Memorandum from Government on the Innovation, Universities, Science & Skills Select Committee Evidence Check

These are the Government's responses to the Committee's questions regarding evidence check. This memorandum was collated by the Government Office for Science.

Within the submission we highlight the contributions of individual departments, the Government Office for Science and the Government Chief Scientific Advisor have not offered any comment on contributions.

Homeopathy

This response was provided by the Department of Health.

Q1 How does the Government license homeopathic products?

Homeopathy has a long tradition in Europe and is a recognised system of medicine across the EU. Homeopathic medicinal products are included in the scope of European Directives and the Medicines Act 1968 and therefore require regulation.

Under current licensing arrangements, homeopathic products either have Product Licences of Right (PLRs) or certificates granted under a Simplified Scheme, or have been granted homeopathic marketing authorisations under the National Rules Scheme. PLRs are licences that were issued to all products on the market at the time that the Medicines Act 1968 was implemented in 1971.

The Simplified Scheme for homeopathic medicinal products was introduced in 1992 under European Directive 92/73/EC. The procedure is regarded as simplified because there is no requirement in the Directive for data to demonstrate clinical efficacy and the eligibility criteria confer a certain reassurance on safety so that the data requirements on safety are usually minimal. The Simplified Scheme does not permit therapeutic indications to be stated on the product label.

In 2006, the UK introduced the National Rules Scheme, which allows the marketing of homeopathic products, with a strictly limited range of therapeutic indications under European Directive 2001/83, in accordance with the principles and characteristics of homoeopathy as practised. Only products which are indicated for the relief of minor symptoms and minor conditions in humans are eligible for a homeopathic marketing authorisation under this scheme. For these purposes, minor symptoms are those which can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor.

The Simplified Scheme, which has been operating successfully in the UK for 17 years, and the new National Rules Scheme ensure that consumers who choose to use homeopathic products are better informed about their purpose, and that they are assured that standards of quality and safety are maintained.

Q2 What scientific evidence was considered during the formulation of the licensing regime?

Because homeopathic products have a long and established traditional use in the UK, the licensing regime functions primarily to ensure that they are both safe and of suitable quality. It also functions to provide improved and consistent product information for consumers.

The three elements of the licensing regime probably lie outside the scope of the IUSS Select Committee Inquiry, because government consideration of scientific evidence was not the basis for their establishment.

Firstly, the Product Licenses of Right were granted to all existing marketed medicines in 1971, under the provisions of the Medicines Act 1968.

Secondly, the Simplified Scheme derives from European Directive 92/73/EC, so probably lies outside the scope of the Inquiry; and

Thirdly, no scientific evidence was examined in drawing up the National Rules Scheme, which also derives from a European Directive. Definitions of `product safety' and `product quality' are commonly understood and did not need to be embedded in the scheme itself. Therefore, the onus to provide supportive scientific evidence is on each individual product that manufacturers put through the scheme - to demonstrate that the product is used as a homeopathic medicine, that it is safe, and that it is of suitable quality.

Dyslexia

This response was provided by the Department for Children, Schools and Families.

Q1 What is the Government's policy on the diagnosis and management of dyslexia?

On 22 June 2009, the Secretary of State for Children, School and Families welcomed the publication of Sir Jim Rose's report entitled "Identifying and Teaching Children and Young People with Dyslexia and Literacy Difficulties." The report makes clear that literacy difficulties and dyslexia are best identified and addressed at an early stage to give children having these difficulties the best chance of staying on the path to success.

To identify children as early as possible, the report says schools need to look carefully at those making poor progress compared to their peers, by making effective use of progress measures. This should entail classroom teachers noticing individual differences and adjusting their teaching. They should continue monitoring the progress of children causing concern, and then, if necessary, arranging more intensive interventions to advance their progress. If a child continues to make little progress, more specialist advice should then be obtained. This is all set out in greater, very practical detail, in Chapter 2 of Sir Jim's report (http://publications.dcsf.gov.uk/default.aspx?PageFunction=productdetails&PageMode=publications&ProductId=DCSF-00659-2009)

The Secretary of State has endorsed all the recommendations in Sir Jim Rose's report and made available £10m to support their implementation. This will include funding for around 4,000 teachers to train in appropriately accredited specialist dyslexia teaching over this financial year and next.

Q2 What evidence is used to support this policy? What methods have been considered to help improve literacy standards of dyslexic children and on what evidential basis has one method been favoured over another?

Essentially Jim Rose considered three sources of evidence as part of developing his dyslexia recommendations which we are now guided by:

1. Responses to a "call for evidence" which resulted in 850 replies including teachers and parents expressing a wide range of views on the quality of intervention strategies;

2. Feedback from visits to schools provided a valuable further source of evidence. In total, 17 primary and secondary schools were visited by the Review Team. Focus groups were undertaken in eight of these schools with pupils who have dyslexia (and related difficulties) and with their parents. The main purpose of the discussions was for children and their parents to describe their experiences of schools responding to their needs. These visits also included discussions with key staff, including specialist teachers, Special Educational Needs Coordinators (SENCOs) and head teachers, who provided

information about organisational structures, early identification and screening, assessment and monitoring of progress and types of interventions to address dyslexia; and

3. Published Research evidence including:

- a summary of published research on the impact of specialist dyslexia teaching and Reading Recovery on progression and outcomes for children with dyslexia, prepared by Dr Chris Singleton of Hull University;

- Dr Singleton's evaluations of the 'No to Failure' Project which monitored the progress made by children identified as being at risk of dyslexia/specific learning difficulties who had received specialist dyslexia teaching; and

- The University of Durham's evaluation of the first two years of Dyslexia Action's 'Partnership for Literacy' pilots, which provide a body of specialist knowledge in some school in order that they will be better placed to meet the needs of those children struggling in the bottom 10 per cent of attainment, including those at risk of dyslexia.

Sir Jim Rose considered the weight and robustness of this evidence with the support of his Expert Advisory Group.

A comprehensive list of all evidence considered by Sir Jim Rose as part of his dyslexia review can be found in the Bibliography section of his dyslexia report (http://publications.dcsf.gov.uk/default.aspx?PageFunction=productdetails&PageMode=publications&ProductId=DCSF-00659-2009).

Swine flu vaccinations

This response was provided by the Department of Health.

Q1 What is the Government's policy regarding the production of a swine flu vaccine and its distribution to the population?

Government policy is to purchase vaccine licensed for use in Europe in accordance with the European Directive on Procurement. The vaccine has been produced in Europe.

The Secretary of State for Health announced the priority groups for the swine flu vaccine on 13 August. More than 11 million people in England will be targeted first. The vaccine will initially be prioritised to those groups of people who are at highest risk of severe illness, as well as frontline health and social care workers.

Based on the current delivery forecasts from both manufacturers, we expect to have approximately 55 million doses available by the end of the year – enough for up to about 30 million people to be vaccinated – with more following after that. The vaccine will be delivered in phases as stocks become available. The vaccine may be licensed by early October and this could result in the vaccination programme being rolled out from mid October.

Q2 What expert scientific and medical advice have been used to steer the Government's policy?

The Joint Committee on Vaccination and Immunisation (JCVI) reviewed the evidence and advised the Department of Health on these priority groups. This advice was also scrutinised and endorsed by the Scientific Advisory Group for Emergencies (SAGE).

We will continue to take the best independent scientific advice to inform our decisions on the response to swine flu.

The following groups will be prioritised for the swine flu vaccine in this order (numbers given are approximate and are for England only):

1. People aged over six months and under 65 years in current seasonal flu vaccine clinical at-risk groups (about 5 million people).
2. All pregnant women, subject to licensing conditions on trimesters (about 0.5 million people).
3. Household contacts of people with compromised immune systems e.g. people in regular close contact with patients on treatment for cancer (about 0.5 million people).
4. People aged 65 and over in the current seasonal flu vaccine clinical at-risk groups (about 3.5 million people). This does not include otherwise healthy over 65s, since they appear to have some natural immunity to the virus.

Vaccination of frontline health and social care workers (approximately 2 million people) will begin at the same time as the first at-risk group, and will continue for as

long as necessary. This group is at increased risk of infection and of transmitting that infection to susceptible patients. Protecting these people will help the NHS workforce to remain resilient and able to treat sick patients.

Literacy and numeracy interventions

This response was provided by the Department for Children, Schools and Families.

Q1 What is the Government's policy on literacy and numeracy interventions for school children?

There is a strong evidence base which highlights the importance of early literacy intervention for children who fall behind at a young age. This is set out, for example, in a review of UK-based literacy interventions by Brooks (2002; revised edition 2007)[1].

An economic assessment by KPMG[2] of the return on investment of early intervention to address literacy difficulties, estimated that the total resulting costs to age 37 arising from failure to learn to read in the primary school years are around £1.73bn to £2.05bn every year to the public purse.

The development of the Every Child Counts programme was informed by evidence on the need for early intervention in numeracy[3]. From this evidence we know that it is more effective to provide intervention support to rectify learning difficulties as early as possible rather than provide remedial support to a child throughout later stages of their schooling. This is also borne out in research commissioned by the Every Child a Chance Trust[4].

This evidence is the backdrop to the Government's policy on literacy and numeracy interventions for school children. Evidence, primarily from Key Stage assessments, demonstrates that although the majority of children achieve satisfactory levels of literacy and numeracy through regular class teaching, some have difficulties which mean that additional interventions are needed. Many schools have their own successful arrangements for providing additional help to children who need it. However, the Government is providing specific support on literacy and numeracy to an increasing number of local authorities and schools in England. The main focus for literacy is reading, through the Every Child a Reader (ECAR) programme. The numeracy programme is known as Every Child Counts (ECC).

ECAR was originally developed by the Every Child a Chance Trust. ECAR follows a three-wave model: Wave 1 - Quality first teaching, Wave 2 – Small group and less intensive one-to-one interventions and Wave 3 – Intensive support. The ECAR pilot began operating in deprived and underachieving areas and is now being rolled out across the country, managed by the National Strategies on behalf of DCSF. The

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[1] Brooks, G. (2002) *What works for children with literacy difficulties? Effectiveness of intervention schemes.* DfES Research Report 380.
Brooks (2007) What Works for Pupils with Literacy Difficulties? The effectiveness of intervention schemes. Third edition. DCSF/National Strategies.

[2] KPMG (2006) The Long-Term Costs of Literacy Difficulties. December 2006.

[3] For example, What Works for Children with Mathematical Difficulties? DfES Research Report 554, Dowker, 2004).

[4] Every Child a Chance Trust (2009) The Long Term Costs of Numeracy Difficulties.

rollout is in its second year.

The ECC programme was created as the maths counterpart of ECAR and was developed in partnership with the Every Child a Chance Trust. The development of ECC was informed by an initial research phase which focused on gathering and studying information focusing on existing practice. Further stages involved trialling a range of interventions for seven-year-olds with numeracy difficulties within five Local Authorities. Edge Hill University was then commissioned to develop a new programme, *Numbers Count*, based on this research. This programme was piloted in summer 2008 and national rollout commences in September 2010.

Q2 What literacy and numeracy interventions have been considered? What evidence has the Government used to determine which are the most cost effective measures?

The above generic evidence provided the backdrop for a Government decision in December 2006 to roll out the ECAR programme nationally over the period 2008 - 2011, with the aim of reaching 30,000 children a year by 2010-11.

In-house analysis of school attainment in ECAR schools, compared with other similar schools found:

- Between 2007 and 2008 the percentage of pupils achieving the expected levels in Key Stage 1 reading and Key Stage 1 writing increased at a faster rate for those schools in the ECAR programme in comparison with the rest.

- For ECAR schools the percentage achieving level 2 or more in Key Stage 1 reading increased by 5 percentage points to 79% in 2008, in comparison with non-ECAR schools where there was a rise of only 1 percentage point to 85%.

- For ECAR schools there was a rise of 4 percentage points to 74% in the percentage achieving the expected level in Key Stage 1 writing whereas there was no change in the percentage achieving in non-ECAR schools.

The ECC research phase data showed that 73 per cent of children went on to achieve level 2 or above at the end of Key Stage 1. Before receiving intervention, none of these children was predicted to reach age-level expectations at this stage.

Both ECAR and ECC are currently the subject of independent evaluations which will inform future decision-making.

Teaching pseudoscience at universities

This response was provided by the Department for Business, Innovation and Skills.

Q1 What is the Government's interpretation of the term 'pseudoscience'?

The Government does not find it helpful to define pseudoscience. It is committed to policy-making based on scientific evidence. By science we mean all-encompassing knowledge based on scholarship and research which is underpinned by methodologies that build up and test increased understanding about the world and beyond.

Q2 What is the Government's position on universities that award BSc and MSc in subjects that are pseudoscientific? When recruiting staff, does the Government recognise such qualifications as providing the holder with scientific expertise?

All universities undertake research and teaching, but HEIs are autonomous institutions and decide the courses or content of the higher education they offer to their students who make informed choices about the curriculum they choose to study. In relation to degrees in specific disciplines, there may be further processes around accreditation and recognition by professional bodies, which may allow some judgements to be made about, for example; the quality of course content, teaching, skills acquired, but this is not for Government to prescribe.

The standards of degrees awarded by HEIs, and the quality of learning opportunities, are subject to independent review by the Quality Assurance Agency (QAA) and external examiners. Since the QAA was established in 1997 its reviews have consistently indicated that quality and standards are being maintained.

Departments have delegated responsibility for recruitment and should have robust processes in place for ensuring that appointments are made on merit. When appointing, departments will look at the skills, experience and qualifications required for the role. For some roles, a particular scientific expertise or qualification might be sought from any range of appropriate disciplines.

Health checks for over 40s

This response was provided by the Department of Health.

Q1 What is the Government's policy on the provision of free health checks for over 40s?

From 2009/10, the NHS is being asked to implement a uniform and universal vascular risk assessment and management programme called the NHS Health Check programme, for everyone in England between 40 and 74. The proposals for this programme were set out in Putting Prevention First published on 1 April 2008.

Vascular diseases, that is heart disease, stroke, diabetes and kidney disease, are the biggest cause of death in the UK, and the NHS Health Check programme could on average prevent 1, 600 heart attacks and strokes and save at least 650 lives each year. The programme could prevent over 4,000 people a year from developing diabetes and detect at least 20,000 cases of diabetes or kidney disease earlier, allowing individuals to be better managed and improve their quality of life.

Vascular disease also makes up approximately a third of the difference in life expectancy between spearhead areas and the rest of England. This programme will help ensure greater focus on the prevention of coronary heart disease, stroke, diabetes and kidney disease, and will help people remain well for longer. Type II diabetes mellitus is a growing public health concern. Its prevalence is increasing and diabetes contributes significantly to overall health inequalities within England. This programme offers a real opportunity to make significant inroads in tackling health inequalities, including socio-economic, ethnic and gender inequalities.

The purpose of an NHS Health Check is to identify an individual's risk of coronary heart disease, stroke, diabetes and kidney disease, for this risk to be communicated in a way that the individual understands, and for that risk to be managed by appropriate follow-up, including being recalled every five years for reassessment.

The check itself involves a standard assessment based on straightforward questions and measurements. These would record basic information such as height, weight, current medication, age, family history, smoking and blood pressure and include a simple blood test for cholesterol and (in some cases) glucose levels. This will be followed up with personalised advice on how to lower that risk and maintain a healthy lifestyle. For those at low risk, this might be no more than general advice on how to stay healthy. Others at moderate risk may be recommended a weight management programme, stop smoking service, or a brief intervention to increase levels of physical activity. Those at high risk might require medication with statins or blood pressure treatment, or an intensive lifestyle management programme for those identified with impaired glucose regulation. A few may need further assessment or tests.

We also expect to identify people who already have a vascular disease where it has so far gone undetected, particularly type 2 diabetes and chronic kidney disease. In such cases patients will benefit from an immediate start

on a disease management programme to manage their condition and prevent adverse complications.

Q2 What evidence (specifically cost-benefit analyses) led to the formulation of this policy? What evidence has been used to support health benefit claims (e.g. lives saved per year)?

The NHS Health Check programme is both cost effective and clinically effective.

The approach taken in the programme is based on economic modelling undertaken by the Department of Health (DH) which has used guidance produced by the National Institute of Health and Clinical Evidence (which reviews the clinical and cost effectiveness of interventions in medicine).

The full details of the analysis undertaken by the Department are set out in the Impact Assessment which can be viewed on the DH website (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_090351). It shows the cost of the programme to be £332m each year and the average annual benefit to be £3678m. *Based on these figures, the NHS Health Check programme is highly cost effective.* (The costs are the costs of the checks and net lifetime costs of interventions given to the cohort of individuals checked in the first 20 years. The benefits are calculated on the basis that each quality adjusted life year a patient enjoys has an estimated social value of £50,000).

Quality-adjusted life years are a measure of how many extra years of life of a reasonable quality a person might gain as a result of treatment.

The modelling also showed that the programme would cost around £3,500 per quality-adjusted life year gained. This is considerably below the £20-30,000 per quality-adjusted life year threshold that NICE uses to assess cost effectiveness and therefore, according to this test, the programme is highly cost effective.

Measuring the benefits of publicly-funded research

This response was provided by the Department for Business, Innovation and Skills.

Q1 What generic social and economic benefits are derived from funding research with public money?

Publicly funded excellent research produces new knowledge and understanding, which is a benefit in its own right, but also generates significant economic impact. The Warry Report[5], drew on the HM Treasury Green Book, to define economic impact as follows:

"An action or activity has an economic impact when it affects the welfare of consumers, the profits of firms and/or the revenue of government. Economic impacts range from those that are readily quantifiable, in terms of greater wealth, cheaper prices and more revenue, to those less easily quantifiable, such as effects on the environment, public health and quality of life."

Economic impact is delivered by publicly funded research via many routes, including:

- Creating new businesses
- Improving the performance of existing businesses
- Delivering highly skilled people to the labour market
- Attracting R&D investment from global business
- Improving public policy and public services

Q2 What evidence is there for social and economic benefits? How is this evidence used to determine funding priorities?

There is extensive evidence of the benefits of publicly funded research. A report that looks at the economic impact of the research base as a whole is produced annually by BIS (formerly by DIUS), and is structured around an Economic Impact Reporting Framework, which portrays the generation of economic impacts at the aggregate economy level[6]. It is wide ranging, and includes sections on the five routes to economic impact bulleted above, as well as others. In 2006 the then DTI published *Making the most of UK Research*, a collection of case studies of benefits from research[7].

Each Research Council prepared initial Economic Impact baselines as part of their Delivery Plans published in December 2007, and updated versions were published this year[8].

The impact of other funding streams has been independently evaluated. The Higher Education Innovation Fund (HEIF) is one such stream[9], and its impact on knowledge

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[5] *Increasing the economic impact of Research Councils* (2006)

[6] *Economic Impacts of Investment in Research & Innovation*, DIUS (2008)

[7] Available at http://www.dius.gov.uk/~/media/publications/F/file35789

[8] Available at http://www.rcuk.ac.uk/aboutrcuk/deliveryplan.htm

[9] *Evaluation of the effectiveness and role of HEFCE/OSI Third Stream Funding*, PACEC (2009)

transfer is borne out by the annual Higher Education-Business and Community Interaction (HE-BCI) survey[10], which shows universities external income rising to record levels of over £2.8 billion per year. The Science Research Infrastructure Fund (SRIF) has been shown to have dramatically improved research infrastructure, and to have wider benefits in terms of researcher productivity and ability to attract other funding[11]. The knowledge transfer performance of Public Sector Research Establishments is also improving, bringing in record levels of external income[12].

The research community itself also regularly carries out evaluation of the economic impact of research. To pick just a few recent examples, the Russell Group have evaluated the impact of research in their universities[13], the Wellcome Trust has assessed the economic benefits of medical research[14], and Oxford Economics have assessed the economic effects of fundamental physics research[15].

Before allocating the Science and Research Budget, DIUS collected evidence on the activities and performance of all funding lines. All the Research Councils and the Academies provided detailed delivery plans, which set out what future investment would deliver against the overarching objectives. Other key programmes, such as HEIF and SRIF, were subject to independent evaluation.

The following factors were taken into account in determining the Science Budget Allocations to individual Research Councils and Academies:

- a thorough assessment of draft Research Council and Academy Delivery Plans for CSR07;
- the strength of the case for increasing the investment in any particular area of research in CSR07; and
- a full evaluation of the performance of each of the Research Councils and Academies through the SR04 period

The allocation of the Quality-related Research block grant to Higher Education Institutions by HEFCE has in the past been informed by the results of the Research Assessment Exercise (RAE). HEFCE are currently developing the Research Excellence Framework (REF) to replace the RAE. The REF will for the first time explicitly take account of the impact research makes on the economy and society.

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[10] *Higher education-business and community interaction (HE-BCI) survey* (2009)

[11] *Science Research Investment Fund: a review of Round 2 and wider benefits*, Technopolis Group (2009)

[12] *Fourth Annual Survey of Knowledge Transfer Activities in Public Sector Research Establishments*, Technopolis (2008)

[13] *The Impact of Research produced by Russell Group Universities*, Russell Group (2009)

[14] *Medical Research: What's it worth?*, Health Economics Research Group at Brunel University, the Office of Health Economics and RAND Europe (2008)

[15] *The economic impact of fundamental physics research on the UK economy*, Oxford Economics (2009)

The future of GM technologies

This response was provided by the Department for Environment, Food and Rural affairs.

Q1 What is the Government's policy on the development and commercialisation of genetically modified crops?

The Government confirmed its current Policy on GM crops in a Parliamentary statement in March 2004. Safety is the Governments top priority and as such we follow the science and assess potential GM crops on a case-by-case basis. This is consistent with the existing EU legislation which requires genetically modified organisms to be cleared for trial or commercial release, with decisions based on an assessment of the risk to human health and the environment.

The Government acknowledges that GM crops could offer potential benefits over the longer term. We should keep an open mind, but continue to be led by the science.

Q2 What evidence and expert advice has been used to determine government policy regarding genetically modified crops?

The Government receives expert advice on individual applications to release GM crops from the Advisory Committee on Releases to the Environment. It conducts an independent scientific evaluation and advises on the potential risks for human health and the environment.

The Government's broad policy on GM outlined above was informed by the findings of the 'GM Dialogue' process that it sponsored in 2003. This had three strands: a public debate run by an independent board; a GM science review led by the then Government Chief Scientist; and a study of the overall costs and benefits of GM crops, undertaken by the Prime Minister's Strategy Unit. Further details can be found on Defra's website http://www.defra.gov.uk/ENVIRONMENT/gm/crops/debate/

Synthetic biology

This response was provided by the Health and Safety executive.

Q1 What is the Government's policy on the regulation of synthetic biology?

The Government recognises that this is a new and exciting field of technology, which has the potential to deliver benefits in areas such as medicine, manufacturing, and the environment. However, there is also a need to identify, anticipate and address any societal issues that might arise from synthetic biology, whilst enabling UK research and industry to harness the technology to develop and deliver benefits for society.

Synthetic biology involves a range of techniques culminating in the insertion of synthetic heritable material into living cells. In many ways this is an extension of existing recombinant DNA technologies. Consequently the Government considers that most applications are likely to fall under existing legislation covering the development and use of genetically modified organisms.

Future work may involve the creation of artificial cells, which would not fall within the scope of existing legislation. Consequently, a minor amendment is being proposed to the definition of GM as part of the development of a single regulatory framework for work with human and animal pathogens and GMOs. This will enable the regulations to cover artificial cells, should the technology develop in that direction. This change will be consulted on prior to the implementation of the new regulatory system.

The Government also recognises that the regulatory system needs to be kept under review to ensure that it is able to deal with the likely development and applications of synthetic biology, including those relating to biosafety, biosecurity and the release of genetically modified organisms into the environment. In doing so, it recognises that lessons should be drawn from the past to help ensure regulations keep pace with, or anticipate, scientific developments.

Q2 What evidence and expert advice will the Government seek to underpin future regulation? Are current regulations adequate or will a new regulatory framework be required?

The Government regularly checks the appropriateness of the existing UK GM legislation (GMO deliberate release and GMO contained use regulations) to deal with new technologies, including synthetic biology. Scientific advice on the topic has been sought from scientific advisory committees (Advisory Committee for Releases into the Environment (ACRE), and Scientific Advisory Committee for Genetic Modification (SACGM (CU)), the UK research councils, and other government departments and agencies.

The Government will continue to consult a wide range of stakeholders to ensure that the regulatory system is appropriate, and that the best advice is available to evaluate developments in synthetic biology.

It is widely anticipated that most applications of synthetic biology will start in the laboratory in compliance with the GMO contained use regulations, before a proportion will progress to deliberate release. Activities falling under the GMO contained use regulations contained will require risk assessment and proportionate and appropriate containment.

Deliberate release applications can only be approved once sufficient supporting knowledge and data is available. Defra and HSE are also involved in a working group under the auspices of the European Commission, which is considering the new technologies in light of existing GM definitions and legislation. The working group will report to the EC in October.

UK legislation covering the contained use of genetically modified organisms is under review, with the intention of creating new legislation amalgamating the GM legislation with the contained use of human and animal pathogens. This provides an opportunity to ensure that aspects of synthetic biology that might be outside the scope of current legislation are encompassed in the emerging single regulatory framework. The proposed amendment extends the definition of genetic modification to include the "introduction of genetic material into a cell artificially created for that purpose, where the cell is then capable of replication or of transferring genetic material". It is felt that this amendment will be sufficient to ensure that synthetic biology is fully covered by UK legislation. A full consultation exercise will be carried out before the definition is incorporated into the regulations.

Use of offender data

This response was provided by the Ministry of Justice.

Q1 What is the Government's policy on the use of offender data (e.g., employment, access to finance)?

Whether offender data relating to convictions can be used for most purposes is dependent on whether a conviction is spent or unspent under the Rehabilitation of Offenders Act 1974. The Act serves to help rehabilitate those who have stayed on the right side of the law for a period of time, thereby assisting reformed ex-offenders find jobs, obtain insurance and avoid discrimination.

Until a conviction is spent it may have to be declared for any purpose - for instance when obtaining financial products, seeking employment, or applying for any sort of licence, for instance a licence to sell alcohol or engage in a certain type of business. This is fair as an unspent conviction may indicate a relevant risk, and is a fair consequence of a criminal penalty.

However once a conviction is spent under the Act it is treated - for most purposes - as if it doesn't exist. This reflects the fact that the ex-offender has remained on the right side of the law for a specified period and proven they pose less of a risk in most circumstances.

As the rehabilitation periods differ according to the sentence imposed the period for which a conviction needs to be disclosed is related to the severity of the individual offence.

However there are certain positions - particularly those involving access to children and vulnerable adults, and working in positions of exceptional trust or for the State - where the employer needs to be able to take the most stringent of assessments in order to minimise a genuine risk. For instance those working in the police, looking after children or vulnerable adults, or working with access to highly controlled substances, can potentially cause a much greater level of harm if they do offend. For this reason there are certain purposes where an exception to the Rehabilitation of Offenders Act exists. These are all specified by the Rehabilitation of Offenders Act 1974 (Exceptions) Order 1975 (as subsequently amended on numerous occasions). Amendments to the order are by means of a Statutory Instrument subject to affirmative procedure.

The government's policy is that those areas listed on this order are deemed sufficiently sensitive that the employer should always be able to see a person's full record, including all spent convictions and cautions, in order to come to a fair judgment on their suitability (and any appropriate safeguards) based on the full available evidence.

But it is equally important to note that having a criminal conviction is not an automatic bar to employment in any of these areas. The government believes that it is important for employers to take a balanced view on the fact that an individual has

a criminal conviction, whether spent or unspent, taking into account factors such as how long it is since the offence, the person's age at the time of the offence, the relevance of the offence, and what else is known about the individual's character and conduct before and since.

In order to obtain a Criminal Records Bureau disclosure containing details of spent convictions, it is necessary for the employer to make a declaration that it is for purposes specified in the ROA Exceptions Order. An employer obtaining details of spent convictions by means of a fraudulent statement would be committing an offence.

It is the government's belief that this system - within the framework of the Rehabilitation of Offenders Act 1974 and the Police Act 1997, and fine-tuned by updates to both primary and secondary legislation - helps create a balance between the need to disclose offender data when there is a need to do so for purposes of protecting the public, and the need to enable reformed ex-offenders to put their past behind them at all other times.

Q2 What evidence is there to support the various ways in which offender data are used?

Statistical evidence is hard to obtain when one is dealing with subjective decisions. The system can be said to have worked either when an offender gets a job and does not re-offend, or when an offender is prevented from entering a job where they intended to cause harm.

The latter is impossible to prove. There is no proof that an ex-offender would re-offend if placed in a sensitive position, even if their criminal conviction was recent, serious and relevant. In some cases an individual who is barred from a sensitive position may - had he or she been employed in that position - have gone on to commit a serious offence or abuse of trust; in other cases they could have gone on to have a faultless record. It is impossible to produce definitive figures on an event which has not been given the opportunity to happen. However when employers make judgments they have to do so on the basis of a fair risk analysis using their knowledge of the job, the opportunities it affords, and the record of the person applying.

CRB statistics, compiled by MORI, indicated that in 2008, around 18,000 unsuitable people were prevented from working with children and/or vulnerable adults as a direct result of a CRB check, bringing the total to around 98,000 people in the past five years. This, even when assessed with the caveats above, would still indicate that the purpose of the system to bar unsuitable candidates is working.

As there is no control study it is hard to use these statistics as proof of the effectiveness of the current system. However they do provide evidence which supports the way in which offender data is currently used. These statistics indicate that there are those on both sides of the system - employers of sensitive positions and ex-offenders - who have benefited from the system. As long as the decision to

share information is balanced in terms of being necessary, e.g. to protect the public, and proportionate, e.g. to the risk the offender poses, it can benefit all parties.

As to whether a better balance could be established, improving one or both of these sets of figures - this is certainly something to which the government aspires. The 2002 Home Office report "Breaking the Circle" recommended reforms to the ROA and the government has made a commitment to work on implementing the proposals. And the Vetting and Barring Scheme, established under the Safeguarding Vulnerable Groups Act 2006, will enable a better, fairer and more joined-up approach to vetting those working with children and vulnerable adults. But the fundamentals of the scheme - that once convictions are spent they are only made available to those who have a need to know - are working and will not be changed. The next phase of the scheme commences in October 2009 with a phased implementation of registration under the scheme being introduced between July 2010 and 2015.

Sharing of information between police and probation

Information-sharing between criminal justice agencies is necessary for effective sentencing and the protection of the public. Information about offenders is currently shared between the police, prison and probation services to enable staff to manage offenders effectively, as provided for within the Offender Management Act 2007 (s14). Probation may request information from the police service for a range of reasons to enable the public to be protected, including for the following purposes: for bail information interviews and reports; at the pre-sentence stage, for making appropriate sentence recommendations; to make appropriate placement decisions for unpaid work (community payback) requirements; assessment for licence conditions prior to the release of a prisoner; for informing reports to the Parole Board for considering an offender’s parole.

However, this must be within the parameters of relevant legislation and guidance, which are designed to balance the rights of the individual, i.e. the subject of the information being shared, with the rights of society to be protected from that individual. Therefore, information shared about a person must be both necessary (e.g. to meet the probation purposes of managing risk of harm) and proportionate (e.g. to the risk posed by that person). These principles should govern the decision by the police service to share information in the first place and the decision by the probation service over whether to use the information to inform their report.

The National Offender Management Service is in the process of agreeing an information-sharing protocol with the Association of Chief Police Officers to formalise the processes for exchanging information between the police and probation services for the effective management of offenders. The agreement will set out the purpose and principles of information-sharing, along with the legal basis for offender management activity, and the legislation governing the disclosure of personal data. It will provide for and encourage the sharing of information in certain circumstances, but make the legal implications to earlier and more widespread information-sharing clear.

Certain offenders are managed under the Multi Agency Public Protection Arrangements. MAPPA is a process where the Responsible Authority (police, prison and probation services together with a number of Duty to Co-operate Services which include Jobcentre Plus and Housing) work together to manage the identified risks presented by these offenders.

MAPPA applies to:
-sexual offenders who are required to notify the police of their details under the Sexual Offences Act 2003
- violent offenders as defined by Schedule 15 of the Criminal Justice Act 2003 who are sentenced to 12 months custody or more; and
- those dangerous offenders who have a previous conviction or caution for a violent offence who the Responsible Authority (police, prison and probation services) consider present a risk of serious harm to others.

MAPPA relates to offenders in the community and each MAPPA offender will be assessed to identify the level of multi agency management they require and in every case whether a disclosure regarding the risks the offender presents should be made to another person/organisation to protect others from harm. There is occasions where disclosure will be made to an employer to ensure that the offender is not placed in a situation which would be unsuitable for the risks they pose; for example, a sexual offender working unsupervised with children or vulnerable adults. All decisions regarding disclosure are recorded on the case management system.

Where an offender is actively multi agency managed through MAPPA at level 2 or 3 (this means that a number of agencies are actively working together to share information, identify risks and establish a multi agency risk management plan which can require the commitment of additional resources), the disclosure decision will be formally recorded at the MAPP meeting. Where disclosure is to take place, the details of the information to be disclosed, who to and who by will be recorded in the MAPP meeting minutes and recorded on ViSOR. ViSOR is a database which has been developed to be used by police prison and probation to assist in the management of violent and sexual offenders. It is a confidential system which is used by the police as their primary case management system with sexual offenders. The prison and probation services use it to share information which enhances risk assessments.