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Contributors

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Better Regulation Task Force

Scientific Research: Innovation with Controls

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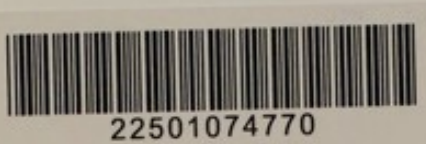
January 2003



Contents

1. Foreword

The UK has a proud history of scientific research and innovation, but in an increasingly risk averse society this is in danger of being undermined by excessive regulation. Scientists need to have the freedom to explore avenues that open up to them, but at the same time they need to understand and acknowledge the concerns of many within society. They should not be allowed complete freedom, especially if that freedom breaches moral, ethical or safety concerns. A properly designed regulatory regime will help achieve that balance. This report suggests how that balance might be achieved.

This is the Task Force's final report of its 2001/02 work programme. It looks at issues not previously examined by the Task Force – genetic modification, embryonic stem cell research and nanotechnology. Controversial fields, but equally all areas of science that have the potential to change our lives.

This report does not discuss whether any of the areas of research we have looked at - seed and plant breeding, including genetic modification, embryonic stem cell research, and nanotechnology – is right or wrong. That is not the job of the Task Force. We do look at how the research is regulated. Government has a fine balancing act to perform when seeking to regulate scientific research. On the one hand it does not wish to inhibit research which holds great potential for the wealth and well-being of the country, but on the other hand it has to take notice of the moral and ethical concerns that many will have about certain areas of scientific research.

As a starting point we propose an outline in this report, which we would like the Government to use to initiate a debate with the scientific community about the regulation of scientific research. The outline will bring more transparency into the process, whilst ensuring adequate controls are maintained. Scientific research largely goes through a four stage process:

- stage 1: pre-research preparatory stage;
- stage 2: blue skies research;
- stage 3: research and development;
- stage 4: practical application.

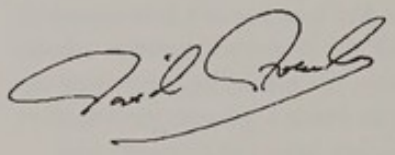
Different regulatory emphases may be needed for each stage. Some regulations must flow through the whole process, for example those that cover moral, ethical and safety issues. Others can be subject-specific regulation when a piece of research reaches a particular stage, such as field and clinical trials.

Of course there will always be those who oppose certain types of research. Government needs to listen to such opposition and decide whether it is based on sound scientific or moral grounds. Government then needs to weigh up those views against the potential benefits. This is all part of devising a transparent and proportionate regulatory regime.

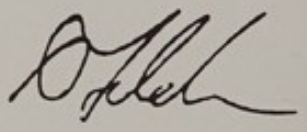
In the latter half of the report we have looked in more detail at the regulation of seed and plant breeding, including genetic modification, embryonic stem cell research, and nanotechnology. All are very controversial areas of science, and ones which excited strong emotions. The UK is seen as the world leader in embryonic stem cell research, and this is largely due to the effective regulations that control it. They are clear and targeted, and we believe that they strike the right balance between allowing new discoveries to be made, whilst at the same time setting clear boundaries as to what is permissible.

Unfortunately the seed and plant breeding regulations are less clear. They contain some requirements, such as Higher Voluntary Standards and the need to demonstrate value for cultivation and use, that we do not believe should be part of a modern regulatory regime. Technology has moved on greatly since these requirements were introduced, and the regulations need to move on too.

Whilst this report is primarily aimed at Government, we trust that other interested parties will read it. It should start a debate about the regulation of science.



David Arculus
Chair, Better Regulation Task Force



Stephen Falder
Chair, Science sub-group

2. Introduction

> "By designing and implementing regulations sensitively, the Government can encourage rather than deter innovation in the UK by creating confidence for firms and research organisations to undertake science"
>
> Investing in Innovation. A Strategy for Science, Engineering & Technology. DTI, HMT, DfES. July 2002

The United Kingdom has a long and impressive history of being a world leader in scientific research and innovation. Many of the world's scientific discoveries have been based on the work of British research and British scientists. In all aspects of our lives at home, at work, in schools and in hospitals the products of science surround us. More scientific discoveries have been made in the last 10 years than in the whole of human history, and even more are likely to be created in the coming decades.

All scientific research holds out the possibility of huge benefits for everyone. But at the same time scientific research carries potential risks, which can cause understandable concerns. Scientific research can also raise profound moral and ethical questions. The public needs to know that scientific research will only be carried out within boundaries that reflect their concerns. This creates a dilemma for government. It does not wish to stifle scientific research, but at the same time it needs to make sure that people and the environment will not be put at risk.

There is a mismatch between scientific research and regulation. Research is a creative and evolutionary process. It pushes back the boundaries of the unknown. Answering one question raises many more, which could not have been predicted at the outset. Regulation tries to exert a controlling force. Most scientists accept that some form of regulation is necessary, but do not want regulations that will close down avenues of discovery.

This first section of this report suggests a regulatory model for different stages of scientific research. We look at the four main stages that research goes through:

- the pre-research preparatory stage;
- "blue skies" research which is conducted in a confined area;
- research and development which moves out of the laboratory and into the field; and finally
- practical application, where a decision is required before a product can be placed on the market.

Such a model would make the regulation of scientific research more transparent, and we hope that the Government will use this report to initiate a wider debate on the regulation of scientific research.

Later in the report we look at how regulation impacts on two areas of bioscientific research – plant and seed breeding and embryonic stem cell research. We then look at nanotechnology, which is a fast emerging area of scientific research. We compare these areas with our proposed model, and make recommendations on how the regulatory regime in each area could be improved.

This report deliberately does not discuss the merits or otherwise of any types of research. That is for others to do. Our role is to examine the regulatory regime that the Government has put in place for scientific research.

2.1 Scope of the report

Science and scientific research, by its very nature, is almost limitless in its scope. For that reason we had to concentrate the focus of our work on just a few areas of scientific research. We deliberately selected areas of research which attract a great deal of public and media interest. Rarely a day goes by when either genetic modification or embryonic stem cell research does not feature in the media. Nanotechnology could attract the same attention in the future.

This report is deliberately non-technical, as we would like it to be read by as wide an audience as possible. If the Government does start a debate on the regulation of scientific research using our suggested model, that debate should be opened up to a wide range of stakeholders.

2.2 Full list of recommendations

Regulating scientific research

Recommendation 1:

Regulating scientific research – innovation with proportionate controls. The Task Force recommends that the Office of Science and Technology use the Task Force's outline for the regulation of scientific research to initiate a debate with the scientific community and other stakeholders on how scientific research should be regulated.

The Office of Science and Technology should report on progress with this debate by January 2004.

Better regulation of seed and plant breeding

Recommendation 2:

Remove outdated legislation

- DEFRA, should, at the earliest opportunity, negotiate to have the value for cultivation and use requirements removed from the EC seed and plant breeding directives. Until negotiations are complete, DEFRA should implement the requirements in a light-touch way;
- DEFRA should, at the earliest opportunity, remove the Higher Voluntary Standards from the seed certification regulations. The Task Force invites the devolved administrations to follow suit.
- DEFRA should report to the Task Force on the progress of the above by the end of July 2003 and January 2004.

Better regulation of stem cell research

Recommendation 3:

HFEA consultation. The Task Force recommends that all HFEA consultation documents should follow the Cabinet Office guidelines, and include a regulatory impact assessment.

Recommendation 4:

Research Ethics Committees. The Task Force recommends that:

- the Multi-site Research Ethics Committee (MREC) system should be reviewed in October 2005;
- by the end of 2003, it should be possible to complete all Local Research Ethics Committees (LREC) and MREC forms online; and
- approvals granted by Research Ethics Committees should be consistent across committees, as far as is compatible with the independent nature of ethical review.

Recommendation 5:

Research licence applications. The Task Force recommends that, with immediate effect, the HFEA ensure that its Licence Committees always have a majority of lay members.

Recommendation 6:

Review the 2001 amendments to the Human Fertilisation and Embryology Act 1990. The Task Force recommends that the Department of Health should review, in 2004, the 2001 amendments to the Human Fertilisation and Embryology Act 1990, to make sure the Act keeps pace with the developments in embryonic stem cell research and public opinion. Thereafter the legislation should be reviewed every three years.

Nanotechnology

Recommendation 7:

Nanotechnology. The Task Force recommends that, in the area of nanotechnology, the Government should:

- enable, through an informed debate, the public to consider the risks for themselves, and help them to make their own decisions by providing suitable information;
- be open about how it makes decisions, and acknowledge where there are uncertainties;
- communicate with, and involve as far as possible, the public in the decision making process;
- ensure it develops two-way communication channels; and
- take a strong lead over the handling of any risk issues, particularly information provision and policy implementation.

2.3 Facts and figures

The UK is a world leader in life sciences – one of the focuses of this report. The impact on human health of further understanding of the development of cells could be enormous. Three quarters of the biotechnology drugs now in late-stage clinical trials in Europe originate in Britain.

The biotech market in Europe alone is expected to be worth $100 billion by 2005. The number of people employed in biotechnology and associated companies could be as high as three million.

The Government has placed increased importance on scientific innovation, and a large amount of money is being invested in scientific research.

In the 2002 Comprehensive Spending Review the science budget annual average was raised in real terms by 10 per cent per year between 2002/03 and 2005/06. Business expenditure on research and development has increased in real terms since 1998. Between 1998 and 1999 the increase in total expenditure in real terms was 7.6 per cent[1].

It is important that as much as possible of this money and expertise is devoted to actual research, and does not disappear in the cost of complying with bureaucracy.

2.4 Our approach

In the course of our work we gathered a great deal of information from many sources – Government Departments and Agencies; academic institutions; research institutions; trade associations; pressure groups; businesses involved in scientific research and development; and, of course, individual scientists and researchers. We read a large number of publications and articles, and attended a number of seminars and conferences on scientific issues.

[1] Comprehensive Spending Review 2002

We held a series of meetings with stakeholders and Government Ministers and officials. We are very grateful for the frankness with which everyone contributed.

A list of all those we met or who submitted written evidence is given at Annex D. Annex E gives a list of all the reports, publications and information sources we used.

2.5 Sponsor Minister

Lord Hunt, at the Department of Health, has agreed to respond to this report on behalf of the Government. Lord Hunt is the Minister with policy responsibility for embryonic stem cell research. He will receive contributions from the Rt Hon Michael Meacher MP, Minister for the Environment at DEFRA, who has policy responsibility for plant and seed breeding, and the Office of Science and Technology. We welcome the co-ordinated approach the Government is taking to this report.

Plant and seed breeding regulations are devolved. The Task Force's remit in devolved matters does not extend beyond England, but we hope that the devolved administrations will work with DEFRA to implement our recommendations relating to seed and plant breeding.

3. Better Regulation of Scientific Research

> "Regulation of science reflects society's demands for an ethical approach to research."
>
> HM Government July 2002

3.1 The world in which scientific research operates

Government has a difficult job in ensuring that scientific research can flourish, whilst at the same time confirming to the public that research being carried out is both ethical and safe.

Over recent years many have become distrusting of some scientific research and are often fearful of what scientists are doing. The media plays a very large part in fuelling these fears. Calling genetically modified food "Frankenstein Foods" for example by some sections of the media makes it very difficult for the Government to generate a sensible debate about genetic modification of foodstuffs. The public questions who is looking after their interests. But it is unrealistic for them to expect scientists to declare something as totally safe.

Risk is often seen as a situation that is unusual: a situation not previously encountered and one that has a significant potential for damage. We all now have much greater access to information than ever before, and this gives us a much greater awareness of risk. But much of this information is presented in a conflicting or contradictory way, which makes it difficult to assess and assimilate.

General attitudes towards science and technology have become more ambivalent. Scientists working in universities are more trusted than those working in a Government Department[2]. In a study carried out for the Better Regulation Task Force in 1999 we found that "government scientists" enjoy less trust than TV presenters, "independent scientists" or pressure groups, but more than private companies or Government Ministers. We also found that television reporting is trusted more than that in newspapers[3].

Risk issues of most concern are those that affect peoples their own and their families' lives. People want to see and understand a real benefit for themselves and society, before they are willing to take on the risk.

There is a clear distinction between the risks that people can see and judge for themselves and those risks where they have to cede responsibility to others. For example, people have a high degree of faith in their GPs whom they can see and experience and make immediate judgements upon. They are much less trusting of the underpinning systems, such as central Government Departments, where it is difficult for them to make a reasoned assessment. Given that many of the failures are systems failures, this is not unreasonable. It is this systems approach which is relevant to this report.

There is concern about the possibilities emerging from biosciences. This is because of successive scares over E.coli, BSE and GMOs. But again there is ambivalence about the acceptance of biological sciences.

[2] Public understanding of science in Britain. Durant and Bauer. Report for the Office of Science and Technology 1997.

[3] Public Attitudes to Risk. Better Regulation Task Force/MORI. January 1999.

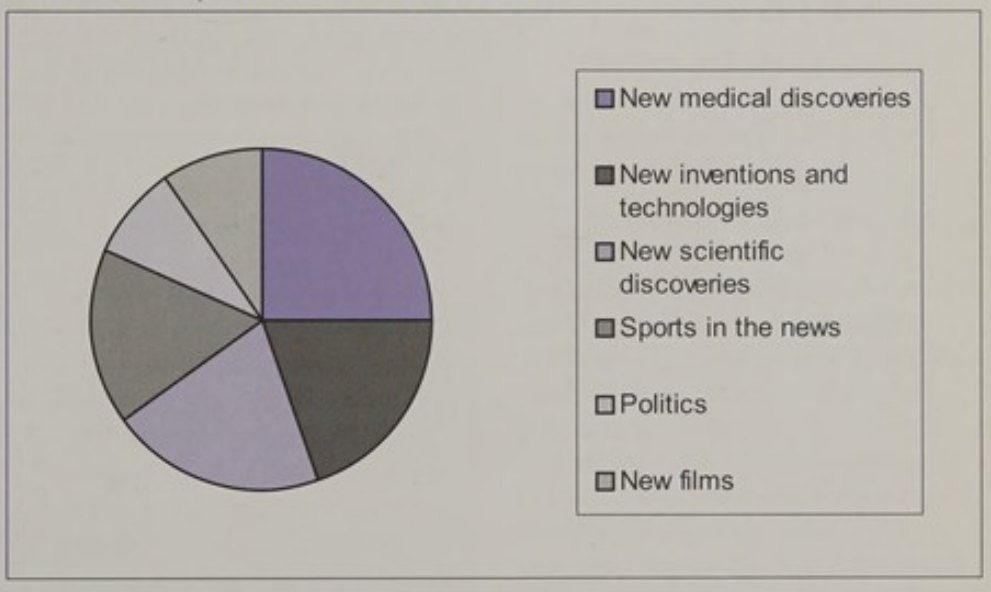
People are more accepting of genetics research that is directed towards health, but disapprove of genetic engineering, particularly if it involves eugenics – attempting to improve the human race by genetic or selective breeding.

Much of this distrust of science and scientists comes from a shift in the relationship between the public and "experts". In all areas of society it is now normal to question the assertions of those in authority. Scientific authority in this respect differs little from the authority of parents, teachers, the police or Parliament.

Government must play a leading role in the handling of risk issues when it comes to information provision and policy implementation. The public wants a transparent decision-making process, with themselves included as part of the process.

Interestingly, against this distrust there is a high interest in science. An Office of Science and Technology (OST)[4] report in 1997 found that people's assessment of their own levels of interest in science, technology and medicine were considerably higher than those for sport in the news, politics and films – see the chart 1 below.

Chart 1: Self reported levels of interest in...



[4] A Review of Science Communication and Public Attitudes to Science in Britain. Office of Science and Technology. 1997

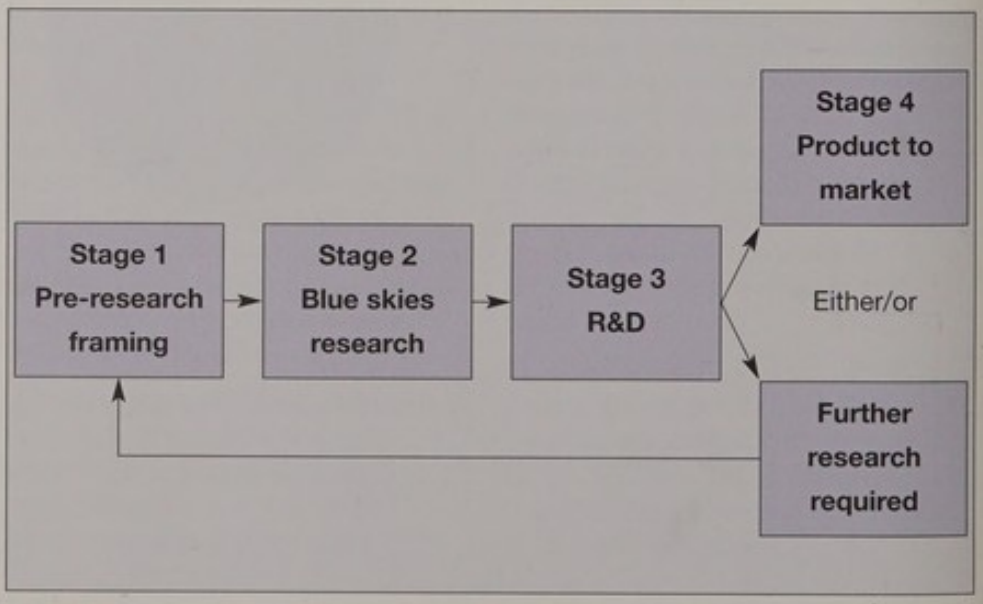
The way in which the media interprets new discoveries has a critical influence on public perception. The Government should capitalise on this interest, and ensure that it engages the public fully in scientific debates. People are very uneasy about scientific research where they feel that something is being held back or where they feel that they are not being told the whole truth. By its very nature, scientific research is about uncertainty. Government is viewed by many as being secretive and selective about disclosing information. Successive food and health scares have left many consumers, plus the media, profoundly sceptical of anything Government says during a crisis. The Government needs to be up front with information and acknowledge doubt and uncertainty where it exists. But at the same time it needs say how it is dealing with those doubts and uncertainties.

Scientists themselves accept the need for regulation. They view it almost as a contract between themselves and the public. Regulation sets out what they can do and what the majority of the public is willing to accept. Clear regulation helps scientists understand where the boundaries lie.

Many felt, however, because the public sector is now the largest funder of "blue skies" research, increasingly control is exercised through funding rather than transparent regulatory structures. Researchers would prefer to see a more transparent process.

3.2 Regulating the different stages of scientific research

Through our discussions with many stakeholders we have concluded that there are broadly four distinct stages of scientific research. At each stage a regulatory regime is needed that balances the ability to be innovative and make discoveries with the public's concerns. Some requirements however, such as State regulations that set boundaries which reflect moral and ethical concerns, must be an integral part of the whole research process from beginning to end.



For simplicity we have drawn our outline as linear but often scientific research does not follow such a time flow. Much primary research will never reach research and development stage; similarly blue skies research may be needed to help inform decisions over whether a product can be placed on the market.

What is most important is that the regulatory regime is appropriate for that stage of the process. If Government is able to decide where a particular stage of research fits within the model, it should be able to adopt the appropriate regulatory regime: one that is proportionate to the research being done and reflects the concerns people may have.

The Office of Science and Technology should report on progress with this debate by January 2004.

Recommendation 1:

Regulating scientific research – innovation with proportionate controls. The Task Force recommends that the Office of Science and Technology use the Task Force's outline for the regulation of scientific research to initiate a debate with the scientific community and other stakeholders on how scientific research should be regulated.

The Office of Science and Technology should report on progress with this debate by January 2004.

3.2.1 Stage 1: Pre-research framing

Before any research can take place there is a framing process during which the nature and purpose of a particular piece of research and its parameters are drawn up.

For this process to work effectively, it must be clear precisely what regulatory structure surrounds the "blue skies" period of research (stage 2), so that once the research is decided on it can move into the stage 2 "box". This framing process does not require regulation, but Government needs to make sure that scientists and researchers can find out easily what regulatory constraints will be on them if they choose a particular course of action. Scientists will then be able to make informed decisions about their research.

If the research to be carried out will raise moral and ethical questions, the regulations controlling these need to be consistent throughout the whole research process.

3.2.2 Stage 2: Blue skies research: containment regulation

The second stage is what some might term "real science" – the voyage of discovery. Such research is where the scientist does not know where they may end up. There may be a number of avenues explored, all of which add to the body of academic knowledge but which may never result in a final product. Despite this, it is important at this stage that the researcher is able to explore all the avenues. Government should not close down avenues, unless the proposed research is unethical or deemed as unsafe for the researcher, the environment or the public in general. Government should set the boundaries through regulation, but these must be as simple and clear as possible.

We see this containing regulatory regime as being applicable to stages of the research process, but is particularly important for "novel" research where new discoveries may be made. This regulation is essential to protect other people and the environment; to ensure that experiments on animals are kept to the absolute minimum; and to take account of society's moral and ethical views.

These regulatory boundaries may be specific: for example health and safety legislation; laboratory control legislation, or deal with ethical and moral issues, such as the use of animals in scientific experiments. All research that involves humans has to receive approval from an ethical committee, and the Human Fertilisation and Embryology Act 1990 (as amended) sets the 14-day limit after which research cannot be carried out on embryos.

However, it is essential that this containment is not excessively restrictive. The regulatory regime that is put in place should be proportionate to the risk and to moral and ethical concerns.

We would describe this containment regime as the 'box' within which scientists should have the maximum freedom to pursue different lines of enquiry. Those lines of enquiry must of course remain consistent with the regulatory framework - or 'box' - within which they are set.

But it is equally important that the science that is conducted within the 'box' is good, high quality research. This is not, however a process which is susceptible to statutory regulation and we see here an important role for effective governance regimes established by the institution through which the research is being done.

3.2.3 Stage 3: Research and development: subject specific regulation

At some stage in a research project there comes a point when the research may move out of the laboratory and into the wider environment. This may be, for example, field trials for new seeds and plants or clinical trials for new medicines or therapies. It is at this stage that the public becomes more involved, and unless briefed adequately, more concerned. Because of the potentially greater risk to the public and the environment, we see a need for subject specific regulation, in addition to the containment regulations setting ethical, moral and safety boundaries described at stage 2.

In drawing up the stage 3 regulatory framework, the Government needs to ensure it conducts an open debate, including effective communication where facts are uncertain. If possible, Government should ensure that the public has input into the decision making process through open meetings or lay representation on committees.

In designing an effective regulatory regime, the Government should consider all options. We have looked in the past at the sunsetting regulations[5]- that is regulations that are time limited. We concluded that such a mechanism could be very effective where there are significant scientific uncertainties or where technologies are moving fast. We see scientific research as fitting well into this category.

3.2.4 Stage 4: Product to market

The final stage, providing the field research has been successful, is to bring the product to the market. The decisions taken at this stage are not primarily scientific, but ones based on information gathered through scientific research.

The decisions at this stage are societal, commercial and governmental ones where trade-offs are being made at a series of levels about the risks and benefits to society, commercial advantage etc. It is because such questions lie at the heart of many of the science issues that the public will wish to be involved.

[5] Annual Report 2000 – 2001. Better Regulation Task Force. October 2001

4. Better Regulation of Seed and Plant Breeding

Plant breeding today is a highly sophisticated industry involving major investment, but its origins go back many years to early farmers who selected their best plants in one year to provide seed for the next. The constant aim of plant breeding is to improve the quality, uniformity and performance of existing agricultural and horticultural crops, and to develop new varieties. The objective has been to develop plants with higher yields better adapted to human needs.

Until the 1960s, plant breeding in Britain was largely confined to publicly funded research. This was mainly in response to food shortages after the war when it was imperative to maximise crop yield. The reliance on publicly funded research changed in the mid-1960s when the Plant Varieties and Seeds Act 1964 was introduced. This Act introduced a system of royalty payments on individual plant varieties, known as "Plant Breeders' Rights'", which led to large expansion of plant breeding as a commercial enterprise.

Today, much research into crop science is still conducted by public sector research organisations, but the majority of commercial plant breeding takes place in the private sector.

There are some 60 plant breeding companies in the United Kingdom who are active across the whole range of major arable crops through to ornamental garden shrubs and flowers. The plant breeding sector employs some 5 000 people, and supports a further 5 000 jobs in seed production and distribution.

4.1 Conventional breeding

Conventional plant breeding involves crossing parent plants, then selecting the best plants from resulting offspring to be grown on for further selection. Selected parent plants can be cross-pollinated to combine desired characteristics. Developing a successful variety is an extremely lengthy process – up to 12 years in the case of cereals, even longer for, for example, potatoes.

4.2 Enhanced breeding

There are several ways to reduce the lengthy interval between the first cross of selected parents and establishing true breeding lines of new varieties. Some methods are developments of conventional breeding – such as maintaining parallel selection programmes in the northern and southern hemispheres which allows two generations to be produced each year. Other methods involve genetic modification. It is this type of seed and plant breeding which has attracted the most attention in recent years.

4.3 Genetically modified seeds and plants

Genetic modification (GM) entails adding, modifying or deleting individual traits in a plant variety without reshuffling the entire genetic makeup of crop species. This enables specific genetic characteristics to be expressed in a crop plant – such as disease resistance or resistance to certain planting conditions. To date this has only been successful in a few animal, plant and microbial species.

In 1999, about 35 million hectares – an area roughly one and a half times the size of Britain – around the world were producing commercial crops from GM plants. The crops ranged across soya, maize, oilseed rape, potatoes, cotton and tobacco, and were mostly grown in the USA, Canada and China. By contrast, the uptake of GM technology by the agriculture and food sector in Europe is at a relatively early stage. Commercial crops of GM maize have been grown in Spain and France. No commercial GM crops have been planted in the UK.

This section of our report does not discuss the principles of genetic modification of plants. The Government has a difficult balancing act to perform. On the one hand it does not want to hamper scientific progress and innovation. On the other it has to take into account of people's concerns about genetic modification. Government has to have an educational as well as protective role towards the general public. At times these messages have been confused.

4.4 The regulatory environment

The development of genetic modification in plant breeding has thrown a spotlight on how seed and planting is regulated in the UK. Regulations that have been around since the 1960s, amended because of European Directives, are used to control the quality standards of seed and plant breeding. However, the regulations were never envisaged as having to deal with genetic modification. As Government officials told us, in relation to marketing regulations, "if we were doing this again, we would not start from here."

But the regulations are there. Short of developing two sets of regulations – one set for conventional breeding and another for genetic modification breeding, it is essential that the current regulations are made to run as efficiently as possible, for both approaches. This is important so as not to hamper research nor hold back the conventional seed and plant breeding industry. The conventional breeding industry feels very strongly that genetic modification has had an adverse impact on them. In the eyes of the conventional breeding industry, public concerns about genetic modification have made DEFRA and the devolved administrations enforce the regulations more precisely than ever before. This has had an unreasonable impact on the conventional seed and planting breeding sector.

The Task Force has examined the seed breeding regulations to see how they fit within our proposed model and to see if there are any elements that could be removed to make the whole system more efficient and less bureaucratic.

4.5 Seed breeding and the better regulation model

Much research involving the genetic modification of seeds and plants is "blue skies" research (stage 2 of our model), as genes are isolated from a source material and placed in a host seed or plant. Equally much of this research is moving into the research and development stage, as more is understood about gene impact. From the start the "blue skies" work has to be carried out in a controlled environment, to ensure the safety both of those extracting and working with the genes and the wider environment.

There are stringent regulations that set out the conditions that must be maintained within a laboratory to prevent potentially dangerous organisms from escaping into the outside environment. These reflect the safety, moral and ethical constraints that society and Government has decided on.

It is when the researchers decide they need field data (stage 3 in our model) to help them decide whether a GM seed would meet the requirements for National Listing, that State regulations on deliberate release come into effect. These regulations are in addition to the normal requirements for National Listing, and are targeted specifically towards GM seeds.

Whilst no GM seeds have been approved in the UK for the National List, foods derived from GM seeds grown elsewhere in the world are available for purchase in supermarkets. It is at this stage that food safety requirements have to be observed, as well as the Novel Food Regulations.

Other seed and plant breeding regulations control the marketing of new varieties. These regulations relate to stage 4 of our model.

4.6 National listing

Before any new crop variety – conventional or genetically modified – can be placed on the market, it must undergo statutory testing under the process known as "National Listing".

The National List system was adopted in 1973 following the UK entry into the European Community. All Member States produce and publish a National List of those seed and plant varieties that can be marketed in their country.

The European Commission compiles the Common Catalogue. This lists those varieties of seed and plant varieties that can be marketed throughout the European Union.

DEFRA is responsible for administering the National List in the UK. It acts on behalf of the Scottish Executive, National Assembly for Wales and Department for Agriculture and Rural Development in Northern Ireland.

In order for a seed or plant variety to be added to the National List, it must meet a number of conditions, including:

- it must be distinct, sufficiently uniform and stable (DUS), and for agricultural crops, have satisfactory value for cultivation and use (VCU); and
- if the variety is genetically modified, it must have been accepted for marketing in accordance with European Directives on deliberate release into the environment of genetically modified organisms.

4.7 Seed certification

Before the seeds of any variety can be marketed either in the UK or throughout the European Union, they also have to be certified. Seed certification is designed to ensure quality for growers. The seed certification process sets minimum standards for variety identity, purity and germination capacity. There are also limits on seed-borne diseases and the presence of physical impurities, such as weed seeds.

Growers can either buy and use certified seed or use farm-saved seed. Royalties are collected on certified seed and farmers pay to use farm-saved seed. The payments are lower for farm-saved than certified seeds. The British Society of Plant Breeders (BSPB) collects and distributes the royalties on certified seeds and farm-saved seed payments.

4.8 Outdated regulations

Recommendation 2:
Remove outdated legislation

- DEFRA, should, at the earliest opportunity, negotiate to have the value for cultivation and use requirements removed from the EC seed and plant breeding directives. Until negotiations are complete, DEFRA should implement the requirements in a light-touch way;
- DEFRA should, at the earliest opportunity, remove the Higher Voluntary Standards from the seed certification regulations. The Task Force invites the devolved administrations to follow suit.
- DEFRA should report to the Task Force on the progress of the above by the end of July 2003 and January 2004.

4.8.1 Value for cultivation and use

When growing trials are carried out, normally over a minimum of two years, data have to be produced to establish whether a variety has value for cultivation and use (VCU). That means that, for a variety to be accepted on the National List, its producer must demonstrate that the variety offers a clear improvement in terms of cultivation or use, when compared to varieties already on the National List.

The Task Force questions whether VCU should be regulated at all. Providing a seed breeder has demonstrated that a seed is safe for cultivation, it is for the market to decide whether the seed is worth buying. It is for the breeder to market the seed. It should not be for the Government to give it a seal of approval on anything other than safety grounds. The safety regime must however be robust enough to balance the drive for market need. The Government provides protection for the consumer, in this case the farmer, through existing consumer legislation. This means that seed breeders cannot make claims for their seeds that they are not able to substantiate.

The Task Force recognises that the requirement to prove VCU is written into the relevant European legislation and the UK has no choice but to implement the requirement. However, the Task Force recommends that DEFRA negotiates to have VCU taken out of the Directive at the earliest opportunity. In the meantime it should ensure that the VCU requirements in the UK regulations are the minimum required to satisfy the Directive.

4.8.2 Higher Voluntary Standards

Within the seed certification regulations there are Higher Voluntary Standards (HVS). These are more stringent than the standards in the parent EC legislation. Those entering seed for certification may apply to have it verified as meeting these higher standards. The higher standards are similar to those used under the voluntary certification arrangements operated in the UK prior to joining the EC in 1973 and have always been retained – most recently in 2002 - at the request of representative organisations of the agricultural and seed industries.

The Task Force questions why HVS should be in the state regulations at all. The relevant seed Directives lay down European wide minimum standards which seeds must reach before they can be marketed. If the industry wishes there to be higher standards it should either propose that the European Commission amend the Directives, or develop and enforce them itself.

When DEFRA last consulted on this issue there was a majority view in favour of retaining HVS in the regulation. From the same consultation DEFRA also received a number of representations about the official costs of certification.

HVS is costly. DEFRA operates HVS on a full cost recovery basis. It has estimated that it would save the seed industry over £100k if it removed HVS from the regulations.

Industry often complains that Government gold plates the implementation of European Directives. This is a clear case of gold plating – but ironically it is not the Government that is to blame. When the Task Force consulted stakeholders for its report on "Environmental Regulations and Farmers"[6], we received a very clear message that there should be no embellishment of EC directives.

4.9 Paying for farm-saved seeds

In the past, farmers who saved seed had to have it dressed – prepared for sowing – by external seed dressers. The dressers collected the royalty payments on farm-saved seeds on behalf of the breeders. However, partly because of financial constraints, but more because of advances in seed technology, fewer farmers have their seeds dressed and more farm-saved seeds risks 'escaping' the relevant royalty.

When the BSPB raised its concerns with DEFRA about collection of royalties on farm-saved seeds, DEFRA wrote to all those farmers who were not complying with the scheme. Ninety per cent of those written to replied. This, therefore, leaves a very small minority of farmers who are known to be not complying, and new regulations are not likely to make them comply unless there is strict enforcement.

It would not be proportionate to introduce regulations to ensure the collection of royalties from farm-saved seed.

[6] Environmental Regulations and Farmers. Better Regulation Task Force. November 2000.

The Task Force welcomes the approach DEFRA has used to date, with some considerable success. Regulations will not improve that success rate.

4.10 Patents

Before the development of genetic modification, patents on plants were not widely granted in the US or Europe. In Europe, the European Patent Convention explicitly forbids patents on plant or animal varieties. Plant breeders' rights cover them. However, the development of genetic modification techniques has challenged the concepts of what is and is not patentable. In general, the US has been more responsive to these new developments. This has lead to a number of legal precedents being set in the US, which have broadened the scope of patentable material.

In Europe the development of patents has been slower. A number of plant patents were allowed in Europe after protracted debates over whether GM crops were varieties or not. It was originally decided that GM crops were not varieties, and could therefore be patented.

However, in 1995 the European Patent Office reversed this policy by refusing a patent on a GM crop, restricting instead the patent to the GM cells. The EC Directive on the Protection of Biological Inventions dictates that varieties, such as wheat modified with the Bt[7] gene, are not plant varieties, as under UPOV, and are, therefore, patentable.

Intellectual property rights and patents are set to become critical to the future development and application of GM technology. Unless handled carefully it could lead to monopolies being established. However, without some elements of a monopoly, investors are unlikely to finance new development if competition prevents them from recovering start-up costs.

4.11 Further efficiency measures

At the moment the seed certification process is paper based. Data cannot be submitted electronically, although the paper work can be downloaded from DEFRA's Plant Varieties and Seed (PVS) Division website. Forms have to be posted back to DEFRA.

DEFRA has been successful in a bid for funds from the Treasury's Invest to Save programme. A pilot programme will be carried out over the next two years to enable data to be transmitted to the PVS via the Internet and automatically downloaded to the certification database. The Task Force welcomes this project, which should make the whole system run more efficiently.

4.12 Concerns about GM seeds and plants

The production of new GM seeds and plants is probably more controlled than conventional plant breeding. But it also means that scientists can do some things with new techniques that would be impossible with old ones. The effects of these changes need to be fully understood before any new GM product can come to market. EU and national legislation rigorously govern such assessment.

There are a number of concerns about genetically modified seeds and plants. There are health and safety concerns; concerns about escaping genes; wider concerns about biodiversity in the countryside; and commercial concerns – especially where terminator[8] genes are introduced to seeds and plants.

[7] Bacillus thurigiensis

[8] So called "terminator genes" prevent plants from producing fertile seeds which can be used at a later date.

Government needs to balance these concerns against the potential benefits. Intensive agriculture may not be sustainable in the long run. The increased use of fertilisers and pesticides has had adverse effects on water supplies and biological diversity. In the long term it could be better to bioengineer crops, which work with nature to reduce the need for intensive use of chemical fertilisers, pesticides, herbicides and fungicides.

4.13 Involving the public

> "The case for genetically modified food remains hard to stomach"
> The Independent. 17 August 2002
>
> "Seeds of Doubt. The real danger is not GM foods, but ignorance and fear"
> The Times. 17 August 2002

Almost daily there are reports in the media about GM crops. These play on the public's fears that new technology is being developed, which they do not understand. Headlines like "Frankenstein foods" do not help the debate. As with all technology the public will be apprehensive unless they feel they are involved in the decision making process; have some understanding of the science; and can perceive some benefit.

Genetic modification is often seen as a moral and ethical issue, but opinion about GM food and crops is also affected by food scares – such as BSE. All contribute to increasing people's anxieties.

The Government announced that it would start a public debate on GM issues in the autumn of 2002, as recommended by the Agricultural and Environment Biotechnology Commission[9]. This was a welcome move. The debate should be as inclusive as possible and the final report should be made publicly available.

4.14 Approved events

In 2000 the issue of GM contamination of other crops came to a head when non-approved events – accidental presence of GM material in non-GM crops – were found in conventional crops. All European Member States reacted differently, and the European Commission was asked to act. The Commission set a non-statutory, interim threshold of 0.5 per cent for approved GM events, and statutory thresholds – which vary between species - are now being negotiated. Statutory thresholds will be helpful for the industry. As suggested at stage 3 of our model for scientific research regulation, scientists need clear, specific State regulations with which to comply.

[9] Crops on Trial. Agriculture and Environment Biotechnology Commission. September 2001

4.15 Non-approved events

The European Commission has proposed that there should be a 0.5 per cent threshold for non-approved GM material provided it has been through a safety assessment process. On any other material, which has not been safety assessed, there is a zero tolerance. This is a welcome move, though zero tolerance could cause some difficulties. If a single seed is found to contain a non-approved event in any sample tested then it will be illegal to market and sow that seed. In order to guarantee zero presence extensive testing would need to be carried out. The onus will be on the producer of non-GM seeds to comply with the legislation and bear the cost of doing so. It is important that realistic testing protocols, including acceptable sampling rates, are set. DEFRA is already discussing thresholds with the seed and plant breeding industry, and other interested parties. The public should also be involved in discussing thresholds and the Task Force welcomes the public debate, which the Environment Secretary announced on 26 July[10].

[10] DEFRA News Release: Public to choose issues for GM debate – Margaret Beckett. 26 July 2002.

5. Better Regulation of Embryonic Stem Cell Research

"I want to make the UK the best place in the world for this [stem cell] research, so in time our scientists, together with those we are attracting from overseas, can develop new therapies..."

The Prime Minister. May 2002

Embryonic stem cell research could produce new treatments for a wide range of medical disorders. Treatments could be used to cure a range of common degenerative diseases such as heart disease, diabetes, Alzheimer's or Parkinson's disease. Such diseases affect millions of people across the world. None at present has an effective cure.

Embryonic stem cell manipulation also has the potential to create new tissue to order. Tissues created in this way could be used to repair or replace body parts damaged by fractures, burns or disease. Potentially embryonic stem cell manipulation could be used to repair spinal cord injuries, alleviating paralysis.

Opinion about embryonic stem cell research is often divided. Many believe that embryonic stem cell research offers enormous potential for human health. Others argue that such research is tampering with human life and that extracting stem cells from embryos is both unethical and immoral.

Possible uses of tissue derived from stem cells to treat disease

Cell type	Target disease
Neural (nerve) cells	Stroke, Parkinson's disease, Alzheimer's disease, spinal cord injury, multiple sclerosis
Heart muscle cells	Heart attacks, congestive heart failure
Insulin producing cells	Diabetes
Cartilage cells	Osteoarthritis
Blood cells	Cancer, immunodeficiencies, inherited blood diseases, leukaemia
Liver cells	Hepatitis, cirrhosis
Skin cells	Burns, wound healing
Bone cells	Osteoporosis
Retinal (eye) cells	Macular degeneration
Skeletal muscle cells	Muscular dystrophy

Chief Medical Officer report 2000

5.1 How are stem-cells collected?

There are a number of sources of stem cells:

- some adult tissues;
- some fetal tissues;
- umbilical cord blood;
- early embryos;
- reprogrammed adult cells (theoretical).

In this report we consider only the regulatory regime covering research carried out on stem cells extracted from embryos.

5.2 The UK regulatory environment

When it first came into force in 1990 the Human Fertilisation and Embryology (HFE) Act only covered research into fertility issues. In 2001, the Act was amended to allow for:

- increasing knowledge about the development of embryos; and
- increasing knowledge about serious disease; or
- enabling any such knowledge to be applied in developing treatments for serious disease.

The Human Fertilisation and Embryology Authority (HFEA) is the statutory regulatory body, established under the HFE Act 1990. The HFEA is responsible for licensing and monitoring clinics carrying out *in vitro* fertilisation, donor insemination and human embryo research.

Research is only permitted on human embryos up to 14 days of development, and where the creation or use of embryos is necessary for specific research. Licences can only be granted if the research is for one of the following purposes:

- promoting advances in the treatment of infertility;
- 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.

The UK regulatory regime is widely seen as being precise. The clarity of what is permitted and what is not is attractive to research scientists. There are some concerns about the process of granting research licences. These are discussed below.

5.3 Embryonic stem cell research and the better regulation model

Embryonic stem cell research is very much at the "blue skies" stage of research in our model. No clinical trials have started on therapies derived from embryonic stem cell lines. This being the case, researchers need to know the boundaries within which they must work. The HFE Act 1990 (as amended) is very clear that embryos can only be used for research up until the 14-day stage of development. Whilst some will object to any research on embryos on ethical and moral grounds, Parliament has set a clear limit. This is helpful for scientists, and the Task Force welcomes such an approach.

5.4 The European Commission's approach

The position on embryonic stem cell research varies considerably between different European Member States. These follow different national traditions and beliefs. These different approaches have been respected to date by the European Commission, which has not tried to impose a common approach on all Member States. This has been of benefit in attracting funding and leading scientists to the UK.

That is not to say that the European Commission will never attempt to regulate stem cell research. However the UK has welcomed recent European developments. The European Parliament's own report on human genetics that included statements hostile to embryonic stem cell research (the Fiori Report) was rejected by the Parliament itself.

Negotiations on framework funding for scientific research in the EU (2003 – 2006) concluded at the end of 2002. The agreement foresees that, until the end of 2003, the Commission will not fund research projects involving the use of human embryonic stem cells, with the exception of embryonic stem cells already banked or isolated in culture.

This agreement means that the compromise text, proposed by the UK Government in July 2002, was accepted and that research projects that use banked embryonic stem cells (such as those going in the new Bank – see section 5.8) will qualify for EU funding from January this year. Other research, such as that involving the extraction of stem cells from embryos, will be subject to a temporary suspension until the end of 2003. This represents a considerable success for the UK Government.

The Task Force very much welcomes the Government's efforts to ensure that the European Commission respects the principle of subsidiarity in this area. The UK's lead in embryonic stem cell research could be lost if the European Commission were to introduce Europe wide standards.

Commission intervention could also jeopardise a great deal of inward investment in research from other countries, especially the United States. Overseas research funders are attracted by the UK's regulatory climate[11].

5.5 The Human Fertilisation and Embryology Authority (HFEA)

The HFEA was set up in 1991, under the HFE Act 1990. It was the first statutory body of its kind in the world, and over the years has gained recognition worldwide as a leading authority on infertility regulation.

The role of the HFEA is to regulate, licence, and collect data on fertility treatments such as IVF and donor insemination, as well as human embryo research, in the UK.

The HFEA's 17 members, who are appointed by Health Ministers, take all of the HFEA's policy and licensing decisions. Members are selected for their personal knowledge and expertise, not as representatives of any particular group or organisation. More than half of the HFEA's members must come from disciplines other than medicine or human embryo research.

[11] Financial Times: US charity plans $20m stem cell research. 18 November 2002

There has been some criticism that membership of the HFEA does not include sufficient experts in the relevant fields to be responsible for such an important policy area.

However the Task Force believes that, in an area which attracts such public interest, it is important to have lay members as well as experts involved in the decision making process.

5.6 HFEA consultations

Recommendation 3:

HFEA consultation. The Task Force recommends that all HFEA consultation documents should follow the Cabinet Office guidelines, and include a regulatory impact assessment.

The HFEA recently consulted on a new fee structure for licensing infertility treatment clinics. However we were concerned that the consultation period does not follow the Cabinet Office guidelines that consultation exercises should last for 12 weeks. The HFEA consultation lasted just over 6 weeks. The Task Force recognises that, although a Government sponsored regulator, the HFEA is not bound by the Cabinet Office guidelines. But the Task Force believes that it should follow them in the interests of transparency. It will be important for the HFEA to follow the guidelines when consulting on its charging regime for licences for embryonic stem cell research. We would like to see the HFEA follow Cabinet Office guidelines for all its consultation and regulatory work.

5.7 Checks and balances

Before a researcher can begin any research on embryos, the following are required:

- an approval (or favourable opinion) from a Research Ethics Committee;
- consent from the embryo donor; and
- a license from the HFEA.

5.7.1 Research Ethics Committees

Recommendation 4:

Research Ethics Committees. The Task Force recommends that:

- the Multi-site Research Ethics Committee (MREC) system should be reviewed in October 2005;
- by the end of 2003, it should be possible to complete all Local Research Ethics Committees (LREC) and MREC forms online; and
- approvals granted by Research Ethics Committees should be consistent across committees, as far as is compatible with the independent nature of ethical review.

The purpose of a Research Ethics Committee is to review the proposed study to make sure that the dignity, rights, safety and well being of all or potential research participants are protected. This is an effective form of governance, with legislative underpinning, which the Task Force welcomes. But the system is very bureaucratic.

In the first instance the researcher, if they are based in a public institution, has to apply for approval from the Local Research Ethics Committee (LREC) for the locality in which they are based. Private research centres can use the LREC, or may set up their own ethics committee providing it is independent of the research centre.

The LREC will consider issues that include:

- the suitability of the local researcher;
- the appropriateness of the local research environment and facilities; and
- specific issues relating to the local community, including the need for provision of information in languages other than English.

These considerations are important as they allow local concerns to be taken into account.

Approval from that one LREC is sufficient to cover the whole of the area covered by the Health Authority in which the researcher is based. However, if the research is also due to be carried out in areas covered by a number of different LRECs, but covered by one Health Authority, an application has to be made to each separate LREC for locality issues to be considered.

The Task Force welcomes the efforts being made to streamline the process.

From October 2002, if the research is going to be carried out within the boundaries of two to four Strategic Health Authority areas, the researcher can apply to the two to four LRECs or the Multi-Centre Research Ethics Committee (MREC) for the region in which they are based. Application to an MREC is now compulsory for research planned which covers five or more Strategic Health Authority areas. There are now 13 MRECs (10 in England, 2 in Scotland and 1 in Wales) which are geographically scattered around the UK. Once MREC approval has been given the approval covers the whole of the UK, although locality approval will still be needed from each LREC in which the research will take place.

Some researchers complain that different ethics committees make different decisions about the same research. This is inevitable, and right, if local considerations are going to be properly taken into account. But the MREC system should ensure more consistency without undermining local input. The MREC system should, however, be reviewed after three years to judge its impact on the speed and consistency of the decision-making process.

MRECs will be piloting a standard application form from early in 2003. It will be downloadable from the Internet, but can not be completed on line. This should be the next step for streamlining the Research Ethics Committee approval process.

Approvals granted by a Research Ethics Committee have to be renewed at between one and three year intervals, depending on the granting Committee. There should be more consistency in how long approvals are granted. This should be easier where approval has been granted by an MREC.

5.7.2 Donor consent

The Act requires that before donating embryos for research the donor must give her consent for the embryos to be used for research purposes. It is important that embryos for research are freely given and that the women donating them make an informed choice. The willingness or not to donate embryos must not affect in any way the treatment the woman might be receiving. Neither must the woman benefit financially from the donation of embryos.

The development of embryonic stem cell research has raised a number of issues about consent. These have been clearly addressed in the Act. It requires patients to be told that:

- any stem cell lines created may continue indefinitely and be used in many different research projects;
- that once an embryo has been used in the research projects the donor will have no control over any future use of the embryonic cells and any stem cell lines derived;
- that cell lines may be used for commercial purposes, but that the donor will not benefit financially from this; and
- that any cell lines derived or discoveries made using them could be patented, but that the donor will not benefit financially from this.

Whilst donors have to receive all this information, it is essential that it is given in as clear and simple a form as possible, and the Task Force welcomes efforts being made by the HFEA and Medical Research Council to ensure that consent forms are easy to read and understand.

5.7.3 HFEA research licences

Recommendation 5:

Research licence applications. The Task Force recommends that, with immediate effect, the HFEA ensure that its Licence Committees always have a majority of lay members.

Having received approval from a Research Ethics Committee a researcher next needs a licence from the HFEA to work on embryos. The researcher has to state the purpose of the research (as defined under the HFE Act 1990, as amended), details of why embryos will be used and how many, and protocols for the study.

When an application for a research licence is received, it is sent out for Peer Review. The HFEA has a large panel of reviewers from which to draw, both in the UK and overseas. All are recognised as experts in the field of reproductive biology and infertility. Before considering a research application the HFEA obtains at least two peer review reports on the project's merits covering:

- whether the research fulfils the categories for which embryo research is permitted;
- the potential importance of the research in the field;
- whether the research has been done before;
- whether the use of human embryos is justified;
- the suitability of the methods to be used;
- length of the study; and
- the applicant's qualifications.

Some stakeholders observed that those individuals peer reviewing licence applications were often the same people who would be making a licence application the next time round. This is inevitable where there is only a small pool of experts who are able to evaluate a licence application.

But the HFEA needs to listen to the concerns that some people have and make sure it has audit trails that can demonstrate that decisions on licences are taken on independent grounds.

Finally, a Licence Committee of the HFEA considers all research licence applications. The Committees are made up of five HFEA members, and the HFEA tries to ensure the majority of members are lay members. In order to counter any criticism of the system the HFEA should ensure that lay members are always in the majority on Licence Committees.

Licences for established research institutions may be granted for three years. This is a recent welcome change and recognises that most research institutions have good compliance with the regulatory regime.

5.8 Stem cell bank

In his report of June 2000, "Stem Cell Research: Medical Progress Report"[12], Professor Liam Donaldson, the Chief Medical Officer, recommended that the Research Councils should examine the feasibility of collecting stem cells lines together in one place for research use. The Medical Research Council has acted on this recommendation, and the Stem Cell Bank will be operational from early in 2003.

The Stem Cell Bank will be the first of its kind in the world, and will enable the UK to maintain its advantage in stem cell research. The Bank will store both adult and embryonic stem cell lines, and researchers – both academic and private sector - will be able to use them. Consent will have been obtained already for the stem cell lines to be used for research purposes which will cut down on the bureaucracy before a piece of research can start.

[12] Stem Cell Research: Medical Progress with Responsibility. Department of Health. June 2000

But more importantly once fully established, the Bank will mean that fewer embryos will be needed to extract stem cell lines from because there will be a supply of lines already held for research purposes. Many people will welcome this.

The Task Force commends how the Medical Research Council (MRC), working with all interested parties, has set up the Bank.

5.9 Looking to the future

Recommendation 6:

Review the 2001 amendments to the Human Fertilisation and Embryology Act 1990. The Task Force recommends that the Department of Health should review, in 2004, the 2001 amendments to the Human Fertilisation and Embryology Act 1990, to make sure the Act keeps pace with the developments in embryonic stem cell research and public opinion. Thereafter the legislation should be reviewed every three years.

In discussions with stakeholders we heard some complaints about the system for approving licenses for embryonic stem cell research. There were complaints about systems, not the Act, which was seen as a model of clarity.

Researchers complained that it can take the HFEA a very long time to assess and award licences. Lobby groups complained that those who carried out reviews on licence applications may have a vested interest in awarding licences.

The recommendations we make in this report should help alleviate many of these problems. The Government, for itself, needs to be alert to the speed at which this area of scientific research is moving. The 2001 amendments to the 1990 Act were welcomed. We recommend that those amendments be reviewed in 2004, in line with the Government's manifesto commitment to review all major pieces of legislation after three years.

6. Nanotechnology

> "Nanotechnology will do wonderful things. But there are almost bound to be risks attached to its usage."
>
> Financial Times. Sept 02

Recommendation 7:

Nanotechnology. The Task Force recommends that, in the area of nanotechnology, the Government should:

- enable, through an informed debate, the public to consider the risks for themselves, and help them to make their own decisions by providing suitable information;
- be open about how it makes decisions, and acknowledge where there are uncertainties;
- communicate with, and involve as far as possible, the public in the decision making process;
- ensure it develops two-way communication channels; and
- take a strong lead over the handling of any risk issues, particularly information provision and policy implementation.

This final section of the report briefly looks at the emerging science of nanotechnology.

Nanotechnology is the science of tiny objects. It is the term applied to the study and manipulation of systems or devices with at least one of its dimensions smaller than 100 nanometre – that is 10 000th of the diameter of a human hair. Nanotechnology is a fast growing area of scientific research, which is attracting large sums of money. For example, in the United States large corporations are estimated to have spent $2.5 billion in research and development in this area in 2001, and the US federal government has allocated $518.8 million towards nanotechnology research in 2002[13].

The ultimate goal of nanotechnology is to produce tiny devices, some of which may be able to design and build other devices. Whilst the image of molecular submarines flowing round a person's blood stream repairing damage and repelling invaders may be a dream, some scientists believe that the reality behind the science may be seen in the next 20 – 30 years. But other products, which rely on nanotechnology, may not be so far away: molecular electronic switches; improved sun creams[14]; and cancer treatments. In medicine, nanoceramics are already being used as bone replacement agents.

[13] Chemistry and Industry. October 2002

[14] nanosubstances are used in sun creams to block ultra violet rays.

To date few have expressed concerns about the risks of nanotechnology. Indeed they may never be fully voiced if, like embryonic stem cell research, the potential benefits to individuals are identified. But the Government needs to be ready to deal with concerns should they be raised.

The Government will need to demonstrate it has clear policies in place to ensure the safety of individuals, animals and the environment, whilst permitting the research to continue.

Good communication will be key. The Government should promote an early dialogue with the public. This will not be easy as few lay people understand the technology – the field is vast and the potential applications numerous. It is this very breadth of possible applications that makes it difficult to predict where the greatest risks of nanotechnology lie.

As an emerging area of science the Government has an opportunity to apply the model for the regulation of scientific research we propose. It also has the opportunity to lead from the front.

Annex A

Better Regulation Task Force and its approach

The Better Regulation Task Force is an independent advisory group established in 1997. Members, appointed in the first instance for two years, are unpaid. They come from a variety of backgrounds - from large and small businesses, citizen and consumer groups, unions, and those responsible for enforcing regulations - and all have experience of regulatory issues. The Chair, appointed initially for three years in April 2002, is David Arculus. Officials of the Regulatory Impact Unit in the Cabinet Office provide support for the Task Force.

Terms of reference

The Task Force's terms of reference are:
"To advise the Government on action to ensure that regulation and its enforcement are transparent, accountable, proportionate, consistent and targeted."

Members of the Task Force

David Arculus, Chairman	Severn Trent plc
Teresa Graham, Deputy Chair	Baker Tilly
Matti Alderson	Fire Horses
Stephen Falder	HMG Paints
Michael Gibbons	Formerly Powergen plc
Kevin Hawkins	Safeway Stores plc
Deirdre Hutton	National Consumer Council
Simon Petch	CONNECT
Ian Peters	Engineering Employers Federation
Penelope Rowlatt	Independent economist
Janet Russell	Kirklees Metropolitan Council
Sukhvinder Stubbs	Barrow Cadbury Trust
Tim Sweeney	Independent consultant: financial services
Rex Symons	Bournemouth Primary Care NHS Trust
Simon Ward	Consultant: hospitality industry
Victoria Younghusband	Lawrence Graham

A Register of Members' Interests has been drawn up and is on our website: www.brtf.gov.uk or is available on request.

Annex B

Sub-group members

Stephen Falder is Marketing Director of HMG Paints Ltd, a medium-sized manufacturer of industrial surface coatings. He is a CBI Regional Councillor and a member of the CBI SME Council.

Deirdre Hutton CBE is Chair of the National Consumer Council. She is also Vice-Chair of the Scottish Environmental Protection Agency and a Non-Executive Director of the Financial Services Authority. Deirdre was recently appointed Chair of the Steering Group for the Food Chain Centre and Vice Chair of the European Food Safety Authority.

Rex Symons CBE is Chairman of Bournemouth Primary Care NHS Trust, Bournemouth Transport Ltd and Dorset Travel Ltd. He is a member of the Council of Southampton University and was, until 2002, a member of the Health and Safety Commission.

Task Force Secretariat
Philip Clarke

Annex C

Principles of Good Regulation

Transparency	• The case for a regulation should be clearly made and the purpose clearly communicated. • Proper consultation should take place before creating and implementing a regulation. • Penalties for non-compliance should be clearly spelt out. • Regulations should be simple and clear, and come with guidance in plain English. • Those being regulated should be made aware of their obligations and given support and time to comply by the enforcing authorities with examples of methods of compliance.
Accountability	• Regulators and enforcers should be clearly accountable to government and citizens and to parliaments and assemblies. • Those being regulated must understand their responsibility for their actions. • There should be a well-publicised, accessible, fair and efficient appeals procedure. • Enforcers should be given the powers to be effective but fair.
Proportionality	• Any enforcement action (i.e. inspection, sanctions etc.) should be in proportion to the risk, with penalties proportionate to the harm done. • Compliance should be affordable to those regulated - regulators should 'think small first'. • Alternatives to state regulation should be fully considered, as they might be more effective and cheaper to apply.
Consistency	• New regulations should be consistent with existing regulations. • Departmental regulators should be consistent with each other. • Enforcement agencies should apply regulations consistently across the country. • Regulations should be compatible with international trade rules, EU law and competition policy. • EU Directives, once agreed, should be consistently applied across the Union and transposed without 'gold-plating'.
Targeting	• Regulations should be aimed at the problem and avoid a scattergun approach. • Where possible, a goals based approach should be used, with enforcers and those being regulated given flexibility in deciding how best to achieve clear, unambiguous targets. • Regulations should be reviewed from time to time to test whether they are still necessary and effective. If not, they should be modified or eliminated. • Where regulation disproportionately affects small businesses, the state should consider support options for those who are disadvantaged, including direct compensation.

A leaflet explaining our Principles of Good Regulation is on our website **www.brtf.gov.uk** and available on request.

Annex D

Contributors to Review

Amersham Health
Animal Science Group, UK Life Sciences Committee
Association of British Pharmaceutical Industry
Association of Clinical Embryologists
Aventis CropScience UK Limited
Biogemma
BioIndustry Association
BioIndustry Association (Scotland)
British Medical Association
British Society of Plant Breeders
Cabinet Office
Central Science Laboratory
Centre for Environment and Society, University of Essex
Centre for Genome Research, Edinburgh University (now Institute for Stem Cell Research)
Centrica
Chemical Industries Association
Chemistry in Britain
Confederation of British Industry
CPB Twyford
Department for Environment, Food and Rural Affairs
Department of Health
Department of Trade & Industry
Economic and Social Research Council
Elsoms Seeds
English Nature
Foundation for Science & Technology
GeneWatch UK
Green Alliance
Greenpeace
Hazards Forum
Health and Safety Executive
Henry Doubleday Research Association
Home Grown Cereals Authority
Home Office
Human Fertilisation and Embryology Authority
Imperial College
Institute of Directors
Institute of Grassland and Environmental Research
IRS Group
Jones Innes Centre
King's College, London
Liverpool University (Medical Genetics)
Medical Research Council

Monsanto
National Association of Agricultural Contractors
Northern Ireland Assistance Board
Office of Science and Technology
Oxford University
People Science and Policy Limited
Prolife Alliance
ReNeuron
Research Defence Society
Royal Academy of Engineering
Royal Society of Edinburgh
Save British Science
Scottish Executive
Scottish Universities Policy Research and Advice Network (SUPRA)
Semondo
Supply Chain Initiative on Modified Agricultural Crops
Sygenta Seeds
The Foundation for Science and Technology
The Royal Society
Unilever
United Kingdom Agricultural Supply Trade Association (UKASTA)
University College London (Anatomy & Developmental Biology)
University of Edinburgh (John Hughes Bennett Laboratory)
University of Sheffield (SIBLE)
University of Southampton
Wellcome Trust

Annex E

Source Material

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Centre for Genome Research **www.helios.bto.ed.ac.uk/cgr**

Christian Aid **www.christian-aid.org.uk**

Council for the Central Laboratory of the Research Councils **www.dl.ac.uk**

Department of Environment, Food and Rural Affairs **www.defra.gov.uk**

Department of Health **www.doh.gov.uk**

Engineering Council **www.engc.org.uk**

European Patent Office **www.european-patent-office.org**

Euroscience **www.euroscience.org**

Financial Times **www.FT.com**

Food Future **www.foodfuture.org.uk**

Friends of the Earth **www.foe.co.uk**

Future **www.globalchange.com**

Health and Safety Executive **www.hse.gov.uk**

Home Office **www.homeoffice.gov.uk**

Houses of Parliament **www.parliament.uk**

Human Fertilisation and Embryology Authority **www.hfea.gov.uk**

Human Genetics Commission **www.hgc.gov.uk**

Medical Informatics Unit **www.medinfo.cam.ac.uk**

Medical Research Council **www.mrc.ac.uk**

Oxford Brookes University **www.brookes.ac.uk**

Prolife Alliance **www.prolife.org.uk**

Royal Academy of Engineering **www.raeng.org.uk**

Royal Society of Chemistry **www.rsc.org**

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The Royal Society of Edinburgh **www.ma.hw.ac.uk**

United Nations **www.un.org**

Annex F

Task Force publications

The Better Regulation Task Force has produced the following reports that are available free on request by:

- writing to - Better Regulation Task Force Team, 2nd Floor, 2 Little Smith Street, London SW1P 3DH
- telephoning - 020 7276 2142
- emailing - taskforce@cabinet-office.x.gsi.gov.uk
- visiting the website at www.brtf.gov.uk

2001/2002	
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2000/2001	
Annual Report 00-01	Oct 01
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Environmental Regulations and Farmers	Nov 00
1999/2000	
Annual Report 99-00	Oct 00
Revised Principles of Good Regulation	Oct 00
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Helping Small Firms Cope with Regulations - Exemptions and Other Approaches	April 00
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Principles of Good Regulation	Dec 97

Better Regulation Task Force
2nd Floor
2 Little Smith Street
London SW1P 3DH
Tel: 020 7276 2142
Fax: 020 7276 2042
Email: taskforce@cabinet-office.x.gsi.gov.uk
Website www.brtf.gov.uk

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