treated as different when it is just one aspect of a decision in the policy process.

This question of what is expected from the experts is an issue that is taken up in the “Guidelines 2000”. It is stressed that Departments need to carefully consider how best to frame the questions that the experts will be asked to answer, and should at a minimum discuss the questions with the experts. They also stress that, “it should be made clear to the experts which of the various possible roles they are being asked to perform. These can include: collection and analysis of new scientific data; review of existing data; interpretation of research from different sources; application of expert judgement where data is lacking or inconclusive; identification of policy options open to departments; and providing expert scientific advice upon policy options proposed by departments. Different sorts of expertise may be required for different roles” (OST, 2000a, p.3).

One of the aims of the proposed Code of Conduct for scientific advisory committees is to clarify whether experts really know what their role is. For example, are lay members there to provide opposition, to go along with the scientists or to try and seek consensus? The need to clarify the role of lay members of scientific committees is something that has been raised by the Select Committee on Science and Technology in their review of the scientific advisory system.
1.4 Selection of Advisor’s

Committees are not appointed according to any uniform process, there is no single statute that says what a scientific advisory committee should look like. The departments select advisers and it is generally a case of trying to get the best advice possible. In the Select Committee report on the use of scientific advice in GM issues it is stressed that “Ministers must, however, secure appropriate expertise on advisory committees rather than attempt to give representation to any particular groups” (Science and Technology Select Committee, 1999). The need to select people on the basis of their expertise is also emphasised regarding the question of scientists affiliations, the select committee recommends that,

“the Government rejects proposals to bar employees of biotechnology or food companies from serving on scientific advisory committees. It is vital that appointments to scientific advisory committees should continue to be made by selecting people with the most suitable and relevant expertise”.

The Select committee also rejected the assumption that researchers integrity is immediately compromised by association with industry. Members of committees are expected to declare their interests and may not take part in discussions where there is any conflict. However, it is recognised that the Government should not deny themselves the expertise of the most appropriate people.

The Guidelines recommend that the committees should not just consist of scientific experts and there is an increasing tendency to involve lay experts, ethicists, consumer group representatives’ etc. They also recommend that where it is likely to benefit the process, e.g. if it is an issue that has already been experienced by another country, then experts from outside the UK should be used.

It is recognised that there is perhaps a need to be more open about how advisors are recruited so that the public can see how a committee is constituted. Recently, the Food Standards Agency took a step towards a more open selection process when they advertised in the national press for appointments to the Veterinary Products Committee, looking for candidates with experience of food chemical safety issues and the assessment of risks to the consumer. However, there is the question of whether this is the best way of recruiting the most appropriate people.

1.5 Operation of advice structures

One of the aims of the Guidelines was to try and ensure that the process of seeking scientific advice became more transparent. The advantage of transparency is that you can see the workings so you know the information that is used in order to come to a decision. Both the guidelines and the code emphasise that results should be published so that outsiders can know where decisions came from. Even with this you may not be able to convince critics that the decision was right but you do remove the possibility of arguing that there was a secret agenda. Should help improve the general level of confidence in the process. A possible problem relates to the fact that a balance needs to be struck between decision making and the length of time that you prepared to spend consulting. You need to decide on the importance of a decision, if committees become unwieldy because they have to go through so many procedures then when can the decision be made?
As a result of this move to try and ensure transparency in the scientific advice process, many committees now publish annual reports, summaries of meetings, or minutes of meetings. It is also expected that any data, particularly if it has not been peer reviewed, that is used in the advice process should be made available to the scientific community.

Such efforts are necessary to not only demonstrate that the advisors themselves are acting independently but also as a check that the committee is not being pushed by a department to arrive at a particular decision.

### 1.6 The science/policy interface

#### 1.6.1 Incorporating science into policy

How the scientific advice is incorporated into the policy process is subject to a range of opinions some suggest that there should be a formalistic model where scientific advice is differentiated from other forms of advice and subjected to a formal procedure before policy decisions are made on it. People who argue for this approach see it as important that the scientific questions are sorted out from the other questions, to ring-fence the scientific advisors so that they only focus on the scientific questions and come up with a scientific output. This can then be presented to policy decision-
makers who can either accept or reject it, but if they reject it they will have to explain why.

This can be seen as a simplistic model. In many of these areas the scientific advice is not cut and dry – there is no definite answer. It may be difficult to untangle the scientific issues from other ethical, legal, social, political etc. issues and it may be undesirable. You may want to develop the scientific case alongside these other issues. Another reason for not ring-fencing science is that science is often only one component of a decision so why give science a higher standing than other factors in a decision.

In general the advice is likely to be discussed with officials, rather than being 'presented' to a Minister. There is often a dialogue whereby certain advice may give rise to further questions that are taken back to the advisors. One advantage of this more iterative process is that the considerations of a committee are just a snapshot – the issues are likely to change over time. This is recognised in the Guidelines and they suggest that committees should consider how long their advice can be reasonably expected to stand for before review, or what events might cause the advice to be changed.

1.6.2 Uncertainty

The uncertain nature of much science and scientific advice can present problems for the advisory/policy interface. Uncertainty cannot be dismissed and needs to be recognised and made clear in the advice that is given. Once the uncertainty is acknowledged then the obligation to deal with it is handed over to the policy maker. While this is necessary it is not perhaps the way that policy makers expect advisory committees to work – on the policy side there is a tendency to want to jump one way or the other.

1.7 Changes in the system

Perhaps one of the most interesting changes in the UK system has been the recent formation of three new more strategic advisory bodies; the Food Standards Agency (FSA), the Human Genetics Commission (HGC), and the Agriculture and Environment Biotechnology Commission (AEBC). The possible importance of these new commissions was recognised in the recent Science and Innovation White Paper where it was stated that,

“These Commissions face a challenging task, bringing together widely different views on very difficult issues and working under the public view. If they are successful, they will provide models for the future. The Government will watch their work closely to see what lessons can be translated into other areas” (DTI, 2000, p.54).
1.7.1 The FSA

Established by Act of Parliament, the FSA has been created to “protect public health from risks which may arise in connection with the consumption of food, and otherwise to protect the interests of consumers in relation to food.”

The Agency's functions are to:
• provide advice and information to the public and to the Government on food safety from farm to fork, nutrition and diet
• protect consumers through effective enforcement and monitoring
• support consumer choice through promoting accurate and meaningful labelling

It will:
• base its decisions and advice on the best evidence available
• consult widely before it takes action and makes recommendations unless urgent action is essential
• obtain independent expert advice from its advisory committees
• commission research to support its functions
• be prompt in making public its advice to the Government

The Food Standards Agency is led by a Board which has been appointed to act in the public interest, not to represent particular sectors. Its members bring a wide range of relevant skills and experience.

The Agency will account to Parliament through Health Ministers, and as a UK body to the devolved administrations for its activities within their areas. To safeguard its independence it has the unique legal power to publish the advice it gives to the government. [Source: www.foodstandards.gov.uk]

1.7.2 The HGC

HGC was established following a comprehensive review in May 1999 by the UK Government of the regulatory and advisory framework for biotechnology. This concluded that the system for regulating individual products and processes operated satisfactorily but the advisory framework needed to:

• be more transparent, in order to gain public and professional confidence;
• be more streamlined, in order to avoid gaps, overlaps and fragmentation;
• ensure capacity to deal with rapid developments, and to take broad social and ethical issues fully into account.

HGC will take forward these issues in the field of human genetics. The Foods Standards Agency (FSA) will have similar responsibilities for GM foods, and the Agriculture and Environment Biotechnology Commission (AEBC) will have responsibility for all other areas of biotechnology. The UK Government's Genetic Modification Issues website provides key policy messages and links to other Government GM-related sites.
As part of streamlining the framework, three advisory human genetics committees have been wound up and their responsibilities have passed to HGC. These are: the Advisory Committee on Genetic Testing, the Advisory Group on Scientific Advances in Genetics and the Human Genetics Advisory Commission. As a result, HGC will need to take forward the work initiated by these bodies and this will need to be built into its initial work plan.

HGC's role should also be seen in the context of other advisory and regulatory bodies in the regulatory and advisory framework for human genetics. HGC will not direct these bodies or interfere with their lines of accountability, but will work with them and help form links between them. [Source: www.hgc.gov.uk].

1.7.3 The AEBC

In 1999 the Government reviewed its advisory and regulatory framework on biotechnology. It concluded that a broader approach was needed for strategic issues. Established in June 2000 the Agriculture and Environment Biotechnology Commission (AEBC) forms part of the new strategic framework.

The Commission will:

- offer strategic advice to Government on biotechnology issues which impact on agriculture and the environment;
- liaise closely with but not duplicate the work of the other two bodies which together with the AEBC form a new strategic advisory framework;
- keep under review current and possible future developments in biotechnology with actual or potential implications for agriculture and the environment;
- advise Government on the ethical and social implications arising from these developments and their public acceptability; and
- consider and advise on any specific issues relating to relevant aspects of biotechnology as requested by the Government.

As part of this process the Commission is expected to:
- identify any gaps in the regulatory and advisory framework;
- consider the wider implications of the lessons to be learned from individual cases requiring regulatory decision;
- advise on any changes which should be made to Government guidelines which regulatory bodies are required to follow;
- make recommendations as to changes in the current structure of regulatory and advisory bodies;
- co-ordinate and exchange information with the relevant regulatory and advisory bodies;
- seek to involve and consult stakeholders and the public on a regular basis on the issues which it is considering; and
- operate in accordance with best practice for public bodies with regard to openness, transparency, accessibility, timeliness and exchange of information.

The Commission will:
• in carrying out its work take into account European and global developments;
• nationally, adopt a UK perspective taking appropriate account of legal and other differences between England, Scotland, Wales and Northern Ireland; and
• draw up a work programme.

The Government may also ask the Commission for advice on a particular issue and, if necessary, direct it not to become involved in an area if this could be better handled elsewhere. [Source: www.aebc.gov.uk]
2 The stem cell case study

2.1 Background

2.1.1 The lead up to the HFE Act 1990

The background to the recent discussions over the use of embryonic stem cells is provided by the Human Fertilisation and Embryology Act 1990. The birth in 1978 of the first ‘test-tube’ baby had prompted concerns about the use of human embryos and in 1982 the Department of Health set up a committee to “examine the social, ethical and legal implications of recent, and potential developments in the field of assisted [human] reproduction (Warnock, 1985, p.vi quoted in Mulkay, 1997, p.3). The publication of this committee’s report, the Warnock report, represented the start of a series of parliamentary debates that would eventually lead to the 1990 Act. The report recommended that the use of human embryos for the purpose of scientific research should be allowed with particular restrictions. It was recommended that research be allowed where it was directed towards: gaining more knowledge of the early stages of human embryos; developing diagnostic and therapeutic procedures regarding hereditary diseases; the alleviation of infertility and the improvement of in vitro fertilisation (IVF). However research would only be permitted for 14 days after the fertilisation of an embryo. A further recommendation was that a statutory body should be established to license IVF clinics and embryo research (Kirejczyk, 1999).

Initially there was significant opposition to the Warnock committees’ recommendation in Parliament. This culminated, in February 1985, with a large vote (238 to 66) in favour of the Unborn Children Protection Bill, which would have prevented any use of IVF embryos for research. However, after the Government refused to grant more time for the bill opponents talked it out at its final stage (Mulkay, 1997, p.25-28).

The Parliamentary opposition to embryo research appeared to lessen as the Government’s White Paper, which followed the recommendations of the Warnock Committee quite closely, was debated. However, it was not until December 1989 that the Government’s Bill was first presented to Parliament. After debate in both Houses, the House of Commons eventually voted 364 to 193 in favour of allowing embryo research. Given earlier objections, there was surprise at the size of the majority in favour.

Kirejczyk (1999) argues that the reason behind this change was “a spectacular shift in the perception of the nature of the human embryo” (p.894). On the anti-research side, was the image of each early embryo as a potential human and it was this that took precedent in the initial stages of the debate. In contrast, those supporting embryo research introduced the concept of a pre-embryo. This was based on the idea that individual embryonic development only begins after 14 days, hence “pre-embryos are not yet human individuals… but only a mass of cells generated by a fertilised egg. Therefore, research did not violate the moral principle of protecting human life” (ibid., p.892).

4 For a full discussion of the issues raised here see Mulkay, 1997.
2.1.2 The HFE Act 1990

The HFE Act 1990 permitted research using human embryos only if it fell into one of five categories, namely:

- Promoting advances in infertility treatment;
- Increasing knowledge about the causes of congenital disease;
- Increasing knowledge about the causes of miscarriage;
- Developing more effective techniques of contraception; or
- Developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation (HFE Act 1990, Schedule 2 paragraph 3(2) in Morgan and Lee, 1991, p.221)

Even for research under these categories, the researchers had to apply for a license from the Human Fertilisation and Embryology Authority (HFEA), the first statutory body of its type in the world, which was established by the HFE Act. In addition to licensing research, the HFEA’s other principal tasks were to license and monitor those clinics that carry out in vitro fertilisation (IVF), and donor insemination (DI) and to regulate the storage of gametes (sperm and eggs) and embryos (from the HFEA website). In order for licenses to be issued the HFEA needed to be convinced that the use of embryos was essential to the research, that embryos would not be kept after 14 days, and that consent had been given for the embryos use.

An important aspect of the Act was that it did allow for other research purposes to be added to the original list through ‘affirmative Regulations’; that is regulations that have to be debated in the House of Parliament before they can come into force. Under the Act, any such new purposes would only be permitted where they would “increase knowledge about the creation and development of embryos, or about disease, or enable such knowledge to be applied” (HFE Act 1990, Schedule 2 paragraph 3(3)).

2.2 The advice structures that were used

2.2.1 The HFEA/HGAC Consultation

The announcement in February 1997 that Dolly the sheep was the first vertebrate cloned from a somatic cell of an adult animal resulted in a good deal of media interest and political attention. It led the House of Commons Science and Technology

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5 The HFEA’s other statutory functions are:
- to produce a Code of Practice which gives guidelines to clinics about the proper conduct of licensed activities;
- to keep a formal register of information about donors, treatments and children born from those treatments;
- to publicise its role and provide relevant advice and information to patients, donors and clinics; and
- to keep under review information about human embryos and any subsequent development of such embryos, and the provision of treatment services and activities governed by the HFE Act and advise the Secretary of State, if asked, about those matters.

6 Basically, the process that was used to produce Dolly was to fuse cells from the adult sheep with an egg that had its nucleus removed, to produce a ‘reconstructed egg’ which could then be implanted into the surrogate mother (HGAC, 1998)
Select Committee to launch an inquiry, the results of which were published in the report “The cloning of animals from adult cells”. One of the outcomes of this inquiry was that the Committee argued that concerns over the cloning of Dolly may have overshadowed the possible benefits, and that the Human Genetics Advisory Commission (HGAC) should provide advise on the implications for human genetics (HGAC, 1998b). Taking up this thread, the HGAC joined forces with the HFEA to launch a consultation exercise on “Cloning issues in reproduction, science and medicine”.

The HGEA and HFEA

As was said earlier the HFEA was a statutory body set up though the HFE Act 1990 to license clinics carrying out IVF treatment, donor insemination and to license researchers wishing to carry out research on embryos under the Act. The Human Genetics Advisory Commission was non-statutory and was operational from December 1996 to December 19997. During that time it offered Government independent advice on issues arising from developments in human genetics. Its terms of reference were (from HGAC website):

- to keep under review scientific progress at the frontiers of human genetics and related fields;
- to report on issues arising from new developments inhuman genetics that can be expected to have wider social, ethical and/or economic consequences, for example in relation to public health, insurance, patents and employment;
- to advise on ways to build public confidence in, and understanding of, the new genetics.

In making appointments to both the HGAC and the HFEA, nominations would have been sought from patient groups, research councils, professional bodies (such as the Royal Colleges), industry and the Whitehall Public Appointments unit.

For the purposes of the consultation exercise in question, the HGAC and HFEA formed a joint sub-committee of four people, two from each body. This sub-group took forward the exercise and then reported back to the parent bodies. The findings were then debated by both authorities before the report was produced.

2.2.2 The Chief Medical Officer’s Expert Group

The work of the CMO’s Expert Group

Given developments in the state of the science concerning stem cells, it was decided in mid-1999 that a second group should look into the stem cell issue. The Chief Medical Officers Expert Group was established to assess:

- Developments in, and the potential benefits of, stem cell research and research involving nuclear replacement;

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7 Subsequently, the work of the HGAC has been incorporated into the recently established Human Genetics Commission (HGC) (see HGC website for details).
• The likely timescales of such research;
• Possible alternatives to research involving embryos which might achieve the same results; and
• The technical and safety issues which might arise from such research (Department of Health, 2000a, p.12)

As such it was an *ad-hoc*, issue specific advisory body.

Importantly, the Expert Group was “not asked to review from first principles the ethical issues of research involving embryos” (*ibid.*). As was the case with the earlier HGAC/HFEA report, it was argued that these debates had been conducted around the HFE Act. Research on embryos was already permitted under the Act, it was a question of what sort of research should be permitted. The Expert Group was only asked to consider new ethical issues arising from the use of embryos for the extraction of stem cells.

The appointment of members to the CMO’s Expert Group was conducted according to the Nolan principles for appointing a short-term, specialist body. The concern was to achieve the best possible mix of expertise and the CMO, Liam Donaldson, and Chief Scientific Advisor (CSA), Robert May, consulted with the Royal Society, the Royal Colleges, and the MRC amongst others. The final make-up of the 14 strong group (including the CMO and CSA) included geneticists (with interests in both human and non-human genetics), other medical scientists, 2 ethicists, and a lawyer.

### 2.2.3 Other possible sources of advice

Aside from the two advisory bodies described, other sources of information have also played a role in the debate. During 1998, the Royal Society produced a document that, as with the HGAC/HFEA report, argued that reproductive cloning was unacceptable and should be prohibited. They did however, support the use of embryos in research, as long as the 14-day limit was respected and a license was obtained from the HFEA. It was seen as important that any modification the existing legislation should be carefully drafted “so as not to outlaw the potential future benefits that could be derived from research on cloned embryos” (Royal Society, 1998). Another report backing the extension of uses for embryos in research was produced by the Nuffield Council on Bioethics.

In the lead up to the recent parliamentary debate the Royal Society produced a further report, “Stem cell research and therapeutic cloning”, outlining the potential benefits of this line of work and backing the recommendations of the CMO Expert Group. Again related to the debate in Parliament, the Parliamentary Office of Science and Technology (POST) has produced a POST note, outlining the science of stem cell research, the potential benefits, the possible dangers and the legal and ethical issues. In addition MPs have received what are regarded as good quality briefings from interested groups, both pro and anti embryo research. There have also been recent reports produced at the EU level that may have some influence.
2.3 The operation of the advisory structures

In order to produce reports providing advice for the Government, both the HGAC/HFEA advisory body and the CMO’s Expert Group undertook consultation exercises, gathering opinion on the issues. However, the way these exercises were conducted, along with other operational matters, differed between the two groups.

2.3.1 The HGAC/HFEA consultation

The HFEA/HGAC report was based on a public consultation exercise. The consultation on the issues for human genetics arising from the advances in cloning technology was launched on 29 January 1998 with comments invited by 30 April 1998. Over 1000 copies of the consultation paper, “Cloning issues in reproduction, science and medicine” were distributed and the paper was placed on the HGAC website (HGAC, 1998b).

The shape of the consultation

In asking people to think about the issues surrounding cloning, the paper made a distinction between the idea of reproductive cloning and ‘therapeutic’ cloning. The paper defined ‘reproductive cloning’ as “where an entire animal is produced from a single cell by asexual reproduction” and the concern of the consultation being “with ‘human reproductive cloning’, which would involve the creation of a human being who was genetically identical to another” (HGAC, 1998a). In addition to this, “there are scientific and therapeutic applications of nuclear replacement technology, which do not involve the creation of genetically identical individuals. These activities are also sometimes referred to as ‘cloning’, and may broadly, (although not cotermious with conventional scientific usage) be referred to as ‘therapeutic cloning’”. These applications may include therapy for human mitochondrial disease and research which might lead to the replacement of damaged or diseased tissues or organs, without the risk of rejection reactions. For example, skin tissue to treat patients suffering from burn injuries” (HGAC, 1998a).

Given this distinction, the consultation paper identified different possible uses for cloning technologies, explaining what had been achieved and what was predicted. It also gave details of the existing legal framework and summarised the reposes to the ‘Dolly’ announcement. It then asked for opinions based on six questions (ibid.):

1. Would research using nuclear replacement technology raise any new ethical issues in what is permitted in work with embryos in the 14-day period?
2. Are there any medical or scientific areas that might benefit from research involving human nuclear replacement?
3. To what extent can a person be said to have a right to an individual genetic identity?
4. Would the creation of a clone of a human person be an ethically acceptable act?
5. Would the likely cost in terms of failures and/or malformations inevitable in developing a programme of human reproductive cloning be ethically acceptable?
6. What ethical importance might be attached to the distinction between artificial processes for which there are parallels in natural processes and those for which there are not?

In addition respondents were asked to make suggestions regarding how Ministers could be advised on ways to build public confidence and understanding.

**Response to the consultation**

Nearly 200 responses were received; 40% from individuals and the rest from “a wide range of constituencies – scientists, clinicians, academics, religious groups, ethicists, lawyers, industry and lay groups” (HGAC, 1998b).

Of the respondents, 23% argued that any form of embryo research was wrong, seeing embryos as having the full moral status of human beings. In addition, 24% felt that the 14-day limit on embryo use was arbitrary, with some arguing that it could be extended. However, in their report the HGAC commented that,

“both these points of view are questioning decisions enshrined in the 1990 Act. Both the HGAC and HFEA have respect for these opinions. However, the relevant issues were fully debated, both in Parliament and by the wider public, at the time of passing of the HFE Act. While the decisions then reached did not command universal ethical assent, they are the basis for the present policy and they necessarily form the framework within which the HGAC/HFEA must make their recommendations to Ministers. It would not be appropriate to use this limited enquiry into cloning to reopen questions relating to work with human embryos” (HGAC, 1998b).

This idea of not wanting to reopen old debates is something that is seen in much of the recent discussion on human cloning.

With regard to reproductive cloning, the consultation was fairly conclusive, with 80% of respondents deeming it ethically unacceptable. However, things were more ambiguous regarding therapeutic cloning. In response to question 2 (see earlier), 55% of respondents felt that there were areas of science or medicine that would benefit from research involving human nuclear transfer, while only 10% did not. Concerns were expressed about the possible commercialisation of therapeutic techniques, with worries that these techniques should not be developed and exploited simply for commercial gain. The HGAC/HFEA response was that they did not see any reason why developments in this area would differ from other kinds of medical advances, arguing that the existing patent system should provide adequate protection.

**2.3.2 The operation of the CMO Expert Group**

As with the HGAC/HFEA report, the Expert Group engaged in a consultation exercise. However, in line with their remit, the consultation exercise was much more focused on the science. As such they invited as much factual material as possible to be submitted so that they could identify the likely benefits, effects and timescales of stem cell research. Through consultation and the use of their own expertise, the Group created a list of about 40 key individuals or research groups that they felt should be involved. In addition the consultation letter was placed on the web. The consultation letter directed the recipients to the HGAC/HFEA report and their recommendations. It then asked for views on (from Department of Health, 2000a, p.51):
1. What are the current research areas on therapeutic cloning, including stem cell studies, and which are most important?
2. The areas of human health in which the use of therapeutic cloning techniques is most likely to provide benefits?
3. How close are we to being able to replicate animal work in humans?
4. What are the technical problems that might arise?
5. Are you aware of any safety issues?
6. Are there any alternatives to research on human embryos, created in vitro, to achieve the same ends? If so, is it likely that they will be available within the next five years?
7. What are the ethical and social implications of such research and its potential therapeutic application?
8. What would be the likely future consequences of the development of therapeutic cloning technology for health care provision?
9. Any other comments you wish to make?

They received over 100 responses both from researchers working in the field worldwide and from a range of scientific, medical, and other bodies and individuals. Although the Group was seeking scientific information, they also considered more opinionated submissions. Indeed, every single submission was catalogued and then circulated to all members of the group, which met for discussion 5 or 6 times over the course of its life. Although the Group’s initial focus was on ‘therapeutic’ cloning this changed over time to the specific focus on stem cells. Although it is stated in the final report that it was not the job of the Group to examine previously discussed ethical issues, the group did re-examine the ethical debates behind the 1990 act, revisiting the Warnock report and the parliamentary debates of the time. This was seen as part of the process despite not being the main objective of the Group. Discussions of the possible economic effects of stem cell research were limited and it was not seen as appropriate to consider potential economic effects in the Group’s recommendations.

2.4 Interaction between advisory structures and decision makers

The HGAC’s decision to look at the issue of embryo research was partly a result of the timing – it started work just after the cloning of Dolly the sheep had been announced – and partly as a response the House of Commons Select Committee Report “The cloning of animals from adult cells”. Unlike the HGAC, the CMO Expert Group was set up by the Government to specifically investigate the issue of therapeutic cloning/stem cell research. Both the HGAC/HFEA and CMO Expert Group reports contained recommendations for the Government regarding embryo research. However, while the recommendations of the CMO Expert Group were largely the same as those of the HGAC/HFEA report, it went a lot further in terms of explaining technological developments, both current and potential.

2.4.1 Recommendations arising from the HGAC/HFEA consultation

Following the consultation the HGAC and HFEA produced a number of recommendations for the Government. With regard to reproductive cloning the
HGAC/HFEA backed the current position that explicitly ruled out reproductive cloning. While seeing existing controls as adequate they did suggest that the Government consider introducing primary or secondary legislation explicitly banning reproductive cloning regardless of the technique used.

More importantly in the context of this study, regarding therapeutic cloning the HGAC/HFEA recommended to the Secretary of State that consideration should be given to adding two further purposes to the legislation permitting certain types of embryo research (see earlier). The two new purposes were,

- Developing methods of therapy for mitochondrial diseases
- Developing methods of therapy for diseased or damaged tissues or organs.

These changes were seen as necessary as “when the 1990 HFE Act was passed, the beneficial therapeutic consequences that could potentially result from human embryo research were not envisaged” (HGAC, 1998b).

2.4.2 Recommendations of the CMO Expert Group

The report of the Group argued that while there were other potential sources of stem cells, human embryos appeared to offer the greatest potential. Regarding the ethical implications, the Group felt that while some people were opposed to any research on human embryos, the proposed new research did not raise any “fundamentally different ethical issues from the currently permitted research” (Department of Health, 2000a, p. 44). However, the Group did feel that such research should continue to be placed under a system of rigorous safeguards. In total the Expert Group made the following recommendations (ibid., pp. 45-48):

- **Recommendation 1**
  Research using embryos (whether created by in vitro fertilisation or cell nuclear replacement) to increase understanding about human disease and disorders and their cell-based treatments should be permitted, subject to the controls in the Human Fertilisation and Embryology Act 1990.

- **Recommendation 2**
  In licensing any research using embryos created by cell nuclear replacement, the Human Fertilisation and Embryology Authority should satisfy itself that there are no other means of meeting the objectives of the research.

- **Recommendation 3**
  Individuals whose eggs or sperm are used to create the embryos to be used in research should give specific consent indicating whether the resulting embryos could be used in a research project to derive stem cells.

- **Recommendation 4**
  Research to increase understanding of, and develop treatments for, mitochondrial diseases using the cell nuclear replacement technique in human eggs, which are subsequently fertilised by human sperm, should be permitted subject to the controls in the Human Fertilisation and Embryology Act 1990.

- **Recommendation 5**
  The progress of research involving stem cells which have been derived from embryonic sources should be monitored by an appropriate body to establish whether

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8 That is diseases that are passed from mother to child through the mitochondrial DNA
the research is delivering the anticipated benefits and to identify any concerns which may arise.

- **Recommendation 6**
  The mixing of human adult (somatic) cells with the live eggs of any animal species should not be permitted.

- **Recommendation 7**
  The transfer of an embryo created by cell nuclear replacement into the uterus of a woman (so called ‘reproductive cloning’) should remain a criminal offence.

- **Recommendation 8**
  The need for legislation to permit the use of embryo-derived cells in treatments developed from this new research should be kept under review.

- **Recommendation 9**
  The Research Councils should be encouraged to establish a programme for stem cell research and to consider the feasibility of establishing collections of stem cells for research use.

These recommendations were submitted to the responsible Health Minister in the form of a draft report, which due to the pace of scientific developments, needed to be updated before being sent to Ministers.

2.5 The incorporation of advice into policy

2.5.1 Government response to the HGAC/HFEA report

It had been expected that the Government would accept and follow the advice given in the HGAC/HFEA report. However, it was decided that the issue needed to be examined further. Public Health minister Tessa Jowell told the Commons:

“The Government reaffirms its policy that human reproductive cloning is ethically unacceptable and cannot take place in this country. However, we recognise that regulations to allow therapeutic research should be very carefully considered. It has been suggested that therapeutic cloning techniques might be able to provide immunologically compatible tissue for the treatment of degenerative diseases of the heart, liver, kidneys and cerebral tissue, or repair damage to skin or bone. We believe that more evidence is required of the need for such research, its potential benefits and risks, and that account should be taken of all alternative approaches that might achieve the same ends” (quoted in The Guardian, 24 June 1999).

The main problem regarding the report was that it was overtaken by scientific developments. Mid-1999, when Ministers were considering the report, saw the announcement that embryonic stem cell lines had been established in the laboratory, and this was followed up by further developments over the next couple of months. Hence, while people were happy with the content of the report, it was felt that it rapidly went out of date. In addition to this problem, it was felt that while the HGAC/HFEA report drew upon the consultation with a range of groups, it did not really touch on the views of the scientific researchers and some people argued that it did not provide enough balance between the potential benefits of research and the ethical issues. Hence, the main response to the HGAC/HFEA report was the decision that the Chief Medical Officer, Professor Liam Donaldson would set up and chair an independent expert advisory group.
2.5.2 The CMO’s Expert Group’s impact on policy

The Government’s response

A proof copy of the Expert Group’s report was presented to the responsible Minister of Health along with a short submission from the officials at the Department of Health with involved with the report, and a letter from the CMO. The minister was then able to question the CMO and officials about the details of the report. Once she was satisfied with it was then circulated more widely in Government. In particular, MISC 6, the Cabinet committee on biotechnology, wanted to consider the report. The discussions of MISC 6 and other Ministers was largely about how the report should be handled and the shape of the Government response, rather than about changing the content of the report. When any further questions arose these came back to the lead civil servant. Devolution complicated the process of generating a response to the report slightly as while genetics policy is reserved for Westminster, things such as provision of health services (and some research funding) is not, making for a potential split between policy and action. These inconsistencies in the system existed prior to devolution but it has meant that closer attention needs to be paid to them. As the report was effectively drawn up by the CMO of England, but dealing with the UK policy context, Donaldson needed to show it to colleagues in Scotland, Wales and N. Ireland.

After CMO presented the report there was reportedly a row between the Department of Health and the Minister for Science, Lord Sainsbury. In interview, Sainsbury said, “the potential medical benefits outweigh any other considerations one might have” (in Wintour, 2000), while the DH was acknowledged by Government sources to be less enthusiastic about the experiments. However, these reports may have been exaggerated, with the lead civil servant believing that there were no significant differences within Government. Indeed, it was decided fairly early on that most/all the recommendations would be adopted. Given that the report was widely circulated within Government, including legal advisors, 9-10 weeks was not seen as a particularly long time to respond. While the first two recommendations could be implemented through regulations, the others would require primary legislation.

The response of the Government (Department of Health, 2000b) was to accept the report’s recommendations in full and to bring forward legislation where necessary to implement them. As was mentioned previously, regulations to amend the 1990 Act needed to be debated, and voted upon, in the both the House of Commons and Lords. As is traditional in matters pertaining to human embryos, the votes were free ones.

This Parliamentary process began with an adjournment debate on the report and the Government response (see House of Commons Hansard Debates, 17 November for details). Subsequently, the Government laid regulations to amend the relevant
schedules to the 1990 Act in order to implement the first recommendation of the report. Reflecting the importance of the issue the new regulations were debated in the both of the Houses of Parliament rather than, as is usually the case, in committee. The new regulations were passed by the House of Commons on December 19th 2000 and by the House of Lords at the start of 2001. The other recommendations will require new legislation and will thus be debated in the House of Commons at a later date.
3 Electromagnetic radiation: power lines and mobile phones

3.1 Background to EMFs in the UK

EMFs emitted from power lines have been a concern in the UK for some time now. Media reports (scare stories?) are not uncommon, despite the electricity industry and the National Radiological Protection Board (NRPB) - which is responsible for protecting people from radiation hazards (including EMFs) - reassuring the public that power lines are safe.

The NRPB is the main government organisation concerned with radiation hazards. More specifically,

*The purpose of the NRPB is to provide advice to protect the health of the public, workers who are occupationally exposed, and patients undergoing medical treatment, from radiation hazards.*

*As principal sponsor, the DH has the main call on NRPB support although NRPB expects to respond to requests for advice on protection issues from all Government departments and agencies. In developing advice for Government, NRPB draws on its own expertise and that of its two independent Advisory Groups [including AGNIR]. It will continue to support COMARE. Formal advice is published in the Documents of NRPB.*

The focus of this paper is on AGNIR (Advisory Group on Non-ionising Radiation) as the provider of advice to the NRPB. The NRPB itself provides advice to other government departments (OGDs) and other actors (e.g. industry), mostly through the provision of guidelines. This last interface will not be considered here for the time being. A further advisory body, known as COMARE (Committee on Medical Aspects of Radiation in the Environment), has the potential to advise on EMFs but has never done so to date. It will therefore be omitted from this paper.

Our remit is, of course, wider than just the consideration of power lines – we are also looking at how the UK scientific advisory ‘system’ has dealt with emerging concerns surrounding mobile phone safety (including base stations, masts, and handsets). We will see below that the Department of Health convened a short-lived group to specifically examine the scientific evidence surrounding the health effects of mobile phones. Known as the Independent Expert Group for Mobile Phones (IEGMP), this group deliberated for about six months, with the NRPB providing secretarial support.

3.2 The advice structures used

3.2.1 Power lines

AGNIR has now been in place since 1990 and so can be considered permanent. Its remit is as follows:
To review work on the biological effects of non-ionising radiation relevant to human health and to advise on research priorities.

AGNIR was established as a result of an approach by Sir Richard Doll, the eminent British epidemiologist, to the then NRPB Director, Roger Clark. A number of epidemiological studies had appeared by the late 1980s that suggested a possible link between power lines and cancer, especially childhood leukaemia. However, these were proximity studies rather than dosimetric, which meant that it would be difficult for the NRPB to draw up guidelines, given the available evidence. Moreover, much of the evidence was conflicting. Nevertheless, Doll thought that this was an area that the NRPB would need to address and the two men came up with the idea of setting up an advisory group that would keep a watch on the scientific literature. This group came to be known as AGNIR, and has been chaired by Doll since its inception.

AGNIR is currently made up of 6-7 eminent scientists. Originally, the Director of NRPB appointed members, including Doll as the Chairman, along with a small number of NRPB staff to serve on the advisory group. However, in the last couple of years, NRPB staff have stepped down from AGNIR to leave only ‘outsiders’, although so-called NRPB ‘assessors’ remain attached. Moreover, under new arrangements introduced in 2000, the NRPB Director no longer appoints members – this is now the task of the Chairman of the NRPB ‘Board’. Both developments are an attempt to underline the independence of AGNIR, although it would be fair to say that this would appear never to have been in question – a sign of the times, perhaps?

NRPB relies upon formal advice from AGNIR as well as its own experimental and epidemiological studies when addressing concerns that may be raised (the NRPB has more than three hundred staff, many being research active). The NRPB also has a Board of eminent scientists, which can also provide advice. For the last 10 years, AGNIR has reported directly to the NRPB Director, and as we have seen above, NRPB staff were even members of AGNIR until quite recently. With NRPB ‘assessors’ still attached to AGNIR, no doubt much informal advice passes through these individuals. However, under new arrangements, formal advice is now to be addressed to the Chairman of the NRPB Board rather than the Director and his staff.

As for the scope of AGNIR’s advice, it is (strictly speaking) involved in neither risk assessment nor risk management. Until now, AGNIR has merely reviewed the scientific literature for the biological effects of non-ionising radiation. These reviews have yet to even acknowledge a hazard at the low frequencies associated with power lines, let alone assess the risks. If the latter could be done, it would be down to NRPB to provide guidelines for risk management. In other words, AGNIR provides strictly scientific advice and does not, for example, comment on proposed NRPB guidelines.

It should be noted that AGNIR is organised along topic-based lines, with new members introduced as specialists in the given area. Thus, although AGNIR was originally set up to look at EMFs associated with electricity generation and distribution, it quickly branched out to look at other issues, such as UV radiation. This tended to be done via the establishment of sub-groups, and in fact, more recently, AGNIR has fragmented into a small number of sub-groups, each dealing with a particular topic.
3.2.2 Mobile phones

In March 1999, the Chairman of NRPB was asked by the Minister for Public Health to set up an independent expert working group to assess the current state of research into possible health risks from mobile phones. NRPB was almost the ‘natural’ place to turn, given its expertise in this area, its involvement in national and international work on this topic, and the work of the existing AGNIR. In fact, we might ask why AGNIR was not asked to consider this issue? This was probably due to a number of reasons, including the fact that the Government wanted:

• quick answers (AGNIR tends to take 2-3 years to provide its advice);
• to demonstrate that it was doing something new in dealing with public concerns over mobile phone safety;
• to obtain clear policy recommendations (as we saw above, this is beyond the scope of AGNIR)
• to demonstrate independence from the NRPB, which to some critics seemed to be too close to industrial interests.

Known as the Independent Expert Group on Mobile Phones (IEGMP), members were chosen to encompass an expert knowledge in epidemiology and experimental biology related to exposures to electromagnetic fields and radio frequencies, and also a knowledge of social science, risk perception and legal issues. There were members with medical and scientific skills in oncology, physics, radio engineering, statistics and neurophysiology.

The appointment of the Chairman of IEGMP, Sir William Stewart, FRS, FRSE, was announced in June 1999. Stewart was Chief Scientific Advisor to the Government during the early 1990s and is a well-known and highly respected figure. The terms of reference and nine members were subsequently announced in August. Two additional members were appointed in October. Delays in appointment were caused by the need for consultation on membership and concerns about ensuring there were no conflicts of interest. One member was from the World Health Organization (WHO) and two were from AGNIR. Member(s) with lay interests were also appointed. In addition to full IEGMP members, observers from the Board of NRPB, from the Department of Health (DH) and from the Department of Trade and Industry (DTI) were also appointed. The same NRPB staff that support AGNIR provided the secretariat and administrative support for the work of the Group.

The terms of reference of the IEGMP were as follows:

To consider present concerns about the possible health effects from the use of mobile phones, base stations and transmitters, to conduct a rigorous assessment of existing research and to give advice based on the present state of knowledge. To make recommendations on further work that should be carried out to improve the basis for sound advice.

3.3 Operation of the advisory structures
3.3.1 AGNIR

AGNIR essentially reviews the scientific literature and provides summary and comment. Members may bring new studies to the table, as might NRPB staff. Commentary may be made on individual publications, particularly if they are considered scientifically significant or have attracted press interest, but usually, collections of studies are considered together and conclusions drawn. Experts are only occasionally invited to provide evidence, since the NRPB tries to ensure that the knowledge of AGNIR members covers all the relevant areas. This means that, on the whole, AGNIR provides opinions without wider consultation, although there have been notable exceptions, e.g. early on, when AGNIR was developing its advice on the adequacy of existing guidelines for limiting EMF exposure, it would seem that some sort of consultation was carried out. As for issues of transparency, formal advice is published in *NRPB Documents*, a sort of newsletter published 3-4 times a year. Besides this, it appears that AGNIR meeting minutes are unavailable, although there is transparency on the issues being considered, since AGNIR proceeds on a specific topic basis.

AGNIR does not commission research, although it has been closely related to relevant leading-edge research in the area – for example, Sir Richard Doll was the co-ordinator for the UK National Childhood Cancer Study (UKCCS). However, it is almost standard for AGNIR to call for more research to be conducted in areas in which it is providing advice.

But how does AGNIR deal with existing uncertainty? This is perhaps best addressed through an example. In 1992, AGNIR produced its first advice on the adequacy of existing guidelines for limiting EMF exposure that had been recently questioned by epidemiological studies and lab data. The first objective of AGNIR was to review epidemiological and laboratory studies relevant to the possible carcinogenic effect of electromagnetic fields and to determine the extent to which the weight of evidence suggests they should be treated as a potential carcinogen. The emphasis of this work was on exposure to time-varying fields.

Conclusions arrived at: the epidemiological findings that were reviewed were judged to provide no evidence of the existence of a carcinogenic hazard from exposure of paternal gonads, the foetus, children, or adults to the extremely low frequency (ELF) EMFs that might be associated with residence near major sources of electricity supply. Much of the evidence cited was judged as being inconsistent, or else deriving from studies that had been inadequately controlled. It was even thought that some studies had been distorted by bias against the reporting or publishing of negative results. AGNIR concluded that, in the absence of any unambiguous experimental evidence to suggest that exposure to these EMFs was likely to be carcinogenic, the findings to date could only be regarded as sufficient to justify formulating a hypothesis for testing by further research. In fact, a whole tranch of research was suggested, including experimental and epidemiological studies, although it is not clear to whom the call was being made . . . the NRPB, the DH, the Research Councils, academics?

In other words, in the face of uncertainty, more research is called for. Power lines are assumed innocent until proven guilty, and in contrast to other countries, no
precautionary measures have been recommended. Indeed, the NRPB interviewee suggested that any precautionary measures would be politically motivated, since the scientific evidence does not justify them.

3.3.2 IEGMP

The first formal meeting of the IEGMP was held in September 1999 when working arrangements and the overall structure of the report were considered. Members agreed to meet monthly, to seek views widely and to have open meetings around the country. Adverts were placed in national newspapers, in the New Scientist in September and on the IEGMP web site calling for written evidence. Replies were received from 174 individuals and organisations.

Meetings of the IEGMP included consideration of how mobile phones work, exposure characterisation and guidelines, future developments in the technology, epidemiology and experimental biology in relation to possible health effects, as well as planning issues. At its meetings, presentations were given by invited representatives of environmental groups and industry, as well as by individuals.

In addition to formal meetings, there were open meetings for the public to give their views. These were advertised in local newspapers and by press releases. Five such open meetings were held in all across a geographical spread of the UK, and these tended to be hosted in universities or medical schools. Summaries of the issues raised are given on the IEGMP web site. Information on the work of the IEGMP was also circulated to all Members of Parliament and Members of the House of Lords, to Members of the Scottish Parliament, the National Assembly for Wales and the Northern Ireland Assembly.

The IEGMP completed its work in April 2000 with the submission of its report, Mobile Phones and Health, to the Minister for Public Health. The report was subsequently published in May 2000. The IEGMP was then disbanded, having discharged its responsibilities in line with its remit.

3.4 The interaction between advice and policy

3.4.1 AGNIR

AGNIR has had a close relationship with the NRPB and has no doubt entered into dialogue with decision-makers in the past (although as we have said above, AGNIR is not formally asked to comment on policy options). AGNIR’s reports are written by members of AGNIR (and not NRPB staff), and are not vetted by the NRPB.

As for impacts on policy, AGNIR’s advice has been used by NRPB to justify sticking with earlier guidelines (which align closely with ICNIRP guidelines), despite calls from some quarters for more stringent exposure limits. More than 23,000 homes in Britain are near power lines, as well as many offices, schools and other premises. Guidelines have to take account of benefits and risks. The former are clear, but the latter aren’t, and it is believed that any risks are small in any case. Therefore, existing
guidelines have been retained, since the risks here are known and quantifiable, but with the proviso that new research findings are kept under review.

3.4.2 IEGMP

In its response to the IEGMP’s report (by this time, commonly known as the Stewart Report, after the Group’s chairman), the Government claimed to be acting on the Group’s recommendations:

We are acting immediately on the findings of the report. Some of its conclusions and recommendations can be actioned straight away. Other issues will require more time for consideration and consultation and we will be issuing further information in due course (Department of Health, 2000c).

However, the Government were not the only audience for the report – the intention had always been for the report to reduce public concern about the health impacts of mobile telecommunications technologies through the provision of information direct to the consumer. This would help them to make informed choices about their own and their families’ use of these technologies. Accordingly, the report was placed on to the web immediately and a leaflet produced shortly afterwards, the latter available at all mobile phone sales outlets.

But what of the contents of the report? In his foreword to the report, Sir William Stewart states that:

The balance of evidence does not suggest that mobile phone technologies put the health of the general population of the UK at risk. There is some preliminary evidence that outputs from mobile phone technologies may cause, in some cases, subtle biological effects although, importantly, these do not necessarily mean that health is affected (IEGMP, 2000).

Nevertheless, the report proposed that a precautionary approach be adopted until more robust scientific information becomes available:

It is not possible at present say that exposure to RF radiation, even at levels below national guidelines, is totally without potential adverse health effects, and that the gaps in knowledge are sufficient to justify a precautionary approach (ibid.).

The Government has accepted this assessment and has since implemented a number of recommendations suggested by the report for managing the risks, as well as funding (with the industry) research programmes into mobile phone safety.
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Web resources

http://www.foodstandards.gov.uk
http://www.hgc.gov.uk
http://www.aebc.gov.uk
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http://www.icnirp.de
http://www.nrpb.org.uk
http://www.powerwatch.org.uk

Interviews

Edmund Quilty, Director, Science in Government Directorate, Office of Science and Technology

Anthony Taylor, Department of Health

Dr John Stather, Deputy Director of the National Radiological Protection Board (NRPB), and Head of Secretariat to AGNIR and IEGMP
Welcome to Powerwatch. It was established in 1988 to help people learn more about electromagnetic fields and how these affect health, and also to promote the responsible and efficient use of power (especially as the UK Government has announced permission for more gas-fired power stations), though this web-site concentrates on the health effects issues. We are now surrounded by man-made Electromagnetic fields (EMFs) millions times higher than the natural background ones due to our use of electricity, radio, TV, and microwaves. We believe that the research now shows there is an association between exposure to EMFs and adverse health effects in people and animals.

UK NRPB "Doll Report Mk II" (ELF Fields and the Question of Cancer) was released on Tuesday 6th March.
(incl. information on powerlines causing cancer and depression and suicide)

LATEST INFORMATION: For further details of recent stories click on NEWS

Site Navigation: Some page links are below, but we suggest that you select POWER or MICROWAVE

These pages are deliberately written (for 800x600 or higher) with a minimum of graphics for fast internet access. Text from this website may be freely used with www.powerwatch.org.uk acknowledgement. Genuine Media professionals and academics can email the main author at: aphilips@gn.apc.org. Please note this is not for general enquiries (as we do not have the resources to answer them), though we do welcome news and notification of any errors and suggested corrections are seriously considered. Last site update 08:00hrs 19 March 2001. More being added soon!

Keywords: Powerwatch, EMF, health, leukaemia, electricity, electric field, magnetic field, non-ionising, radiation, microwave, ES, mobile phone, base-station, transmitter, masts, UKCCCR, UKCCS, epidemiology, cancer, child, book, meter, Alzheimer, depression, pylon, substation, railways, leukemia, VDU, computer, monitor, EMC, wiring, radiation monitors
# Science and Governance: the US case

Patrice Laget

## The US case

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## Interviews

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1 Scientific advice in the US

1.1 Summary

The general impression in the US is that science is good. Technology drives the economy and everything should be done to keep this momentum. If and when a problem arises a solution will be found. And, if people abuse the system, litigation will follow. This long standing support of science has led to a huge reservoir of knowledge. On top of that, many efficient mechanisms exist, within and outside the government, to provide good scientific expertise to the decision makers.

Governance is the result of a fine checks and balances system between the executive, the legislative and the judiciary branches. At the political level the access and use of scientific expertise is rather informal and distributed. What counts the most is educating the politician and building a consensus among the majority of them. Yet, while it is easy to describe the sources of scientific expertise, it is not easy to say what role science plays in major political decisions. At the regulatory level, the process of gathering and using the scientific expertise is more formal. Still, because the mood is to avoid unnecessary barriers, the implementation of the political decision often lead to litigation. In turn, the courts plays a critical role to interpret the law.

The key question nowadays is the independence of the experts. Decisions often follows the recommendations of advisory committees. But more and more, the case that experts sitting in these committees have financial links with the industry facing new regulations.

All in all, the system works, but it does so in the context of the American culture. Priorities are set in this context. The White House often drives the political agenda. Members of Congress listen more to their constituencies than they respect the party lines. Federal regulatory agencies walk a fine line between the protection of the citizens and the interests of the companies, or the other way round.

1.2 Introduction

A research project has just been launched by IPTS and the ESTO network to identify and typify the advisory structures in the science-related policy and regulatory decision making systems at work in Europe, the US and Japan. This note was requested by IPTS as an input to the project in providing: (i) a general description of the situation in the US; (ii) a list of people who could be interviewed at a latter stage.

Seen from an American perspective, the bottom line is that technology is good. This is especially true in the age of the new economy: technology is good for Wall Street; it is also good for Main Street! Nothing should be done that risks to break the current expansion. In a nut shell, when science fuels the market growth it does not create many
problems, even if there are questions on its possible societal impacts (biotechnology or
the Internet are well accepted). On the other hand, science is less than welcome if
regulatory agencies use it as a basis for tougher rules, which ultimately may hurt the
business.

There are two separate but interconnected issues pertaining to the above mentioned
subject: (i) the source of scientific expertise for the benefit of the decision making
system; (ii) the use of this expertise by the policy makers and the regulators. While there
is little doubt that the scientific expertise abound in the US and is easily accessible to the
various governmental bodies, the difficulty lies with the many other parameters that, at the
end of the day, govern most of the policy and regulatory decisions. A full description of
the complexity of the American system is beyond the scope of this note. Selected
examples, however, may help to highlight its main characteristics.

1.3 The context.

The first element to keep in mind is that many policy or regulatory issues are dealt with at
the local level and sometimes lead to discrepancies between state and federal decisions.
This is true for health, education, food safety, environment, support to innovation … Two
recent examples illustrate this point:

• When USDA inspectors ordered the closing of a meat factory in Texas, because of
the contamination of the products, the manager went to court and won. The judge
allowed the company to continue its operation because the products were sold within
Texas and USDA had no jurisdiction since there was no interstate business. Officials
in Washington claim that the law is wrong but it is still the law. The scientific
expertise on food-borne disease is there, but the popular wisdom has it that well
cooked hamburgers are safe.

• The potential impact of genetic testing for employment or health insurance has been
debated for years in Congress without any conclusion. Meanwhile, many state
legislatures have enacted laws that protect their citizens.

The problem, however, in this second case, as in many other decisions taken at the state
level, is that the local access and/or use of scientific expertise differ widely from place to
place. This leads to a patchwork of legislation, which may not always be easy to
incorporate in federal laws at a later stage.²

²However, the dual system of federal and state policies may also provide a useful flexibility to the
economy. A case in point is the industrial policy. This is anathema in Washington but it is fair to say that
most of the states have policies designed to help nurture their local industries or attract large multinational
companies. Again, there is a large body of knowledge pertaining to the process of innovation, but several
White House initiatives on innovation were dead on arrival in Congress, because of partisan reasons. Still,
the same politicians have a totally different attitude at the local level.
A second key element to look at, especially in Washington, is more procedural. It pertains to the way sound decisions often become embroiled in legalistic disputes, which can drag on for years. This is especially true for environment or health related measures:

- For example, it took ten years for USDA to implement an Act on organic food and to come up with a definition of what that really means. The proposal is, now, open for discussion and a regulation will be enacted in a distant future.

- An other recent case in point is the difficulty encountered by EPA to enforce the pesticide provision of the Food Quality Protection (FQPA) Act of 1996. The legislation was largely an outgrowth of a National Academy of Sciences (one of the prominent sources of scientific expertise) study, which concluded that children experience greater risk from pesticides, especially organophosphates. Congress passed FQPA almost unanimously. EPA was ordered to provide new margins of safety for the legal limits of residues in food. One third of the chemical products on EPA’s list had to be reassessed by August 1999 and the whole process should be finished by 2006. So far, nothing has really happened. Every aspect of the reassessment has led to controversy and to lawsuits by the industry and the consumer groups. A good scientific expertise has been jeopardised by the contradictory interest of various lobbying groups!

Still, one should look beyond the above mentioned anecdotal evidence. The beauty of the system is that, overall, it works! The main reason for this to happen probably lies in the chaotic nature of the political debate and on the delicate checks and balances process, which exist between the legislative, executive and judicial branches. The fact of the matter is that there is an easy access by the various spheres of government to numerous sources of scientific expertise. They, in fact, often rely on the same experts to produce reports or attend committee meetings. This, in turn, creates a consensus, among a majority of the policy makers from both parties as well as within the society at large, on what should ideally be done. What is eventually done is another story!

- A good example was the attitude toward the Kyoto protocol. It took some courage for Al Gore to participate, against the wish of his advisers, in the last phase of the Kyoto conference and to help unlock the debate there, while he knew that a vast majority of Senators in Washington had made it clear that they will never ratify the treaty. Still, government agencies and companies alike are slowly implementing measures to control CO2 emission in the US. But, in the meantime, consumers continue to prefer gas-guzzler SUVs and, when they buy new hybrid vehicles, it is mostly because the price of gas has jumped or because their design looks cool! Saving planet earth is only a bonus. Once more the debate is largely over on the impact of the rise of atmospheric CO2. The expertise is there, but public attitude towards the rational use of energy has not changed, yet. Congress’s position reflects this, while business managers are discovering the productivity benefits of a more frugal approach.
1.4 The source of scientific expertise

Obviously there is abundance of scientific knowledge in the US. The question, though, is how to translate this knowledge into an expertise the non scientists can understand and use. Several ways, some formal and some less formal, do exist to provide this scientific expertise to the decision makers. This includes the various mechanisms set up within the executive and legislative branches of the government as well as a number of non governmental organisations, which often work under contract from the federal government.

There are, however, two different levels at which this expertise is sought, namely the political process and the regulatory system where the political decisions are reduced to practice. Of course, the players are not the same and the information needed is not identical at these two levels, even if there is only one underlying scientific knowledge.

Yet, advisory committees play an increasing role at all level in the system. The emerging issue is that, in many instances, experts who sit in these committees have financial links with companies. In turn, the same companies have interests at stake in the decision made by the regulators upon recommendations of the experts. There is, here, a clear conflict of interest. Recent cases concern the Academy of Sciences report on GMOs or an FDA panel on vaccine.

1.4.1 The political process.

This is mostly the realm of Congress and the White House. They both have a series of formal mechanisms to prepare analyses based on scientific expertise. They also often commit studies to external bodies. It is, however, especially in Congress, that the informal relations between various people from different horizons shape the scientific input into the political agenda.

Congress.

In Congress two elements have to be taken into account. First, the staffers of the members of Congress and of the various committees have a strong level of expertise in different areas, including S&T. That quality of staff and its large size is critical for having a constructive dialogue with the scientific community and for deciphering the hidden

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2 The President announces his vision during his yearly State of the Union address. He, then, translates his vision into concrete plans when he sends the budget proposal to the Hill a few days later. Congress, in turn, enters into long debates on this budget, during which time a lot of policy decisions, going beyond the budgetary debate, are also made. This leads to the vote of numerous Bills by both the House and the Senate, which when signed by the President become Acts. Even if the discretionary expenditures of the federal government represent only a mere 7% of the GNP, the budget exercise is a cradle in which a large chunk of the political debate takes place.
agenda of the powerful lobbying groups. Second, Congressional hearings of all sort on every subject bring together the most knowledgeable people from the US and abroad. The meetings are well prepared by the staffers, who seek advice and information from their own networks and prepare synthesis for the benefits of the members. These hearing are public and usually lead to reports.

- One recent example is a series of hearings that focused on genomic research, its promise, and its impact on society. Others focused on what to do with Microsoft or the future of the e-economy. More classical areas such as policy for education, energy, environment…were also explored. In every case, one of the inputs was the available scientific knowledge pertaining to these fields.

What is also important to consider is the fact that each member of Congress belongs to several committees. Thus, if one of them participates in the House Science Committee hearing on GMOs and is also involved in the House Agriculture Committee there is a natural continuum from scientific issues to, let say, the question on labelling. The debate organised with the scientists is part of the educational process of the decision makers. This education is critical in a system where the lawmakers do not always vote along party lines but according to the concerns expressed by their constituencies. They need to have answers to their specific problems. When it come to technical questions the role of the staffers is to try to avoid interference with more ideological positions on the issues at stake, something that, ultimately, risks crystallising votes along party lines. Building consensus, by bringing in the views of different stakeholders at an early stage, is the rule of the game, but it takes a lot of time.

On a more internal basis, Congress commits the Government Accounting Office (GAO) to produce reports on many subjects. They cover all aspects of the political life, from agriculture and food to veterans affairs and often contain good scientific inputs. Congress also relies on the works done by the Congressional Research Service (CRS).

It is, thus, fair to say that Congress does not lack access to the best available scientific expertise and bring a lot of it to the work of its committees.

The White House

There is a constellation of councils or other bodies within the Executive Office of the President (EOP). Some are established by Congress within EOP. Others are the results of executive orders signed by the President. This creates the inner circle of thinking and this is were the scientific expertise mostly comes into play to fuel the political thinking. A broader circle corresponds to the Members of the Cabinet, who rely on the knowledge produced within their respective Departments and Agencies, many of which are supporting R&D activities and have in-house scientific expertise.

The purpose here, is not to give an exhaustive list of all the players and to describe their respective roles but to look at how the scientific expertise, from various parts of the civil
society, reaches the highest level within the executive branch. This goes beyond what
does the President’s Science Adviser, who is also Director of the Office of Science and
Technology Policy (OSTP). Some examples may help understand how the process works.

- In 1997 the administration had to elaborate a clear position for the forthcoming Kyoto
Conference. The President created, through an executive order, a Climate Change
Task Force (a group of some 25 experts from academia, industry and administration)
in the framework of the already existing Council on Sustainable Development. The
task force liaised with the on-going activities of the Council of Environmental Quality,
which was also active on climate change related issues. Meanwhile, the President’s
Committee of Advisors in Science and Technology (PCAST), which is part of the
OSTP, was asked to come up with proposals for the future of energy research. Lastly,
five DOE laboratories produced a very extensive report on the various ways the
pattern of energy production and use in the US could be brought in line with the need
to emit less CO2. All the information processed by these various bodies was used by
Clinton and Gore in a series of media events during the month of October 1997: a
seminar at the white House with Nobel prize winners, a conference at Georgetown
University…

But this is only part of the story. Congress held hearings on the very same issue. It heard
testimonies from the same people who were involved in the White House exercise. But,
the same data led to somehow different conclusions in the Republican dominated House
and Senate. In the meantime, the Board on Sustainable Development from the National
Research Council was asked to prepare a report on priorities for global environmental
change research. The report was released in May 1998.

- A second example is the quick reaction of the White House after the cloning of Dolly.
Bill Clinton immediately asked the National Bioethic Advisory Commission (NBAC)
to produce, within 90 days an analysis and recommendations on how to handle the
consequences of this scientific breakthrough. NBAC dropped other pending issues
and shifted gear on this new priority. It held several public discussions and produced
a huge report reflecting the consensus reached among the commission members. The
NBAC recommendations were used by the White House to draft a Bill that was sent
to Congress. In the meantime several other Bills containing contradictory language
were introduced in the House and the Senate. Nothing has happened since then, but
the overall situation on embryo research will probably change soon because of the
new hope offered by the use of stem cells. This is, however, another story!

- Yet, a more recent example can be found in the hype and excitement about the
urgency to close the so called digital divide. Again, committees have been brought in
to produce recommendations. Major events were held at the White House, with key
figures from industry. The President visited places where local initiatives had been
launched and talked to community leaders. And, more money was committed in the
budget to solve the problem. The issue here is that little time and support were given
to scholars for understanding what the problem really is! Decisions have to be rushed
so that policy makers are not left behind on issues that have high visibility in the media.

The key point, however, is that, whatever the uncertainty in the current scientific knowledge, the White House uses a very open system to seek advice from academia or from industry. For example the efforts of the PCAST group, which were later translated into the budget proposal, were led by John Holdren from Harvard. The PCAST itself is co-chaired by John Young a former CEO of Hewlett-Packard. The NBAC is chaired by Harold Shapiro from Princeton. On the digital divide issues, a leading figure is Steve Case, the AOL chairman. This means that the White House is able to tap, at any time, the best available expertise through the activity of its various committees and councils.

But the fundamental question remains: is this a genuine effort to understand the issues and to shape the debate, or is it a mere alibi to support political decisions? Probably both.

1.4.2 The regulatory system

While the input of science in the political debate often stays at a macro level—i.e. the potential of stem cells or the effect of rising CO2 in the atmosphere—the regulatory system has to go down to more specific issues—i.e. the level of dioxin or the size of refuges in Bt corn fields. It is also where the culture of litigation in the American society comes into play to challenge government decisions. In this context it is critical that the regulatory decisions be based on the best available scientific evidence and be taken after a wide public consultation of all the interested parties.

Several federal agencies have the responsibility to translate into regulations the decisions made by the political process. This is where the regulatory science comes into play, as one of the many inputs in the design of the final rules. It does it at three different levels: knowledge production, knowledge synthesis and prediction. In the latter case, regulators have to determine how serious is the risk of a newly regulated product or process.

There is, of course, a heavy involvement of government and industry in producing and certifying this knowledge. Agencies are mandated by Congress to interpret and to validate the data, but it is often the role of the industry to provides these data. When there is a gap, agencies are requested to focus their own research on ways to bridge it. To some extent, the regulatory science, which provide the relevant expertise to the decision makers, is performed in a non-academic setting, under stringent time constraints and under the supervision of non-scientific watchdogs.

3 Other illustrations of this behaviour are found elsewhere. In some areas of health or social sciences, there is often a gap between the available knowledge and the question at stake. The problem is that policy makers ought to do something. In Washington the very first step is to increase the budget. A classical example is the reaction towards the AIDS epidemic in the mid 1980’s. The budget for NIH skyrocketed but the real public health actions, which aimed at preventing contamination of gay people in San Francisco and drug users in New York, were implemented by local people with local financial support.
Nevertheless, as we have already seen, most of the regulatory agencies have their own research activities and have access to their in-house scientific resources. This provides them with a good interface with the other segments of the US S&T enterprise. They also extensively rely on the works of committees, as a source of scientific expertise, in their decisions. This practice is carried out under the provisions of the Federal Advisory Committee Act (FACA) of 1972.

The passage of the Act corresponded to a new era favouring a strong public scientific base for public policy. Several agencies were created, at that time, in the fields of health and environment. In the meantime, however, Congress was willing to keep transparency and democratic procedures in establishing these committees defining the way they should work. By law, the committees have to be balanced in terms of point of views. Private lawsuits can be filed to enforce the FACA provisions.

1.4.3 The other sources

There are plenty of well known non governmental organisations that process the scientific knowledge and produce very good reports and position papers. To name a few, one should mention the Rand Corporation in Santa Monica, California, the Battelle Institute in Columbus, Ohio, the Brookings Institution in Washington DC, the Hoover Institution at Stanford University, the Stanford Research Institute in Palo Alto, California… But the most important one is probably the National Research Council (NRC), whose members are drawn from the National Academy of Sciences, the National Academy of Engineering and the Institute of Medicine.

The Academy of Sciences was established by Congress in 1863 at the height of the Civil War: “…the Academy shall, whenever called upon by any department of the government, examine and report upon any subject of science or art…”. NAE and IOM were created at a latter stage. Nowadays, NRC conducts the bulk of the work requested by the various parts of the government. NRC is composed of several boards. For each study it enlists the nation’s top scientists, engineers and other experts. NRC works for both the legislative and executive branches. Even if the studies are financially supported by public money, the Academies maintain a high level of independence in their opinions and recommendations.

Besides, since OTA was disbanded by Congress several years ago, NRC has filled a vacuum in Washington. It is fair to say that science and governance often meet at the Academies.
1.5 The use of the scientific expertise

1.5.1 The political process

It stems from the above, that the political arena has a wide access to scientific expertise, but it is difficult to say what role this information ultimately plays in the decision making. More often than not, the process of accessing the knowledge is rather informal and highly distributed. It is thus not easy to track the fate of a specific scientific advice into the ultimate political stance on a specific issue. Moreover, the checks and balances system that exist between the White House and Congress, allows interested parties with opposing views to push their case. In Congress, there is also a fine balance between House and Senate, as well as between their various committees. For example, the house Science Committee has no jurisdiction on some issues that have a technical angle. Still, it is widely consulted by other committees.

One should also keep in mind the very nature of a political culture that, with the exception of national security issues, has a “wait and see” rather than “what if” attitude. In this context, there is a lot of room for people to push the system to its limit. The pendulum swings one way and, when things go wrong, political decisions, reflecting the outcry of the citizens, send it in the other direction. The environmental damages of the 60’s and the 70’s, resulting from unchecked defence and industrial activities, paved the way for a pro-regulatory government and the use of public money for clean up. Twenty years later, the environment is much cleaner, and people are questioning the need for further efforts. If polluted lands cannot be reclaimed at a reasonable cost and put back on the market, they should be sealed off by the government!

1.5.2 The regulatory system

The use of scientific expertise in the regulatory system is much more formal. The decisions correspond to very specific and detailed sets of rules. The responsibility to make them belongs to the agencies, which should justify the basis of new regulations. In practice, however, the advisory committees play an important, albeit, indirect role, since their recommendations are more than often followed by the regulators.

When the knowledge is imperfect or when there is disagreement between the experts, the agencies, which are the politically accountable bodies, have the obligation to make decisions. If this happens, the use of the precautionary principle is not really part of the process. While regulations are supposed to protect the consumers, they are also carefully crafted in order to take into account the economic interests at stake. The popular wisdom

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4 A classical example is given by the regulatory approach towards fuel additives over many decades. Back in the 1920’s, auto makers and oil companies had to find an anti-knock agent. Engineers came up with two possible solutions. One was the use of alcohol, the other was the addition of a lead compound. The latter solution had a strong economic advantage since Dupont had an exclusive licence on it. There was,
has it, indeed, that if a useful technology has possible negative side effects, new technologies will be found to solve them. In other words, if science is the problem then science should also be the solution.

- An interesting example is attitude towards GMOs. The main thrust of the decision taken by the regulatory agencies in the mid 1980’s, after consultations with the scientific and industrial communities, was that the already existing approval process should work just fine for these new crop varieties. There was no need to single out GMOs. Companies had to work, on a voluntary basis, with the relevant agencies.

There is a lot of procedural activities behind the many regulations that govern the life of the US consumers. In short a regulatory agency is mandated, usually through an Act, to set up a piece of regulation. It usually conducts a risk assessment and drafts a text which is published in the Federal Register for comment by all interested parties. Comments are analysed, possibly taken into account, before a final version of the regulation is enacted. The scientific expertise comes into play at two different levels. First, the experts from the agencies and their advisory committees base their recommendations on the available knowledge and process it for the decision makers. Second, public comments may also be based on an interpretation of the existing scientific knowledge.

All in all, the regulatory agencies walk a fine line that delineates public concerns and private interests. This is probably why they use a cautious step by step approach.

- When the new miles-per-gallon performance rules were set up by the administration, the focus was only on the classical personal automobile. Light trucks, which were mostly used in the countryside by farmers and other small businesses were not included. Now that people have understood the benefits of mpg performance and that many pick-up trucks, four-wheel drive vehicles and SUVs are seen in the cities, it makes sense to include these various categories. Doing that some years ago, would have blocked the regulatory process. At the end of the day, a consensus has to be reached and the agencies listen carefully to all the parties during a transparent process.

This process, however, may be long and painful. Often an Act is vague and leaves the details of setting up the standards to the agency. Everybody agrees on the need to act but not necessarily on the way to do it. Protecting children’s health is a given. How to do it is less obvious. In other instances, the Act is too strict in its mandate to the agency but request actions that can not be implemented. In both cases it becomes a nightmare for the

however, a potential risk associated with the release of lead in the atmosphere. But, the Bureau of Mines, deciding that this risk was not obvious, allowed the use of lead gasoline. Dupont and GM established a joint venture to produce it. Eventually, the use of lead was banned, not because of its inherent risks to health, but because of the mandatory use of catalytic exhausters in cars, which resulted from the implementation of the Clean Air Act. The problem, though, is that lead additives were replaced by MTBE. Air in big cities got much better but leaks of MTBE have now contaminated the underground water. Logically, California decided to ban MTBE last year and EPA is considering to do the same nation-wide. The ultimate solution will be to use...alcohol, as originally proposed in the 1920’s!
agency in charge. This is why it is critical that a good dialogue exists between the experts from the agency and the staffers in Congress. This work behind the scenes helps render the results of the political dialogue more easy to implement.

### 1.6 Conclusion

In *the land of the free, the home of the brave*, everything is allowed unless it is expressly forbidden. Less regulation is good government. Little should be done that prevent entrepreneurs to take risks and to bring new products or processes to the market.

Except for a brief period in the 1970s, when the mood was to support the use of public science for better policy, the anti-regulatory attitude was the norm. It came back with the Reagan administration in the early 1980s and has not receded since then. The recent boom of the economy, which is attributed in part to the diffusion of new technologies, is not going to change that. Science is good and if problems arise, the market will take care of them. Ultimately, if something goes wrong, litigation will follow and the plaintiffs will get compensation.

The problem, thus, is not the access to scientific expertise. Science is everywhere in the decision making system, at the political and regulatory level. The difficulty lies with the use of this expertise, which to say the least, is very cautious. When it comes to making decisions that will shape the work of the government, politicians need to be convinced with hard indisputable data. And, even when there is good reason to do something, ideologies may prevail. Public support of embryo research is banned because of the pro-life lobby, climate change is a non-issue because of industry’s fear of loosing its competitive edge, nuclear energy is dying because of a not-in-my-backyard attitude. And, when it comes to implementing decisions that have already been made, it may take years of bargaining and court fights.

The paradox is that, with all these apparent limitations, the system works. Or, at least, it works in the system of reference that corresponds to the prevalent culture in the US. The system is not better or worse than others, it is different. There is nothing wrong with that unless some imperialistic attitude, for example in Congress, tries to export this system elsewhere. As far as the question of science and governance is concerned, the buzz-words seem to be: education of the policy makers, consensus among various stakeholders, support of technology for economic growth, minimal regulations to protect the basic rights of the people.
2 Stem cells

The main ethical and regulatory issues arise by the potential use of pluripotent stem cells, be they embryonic stem cells (ES cells) or embryonic germ cells (EG cells). This is because they are derived from aborted foetuses or from embryos obtained by *in vitro* fertilisation (IVF) or, potentially, by cloning. The successful isolation and culture of ES and EG cells have renewed a longstanding controversy about the ethics of the research involving human embryos and cadaveric foetal material. On the contrary, stem cells derived from adult organisms or tissues do not pose ethical questions and have been used for research or therapy for many years. Their medical applications are regulated by well-established procedures.

The following information concerns, thus, the use cells derived from embryos or foetuses.

2.1 Background for the case study

The legislative background is fuzzy, to say the least. There is no regulation, whatsoever, for research activities undertaken by private entities and supported by private money. The first successful culture of human stem cells, in 1998, by two groups at the University of Wisconsin and at Johns Hopkins University was entirely supported by a private company based in California. In the same vein, human foetal neural stem cells have been used for more than ten years for the treatment of Parkinson’s disease.

On the other hand, Congress and the White House have banned the use of federal money for research on a human embryo for the last five years. Several pieces of legislation have been introduced lately to solve the stem cell “dilemma”. None have passed and the new Congress, which has kept a slight Republican majority, is not likely to agree any time soon, especially if Bush wins the Presidency!

The only move came from NIH, which approved, in August 2000, a set of guidelines for the use of human stem cells in federally supported research. In short, NIH scientists or grantees can use existing human pluripotent stem cells but cannot undertake derivation

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5The term *stem cell* has been commonly used for a while to refer to the cells within the adult organism that renew tissues. They can be *progenitor cells* whose differentiated progeny consist of a single type of cell or *multipotent stem cells*, which can give rise to several terminally differentiated cells. In recent years, however, the more extraordinary human stem cells have been derived from *foetus or early stage embryos*. They are found in the following sources:

- foetal tissue following elective abortion (EG cells);
- human embryos that are created by IVF and are no longer needed (ES cells);
- human embryos that are created for the sole purpose of providing research material (ES cells);
- potentially, human (or hybrid) embryos generated asexually by somatic cell nuclear transfer or similar cloning techniques (ES cells).
of these cells from human embryos or foetus. Of course, opponents to stem cell research have challenged those guidelines in Congress.

### 2.2 The advice structures that were used

Three main institutions are worth mentioning in this context: NBAC (National Bioethics Advisory Commission), AAAS (American Association for the Advancement of Science) and Congress.

In November 1998, President Clinton charged NBAC “with the task of conducting a thorough review of the issues associated with human stem cell research, balancing all ethical and medical considerations.” This Commission presented its conclusions and recommendations in September 1999. Its members found substantial agreement among individuals with different perspectives that although human embryos and foetuses deserve respect as forms of human life, the scientific and clinical benefits of stem cell research should not be foregone. NBAC recommended that:

- research involving the derivation and use of EG cells from cadaveric foetuses and the derivation and use of ES cells from embryos remaining after infertility treatments should be eligible for federal funding;
- federal agency should not fund research involving the derivation or use of ES cells derived from embryos made solely for research purposes and the derivation or use of human ES cells from embryos made using somatic cell nuclear transfer into oocytes;
- prospective donors should receive timely, relevant and appropriate information;
- no promise should be made to donors by federally funded scientists that stem cells derived from remaining IVF embryos will be used to treat patients specified by the donors;
- embryos and cadaveric foetal tissue should not be bought or sold;
- DHHS should establish a National Stem Cells Oversight and Review Panel, with a sunset provision of five years;
- IRBs review the derivation and use of stem cells;
- all federal agencies should comply to the Review Panel recommendations;
- privately funded research that involve deriving ES cells from embryos created solely for that purpose should be subject to guidelines to be developed by professional societies.

In November 1999, AAAS and the Institute for Civil Society released a report titled: “Stem Cell Research and Applications: Monitoring the Frontiers of Biomedical Research.” The two institutions found among other things that:

- existing federal regulatory and professional control mechanisms, combined with informed public dialogue, provide a sufficient framework for oversight of human stem cell research;
- federal funding is necessary to promote investment in this promising line of research;
- public and private research on human stem cells derived from all sources should be conducted;
- public funding should be provided, but not at this time for activities involved in the isolation of embryonic stem cells, about which there remains continuing debate;
• the consent of progenitors should be explicit before using their embryos;
• intellectual property regimes should not restrict basic research or encumber future product development.

The debates in Congress were much less favourable for stem cell research. The hope was that adult stem cells could replace embryonic material and thus, eliminate all of the issue. However, several testimonies at various hearings held in Congress were not so optimistic. Though the debate has similarity with the abortion debate, the two issues are not entirely parallel. The hope is that some of the “pro-life” members of Congress will, nevertheless, support legislation that favours the use of federal money for embryonic stem cell research.

2.3 The operation of the advice bodies

All the above mentioned activities were fully transparent. NBAC hold regular public debates, AAAS hosted a public meeting and hearings in Congress are open to the public. NBAC may, in some cases, commission specific research. AAAS assembled a working group of experts. As usual, Congress is asking for testimonies. Overall this was a fairly transparent process.

2.4 The interaction between the advisory bodies and the decision-makers

NBAC was asked by the President to look at the stem cell controversy. AAAS acted on its own initiative. Hearings in Congress are part of the advisory system of the Legislative Branch. The members of the House or of the Senate call them. While there is always a political agenda behind the hearings in Congress, the work of NBAC and of AAAS are fully independent.

2.5 The incorporation of advice into policy

This is clearly the weakness of the system, especially in the very partisan issue of embryo research. Congress is blocked for the moment and will remain so for a while. There is little room for bipartisan action here. The outgoing administration has used this vacuum to let the NIH adopt its guidelines, which are even more restrictive that the NBAC proposal. Yet, private research continues unabated. Several companies have been formed, not only to further develop EG an ES cells research and applications, but to combine this expertise with cloning techniques and breakthrough in telomers! There is no reason for this situation to change any time soon.

But, the truth of the matter is that, while there is quite a bit of debate of usually great quality, decisions have been taken so far at the lowest possible operational level in order to keep things moving. Pragmatism, not rhetoric, seems the most appropriate approach to a pure application of the American tradition.
3 Electromagnetic fields

For the purpose of this note, the analysis of regulatory issues pertaining to health effects of electromagnetic fields (EMF) is restricted to those possibly caused by mobile phones or their related telecommunications transmitters. For the time being, this is the most debated EMF question in the US. There are two possible sets of question, one pertaining to the mobile phone based stations and the other to the cell phones. For the former, the level of radiation near a cell phone tower (maximum 0.01 mW/cm²) is well below the FCC public exposure standard (1mW/cm² at 2000MHz and 0.5 mW/cm² at 900MHz). The key issue is, thus, the local irradiation produced by cell phones. The following discussion mostly deals with that specific part (the cordless phone is not an issue because the level of radiation is deemed much lower).

3.1 Background for the case study

This is a regulatory affair. The Federal Communications Commission (FCC) has the leading role. Yet, an interagency group has the responsibility to co-ordinate mobile phone safety at the federal level. It comprises FCC, FDA, EPA, NTIA, NIOSH and OSHA, the last two dealing with occupational safety problems. The bottom line is that manufacturers must prove, not that their products are safe, but that they meet exposure limits. This is an entirely different matter.

3.2 The advice structures that were used

FCC is required by the National Environmental Policy Act of 1969 to evaluate the effects of emissions from FCC-regulated transmitters on the quality if the human environment. At the present time there is no federally mandated radio frequency (RF) exposure standard. The FCC has issued safety guidelines for all RF emitters including cellular phones.

In 1996, FCC guidelines were updated. These guidelines are based on recommendations from ANSI (American National Standard Institute), NCRP (National Council on Radiation and Measurements) and IEEE (Institute of Electrical and Electronics Engineers). These are non-governmental organisations, which have developed widely accepted safety standards on their own initiative. The FCC set maximum permissible exposure (MPE) limits for ground transmitters, based on NCRP recommendations, as well as specific absorption rates (SAR) for hand-held devices, following the ANSI/IEEE

6 Electromagnetic fields are divided in four broad categories by the WHO International EMF Project:
- static fields (0 Hz) from magnetic or electrolytic systems;
- Extremely low frequency fields (>0 to 300 Hz) from transmission of electric power;
- Intermediate frequency (>300 Hz to 10 Mhz) form security or video display units;
- Radio frequency fields (>10 Mhz to 300 Ghz).

In the US, cell phones operate in two main frequencies, the older systems near 850 Mhz and the newer personal communications systems (PCS) near 1990 Mhz.

7 SAR limits for cell phone became effective on October 1997. The FCC limits peak exposure to 1.6W/kg of tissue averaged over any single gram of tissue (or 1.6W/g). Mobile telephone handsets antenna radiates
guidelines. New efforts are underway to revise them. The problem is that the FCC is waiting for specific uniform procedures and methodologies for testing cell phone radio frequency emissions.

By September 2000, all FCC licensees were expected to be in compliance with the new limits. For portable phones authorised since June 2000 maximum SAR levels should be noted on the grant of equipment authorisation. Users can access the FCC web page and get information of the maximum SAR levels for their handsets by using the ID number of their phones.

The Food and Drug Administration has authority to take action if mobile phones are shown to emit a level of radiation that is dangerous to the user. However, according to FDA, the available scientific evidence does not demonstrate any adverse health affects associated with the use of mobile phones. Nevertheless, in June 2000, the agency and the telecom industry launched a $1 million research programme on mobile phones and health. The problem is that while there is no conclusive evidence of damaging effects, there is not either proof that mobile phones are safe.

3.3 The operation of the advice bodies

As noted earlier, the basis for the regulation came from non-governmental organisations. Details on NCRP recommendations were published in 1986. ANSI/IEEE safety standards were released in 1992. In addition, FCC has also used more recent guidelines recommended by ICNIRP (International Commission on Non-Ionising Radiation Protection).

3.4 The interaction between the advisory bodies and the decision-makers

All the above mentioned non-governmental organisations have agendas of their own. FCC uses the body of works they produce.

3.5 The incorporation of advice into policy

As usual, the FCC undertook a wide public consultation of various stakeholders, i.e. other agencies, industry and the public at large, before issuing its final safety guidelines. Notices were published in the Federal Register with deadlines for comments.

The bottom line is that the issue of radiation exposure related to cell phone use is a purely regulatory affair. It concerns the safety of the consumers. There are no standards per se but only guidelines. However, as FDA puts it, there is insufficient scientific basis

about 600 mw for an analog devices and 125mW for a digital unit. This can push exposure level close to regulatory limits especially because this exposure depends greatly on the exact position of the handset with respect to the head. Industry and academic investigators have reported data showing that mobile phone on the market meet regulatory limits. There have been some exceptions. Sony has recalled 60 000 phones that exceeded FCC exposure limits.
for concluding either that wireless communication technologies are safe or that they pose a health risk to millions of users. More research is currently being carried out. But, under this uncertainty, the rapid growth of the cellular phone business continues unabated.