GENETIC TECHNOLOGIES: a review of developments in 2006

GeneWatch UK

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This briefing examines the main issues in genetic technologies that occurred in 2006.The stall in new GM crops continued, with no new commercial applications, due largely to technical difficulties in introducing complex traits such as drought-resistance, enhanced nutritional value or drug production. Difficulties preventing contamination also continued to dog the industry.

The police National DNA Database in Britain remains the largest in the world and continues to expand. However, a decision by the Scottish Parliament means that England and Wales remain isolated as the only countries in the world which allow the DNA of innocent people to be retained permanently. The UK Biobank completed a pilot study, but controversy remains about the role of genetics in the study and the privacy of both electronic health records and DNA. At the end of the year, a new UK company called Genetic Health also began marketing dubious genetic tests via its Harley Street clinic.

New legislation was proposed for the genetic selection of embryos and the use of human cloning, genetic modification and the creation of human-animal hybrids (chimeras) for research.

GM CROPS AND FOOD

Commercial growing of GM crops in 2006

During 2006, 22 countries grew GM crops commercially on 102 million hectares, a 13% increase on 2005 (see Table 1). The USA accounts for over 50% of this area. In Europe, Romania, Slovakia, France, Portugal, the Czech Republic and Germany grew small amounts of GM crops commercially.

Once again, the only GM traits in commercial use (except for some GM disease-resistant papaya in Hawaii and squash in the USA) are herbicide tolerance and insect resistance using Bt genes. The herbicide tolerance and insect resistance traits have also both been included in some varieties of cotton and maize which is known as gene 'stacking'. Herbicide tolerance made up 68%; Bt insect resistance, 19%; and the two traits 'stacked', 13% of the area of GM crops grown. Soybeans (57%), cotton (13%), oilseed rape (5%) and maize (25%) are the only GM crops grown on a large scale. GM herbicide tolerant alfalfa was grown commercially for the first time in the US in 2006 on 80,000 hectares.

Experimental GM trials in Europe

During 2006, there were no field trials with GM crops in the UK. However, approval was given to the company BASF to conduct trials with potatoes genetically modified to be resistant to blight, starting in spring 2007.[2] The trials were to be conducted in Derbyshire and Cambridgeshire but the Derbyshire farmer has pulled out because of concerns about the likely controversy. Permission was also granted to Emergent Europe Ltd, for a clinical trial with a genetically modified bacterium, *Salmonella typhi,* as part of a hepatitis B vaccine development programme.[2] The trial started at two London hospitals in September 2006 and will run until June 2008.

There were 93 experimental releases of GM organisms notified to the European Commission.[3] Most of these took place in Spain (41) and France (18) and involved maize. There were three trials with GM organisms other than plants notified to the European Commission in 2006.

GM regulation and approvals in Europe

In Europe, there is continuing confusion and disagreement over the regulation of GM crops and foods. There were only three approvals given for import and use in food and feed (see Table 2). These were given approval by the Commission despite disagreement between member states.

There are 36 products pending authorisation. One of these, a potato genetically modified to increase the proportion of amylopectin starch it produces, is intended for growing in Europe.[4] Made by BASF, the starch composition has been altered to make it more suitable for use in certain industrial processes such as printing. The potato

was considered at a meeting of member state officials in December 2006, but the qualified majority necessary for approval was not reached. It will now be considered by Environment Ministers and, if they do not agree, the Commission could take the decision. If authorised, this would be the first GM plant intended for cultivation to be approved since 1998.

Table 1: Commercial cultivation of GM crops worldwide in 1999-2006
(in millions of hectares)[1]

COUNTRY	1999	2000	2001	2002	2003	2004	2005	2006
USA	28.7	30.3	35.7	39.0	42.8	47.6	49.8	54.5
Argentina	6.7	10.0	11.8	13.5	13.9	16.2	17.1	18.0
Brazil	0.0	0.0	0.0	0.0	3.0	5.0	9.4	11.5
Canada	4.0	3.0	3.2	3.5	4.4	5.4	5.8	6.1
India	0.0	0.0	0.0	<0.1	0.1	0.5	1.3	3.8
China	0.3	0.50	1.5	2.1	2.8	3.7	3.3	3.5
Paraguay	0.0	0.0	0.0	0.0	0.0	0.0	1.8	2.0
South Africa	0.1	0.20	0.27	0.3	0.4	0.5	0.5	1.4
Uruguay	0.0	<0.1	<0.1	<0.1	<0.05	0.3	0.3	0.4
Australia	0.1	0.15	0.21	0.1	0.1	0.2	0.3	0.2
Philippines	0.0	0.0	0.0	0.0	<0.05	0.1	0.1	0.2
Mexico	<0.1	<0.1	<0.1	<0.1	<0.05	0.1	0.1	0.1
Romania	<0.1	<0.1	<0.1	<0.1	<0.05	0.1	0.1	0.1
Spain	<0.1	<0.1	<0.1	<0.1	<0.05	0.1	0.1	0.1
France	<0.1	<0.1	0.0	0.0	0.0	0.0	<0.1	<0.1
Germany	<0.1	<0.1	<0.1	<0.1	<0.05	<0.05	<0.1	<0.1
Columbia	0.0	0.0	0.0	<0.05	<0.05	<0.05	<0.1	<0.1
Honduras	0.0	0.0	0.0	0.0	<0.05	<0.05	<0.1	<0.1
Iran	0.0	0.0	0.0	0.0	0.0	0.0	<0.1	<0.1*
Portugal	<0.1	<0.1	0.0	0.0	0.0	0.0	<0.1	<0.1
Czech Republic	0.0	0.0	0.0	0.0	0.0	0.0	<0.05	<0.1
Slovakia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	<0.1
Bulgaria	0.0	0.0	0.0	0.0	<0.05	0.0	0.0	0.0
Indonesia	0.0	0.0	0.0	0.0	<0.05	0.0	0.0	0.0
Ukraine	<0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total	**39.9**	**44.2**	**52.6**	**58.7**	**67.7**	**81.0**	**90.0**	**102.0**

* whether GM crops are grown commercially in Iran is disputed as none are approved

Table 2: GM crop, food and feed approvals in Europe in 2006[5]

GM organism	Uses	Decision
Maize line MON 863 – resistant to corn rootworm (Monsanto)	For import and use of grain and grain products, *not for cultivation*	Given approval under Food and Feed Regulation, 1829/03 – 13/01/06
Maize line GA21 – herbicide tolerance (Monsanto)	For import and use of grain and grain products, *not for cultivation*	Given approval under Food and Feed Regulation, 1829/03 – 13/01/06
Maize line 1507 CRY1F – herbicide and insect resistant (Pioneer/Mycogen)	For import and processing, *not for cultivation*	Given approval under Food and Feed Regulation, 1829/03 – 03/03/06

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The WTO dispute

The final report from the dispute panel considering the challenge by the USA, Canada and Argentina about Europe's approach to GM crops and foods was published on 29 September 2006.[6,7] The failure to approve any GM crops or food between 1998 and 2003 and member state bans on GM foods approved before 1998 were the focus of the complaint. The panel found against Europe in several instances and has recommended that the EC correct flaws in the implementation of the pre-market approval system for GM products in light of the WTO rules prohibiting undue delays and requiring risk assessments. The main findings of the

panel and their implications are outlined below.

1. Europe did have a moratorium on GMO approvals

First, the panel had to determine whether there was a moratorium or not because this was what the complaining parties claimed and it was disputed by the EC. The panel found that there was clear evidence that between June 1998 and August 2003 (when the dispute process began) GMO approvals were halted because of a moratorium.

2. The moratorium concerned the operation of Europe's safety rules

Next the panel had to determine whether the moratorium was subject to the WTO agreements - whether it was a 'measure'. The panel decided it was not a measure under the Sanitary and Phytosanitary (SPS) Agreement that covers rules to protect human health and the environment from pest and food-borne risks, but that the moratorium affected how Europe operated its rules on safety. In other words, the EC's Directives and Regulations concerning the safety of GMOs (such as the Deliberate Release Directive and Novel Foods Regulation) are measures and the moratorium affected how these were administered.

The panel found that there had been 'undue delay' in the assessment of the GMOs which had halted decisions on product approvals, and these delays could not be justified

3. Europe's moratorium led to 'undue delay' in assessments

Because the panel considered the moratorium to be about the operation of human and environmental safety laws, it falls within rules which lay down how the administration of such laws should be conducted. The panel found that in 24 of 27 cases involving specific GMO products, there had been 'undue delay' in the assessment of the GMOs which had halted decisions on product approvals, and these delays could not be justified.

4. Member state bans violated WTO rules because they were not based on a risk assessment

The panel also had to consider whether EU member state bans on certain GMOs, approved before the moratorium began in 1998, broke WTO rules. The dispute panel considered the information that the EU member states had relied upon when they had introduced their GMO bans and decided that this did not constitute a 'risk assessment' as required within the meaning of the SPS Agreement. Because the member state bans are still in place, the panel found that steps should be taken to bring the EC into conformity with WTO rules. One way to bring the bans into conformity would be to abolish them, but several of countries with bans have already signalled their unwillingness to do this. Another way might be for the EU member states to conduct their own risk assessments within the meaning of the SPS Agreement, and then demonstrate that their ban is based on those risk assessments. Under WTO law, a ban can be based on a risk assessment even if the risk assessment is undertaken after the ban is created.

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5. Because the USA is not a party to the Cartagena Protocol on Biosafety, its rules have only limited relevance to the dispute

There is an international agreement known as the Cartagena Protocol on Biosafety that was agreed under the Convention on Biological Diversity (CBD). This relates to environmental safety of transboundary movements of GMOs and relevant to the dispute. The Biosafety Protocol requires states to take a precautionary approach to safety and allows them to take socio-economic issues into account in their risk assessments. However, the USA has not ratified the CBD, and neither Canada, Argentina nor the USA has signed the Biosafety Protocol. The panel said that it considered that if a member of the WTO was not a party to another international agreement, such as the CBD or the Biosafety Protocol, then that other international agreement was not relevant in a given dispute.

6. Implications of the findings

One important point is that the dispute was only about the *implementation* of the EC's

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rules not their substance. Issues that were not questioned by the complaining parties or addressed by the panel include:

- the right to conduct pre-market risk assessments of GMOs;
- the right to establish a level of risk acceptable to individual countries, including zero risk;
- whether GMO products are 'like' non-GMO products and can be treated differently - so the decision has no relevance to GMO product labelling;
- whether GMOs were 'safe' or 'dangerous'.

Therefore, in many respects, although the outcome has been characterised as a victory for the USA, it in no way limits a country in the kind of regulations it introduces but only affects how they must be conducted.

Europe took the unusual decision not to appeal against the findings of the WTO dispute panel

However, the panel's ruling was negative in relation to its consideration of international law and what constitutes a 'risk assessment'. This could mean governmental regulations aimed at health, environmental and consumer interests will have to be backed up by narrowly defined risk assessments, leaving little room for precautionary measures in the face of scientific uncertainty and irrespective of other obligations under international law.

Europe took the unusual decision not to appeal against the findings of the WTO dispute panel. Europe will now be required to bring its procedures into conformity with the WTO rules. If the EC refuses, or does not do this within a reasonable time frame (usually about 15 months), the complaining parties may then go back to the Dispute Settlement Body and, under a separate process, ask for counter measures to be approved. This could be compensation or, more likely, increases in import tariff levels for agricultural or other products imported into the complaining countries from the EC.

The European Commission has already faced problems in ending the national bans as the ruling required

The European Commission has already faced problems in ending the national bans as the ruling required. On 18 December, Ministers rejected a proposal to require Austria to drop its ban on two GM maize varieties.[8] Only four countries - the UK, Sweden, the Netherlands and the Czech Republic - supported the Commission's efforts.

GM contamination

GeneWatch UK, with Greenpeace, has continued to monitor incidents of GM contamination and record this on a dedicated website (www.gmcontaminationregister). It includes records of:

- when food, feed or a related wild species has been found to contain unintended GM material from a GM crop or other organism;
- illegal plantings or releases of GM organisms - when an unauthorised planting or other release into the environment or food chain has taken place;
- negative agricultural side-effects - when there has been a report of agricultural problems arising from the GM organism and how it is managed.

The 24 incidents added to the register in 2006 involved 15 incidents of contamination and nine illegal releases

A review of the all the incidents on register up to the end of 2005 was published in early 2006.[9] During 2006, records of 24 incidents were added. In addition, three cases for 2005 and one for 2000 were included in the register in 2006, bringing the total number of incidents recorded in the database to 141. The number of incidents recorded for 2006 is the highest for any year.

The 24 incidents added to the register in 2006 involved 15 incidents of contamination and nine illegal releases. The contamination incidents were in the following 12 countries: Germany (three); China (two); France (one); Japan (one);

New Zealand (one); Romania (one); Bulgaria (one); Hungary (one); Slovenia (one); South Africa (one); South Korea (one); and the USA (one). These contamination incidents involved food (nine); seed (four); feed (one); and wild relatives (one). The cause of the contamination in food and feed was often neither determined nor investigated, but in most cases this must have been the result of poor-quality control measures following either cross-pollination or post-harvest mixing.

The illegal releases were recorded in Brazil (two); the USA (two); Europe (one); France (one); Japan (one); Mexico (one); and the Philippines (one).

The 2006 incidents of contamination and illegal release involved soybeans (eight); maize (seven); rice (four); cotton (two); grass (one); papaya (one); and killifish (medaka) (one).

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Since GM crops were first grown commercially, contamination incidents have taken place in a total of 43 countries and twice affected Europe as a whole. Bulgaria, Hungary, Slovenia and South Africa recorded their first GM contamination incidents in 2006.

One of the most serious incidents that occurred in 2006 was the finding of US long-grain rice contaminated with an unapproved GM variety, Bayer's LLRICE601. This was an almost identical situation to that which occurred in 2005, when Syngenta's unapproved GM maize Bt10 was found to have been mistakenly sold as the approved Bt11 variety. Bayer's LLRICE601 was not intended for commercialisation and had last been grown in field trials in 2001 yet it was found throughout the rice growing areas of the USA in the most commonly used variety, Cheniere. See Box for more information about this incident.

BOX: Bayer's LLRICE601 contamination incident

On 18 August 2006, the US Secretary for Agriculture announced that Bayer CropScience had reported that rice from the 2005 US crop had been found to be contaminated with a GM variety, LLRICE601, that is not approved for growing or consumption.[10] The rice is genetically modified to be tolerant to the herbicide glufosinate (trade name: Liberty), made by Bayer, but development of the GM rice variety was ended in 2001 when the last field trials took place. Two other varieties of glufosinate-tolerant rice, LLRICE62 and LLRICE06, are approved in the USA but are not being grown commercially.

Rice from the 2005 US crop had been found to be contaminated with a GM variety, LLRICE601, that is not approved for growing or consumption

Rice contaminated with LLRICE601 has now been found in food and feed across the world in Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Poland, Slovenia, Sweden, Switzerland, the UK,[11] the United Arab Emirates, Dubai, Kuwait,[12] the Philippines,[13] Ghana, Sierra Leone[14] and Russia.[15]

Because LLRICE601 does not have approval anywhere in the world, its presence is illegal in any country that requires pre-market safety assessment of GM crops and foods. As a result, Japan suspended imports of long-grain rice from the USA on 20 August.[16] Europe requires all imports of rice to be tested for the unauthorised GM rice.[17 18]

Despite the lack of a safety assessment, as soon as the contamination came to light, both the US Food and Drug Administration (FDA) and Bayer CropScience made statements that they considered LLRICE601 to be safe.[19] The USA gave the rice *post hoc* authorisation in November 2006.[20] The European Food Safety Authority's GMO Panel's view was that there were insufficient data to provide a full risk assessment. However, 'on the basis of the available molecular and compositional data and the toxicological profile of a newly introduced protein, the Panel considers that the consumption of imported long grain rice containing trace levels of LLRICE601 is not likely to pose an imminent safety concern to humans or animals'.[21] The presence of LLRICE601 in rice exports to Europe and Japan, where LLRICE601 is not approved, remains illegal.

The lack of an explanation for the contamination is one of the most worrying aspects of the case because it means that it remains impossible to implement specific safeguards to prevent recurrence

The USDA's Animal and Plant Health Inspection Service is conducting an inquiry into how the contamination incident took place and whether laws were broken. The contamination has been found in one variety of rice, Cheniere, grown extensively in the USA in 2005 and 2006, and it seems that other varieties are not affected. But how it arose remains a mystery. The lack of an explanation for the contamination is one of the most worrying aspects of the case because it means that it remains impossible to implement specific safeguards to prevent recurrence.

The dilemma for food producers remains, as was illustrated with Syngenta's Bt10 maize: the fact that no tests are undertaken for contamination by unapproved varieties of GM crops. Officially these do not exist and validated testing is not routinely available.

HUMAN GENETICS

There was growing recognition that the Human Genome Project had not created a 'genetic revolution' in healthcare. A report by Nottingham University concluded that the expectations created for genomic medicine by scientists, industry, policy makers and patients were unrealistic.[22] A paper in the British Medical Journal concluded that common cancer susceptibility genes are unlikely to exist or, if they do, are unlikely to have much of an effect on the incidence of cancer.[23] Another paper reiterated concerns that most of the biomedical information that is published – including studies identifying genes as risk factors for disease – is likely to be false.[24] The failure to find genes for most common diseases in most people may be because twin studies have exaggerated the importance of inherited genetic factors, by ignoring the complex interactions which occur during development and ageing.[25,26]

The police National DNA Database

Keeping ever larger numbers of innocent people on the National DNA Database (NDNAD) has not increased the chances of solving a crime

In January 2006, the Home Office published the first detailed figures on its DNA Expansion Programme.[27] The report showed that keeping ever larger numbers of innocent people on the National DNA Database (NDNAD) has not increased the chances of solving a crime.[28] Despite this, DNA retention was used to justify a change in the rules on police computer records, so that these are now also kept permanently, even if a person is acquitted or has committed only a minor offence.[29]

In 2006, the Scottish Parliament rejected plans to bring Scottish law in line with England and Wales by keeping DNA from innocent people permanently. Concerns raised by MSPs included the lack of evidence that the policy had contributed to tackling crime in England and Wales; the privacy issues associated with keeping DNA samples; and the erosion of the presumption of innocence.[35] In May, Scotland adopted a new compromise amendment, which allows the temporary retention of DNA from people charged with but not convicted of serious violent or sexual offences in Scotland, for a period of up to five years.[36] Retention beyond three years requires the police to apply for approval from a Sheriff. The Scottish Parliament's decision leaves England and Wales isolated internationally as the only countries where DNA can be kept for life even if a person is never charged or convicted of any offence.

Throughout the year, the expansion of the DNA Database in England and Wales continued to cause controversy. In December, it was revealed that the DNA Data base now contains more than a million people who have not been convicted or cautioned for an offence, although some of these people will be awaiting trial.[37] Many other individuals, including children arrested from the age of ten, are held permanently on the Database for relatively minor public order offences. Black men continue to be disproportionately represented on the DNA Database, with reports suggesting that up to three out of four young black men (aged 15 to 34) are now on

Table 3: DNA detections†

Year	2002–3	2003–4	2004–5	2005–6
Number of individuals' DNA profiles on NDNAD‡	2,099,964	2,371,120	2,802,849	3,534,956
DNA detections	21,098	20,489	19,873	20,349
Recorded crimes	5,920,156	6,042,991	5,623,263	5,556,513
Percentage of crimes detected involving DNA	0.36%	0.34%	0.35%	0.37%

† A detected crime involves sufficient evidence for someone to be prosecuted.
‡ These figures include some repeat records (an estimated 10% of the total).
Sources: NDNAD Annual Report 2002–3,[30] Home Office,[31,32] Hansard.[33,34]

Researchers found that both parents and children have reservations about samples being taken for petty crime and feel that there are dangers in stigmatising young people for a one-off act

it.[38] As the number of children on the Database increased, researchers found that both parents and children have reservations about samples being taken for petty crime and feel that there are dangers in stigmatising young people for a one-off act.[39] A report by the Foundation for Information Policy Research warned that the proliferation of databases on children could lead to discrimination against them by police or social workers.[40] The total number of innocent children on the DNA Database is still unknown.

Freedom of Information requests by GeneWatch UK to the NDNAD Board revealed that since the year 2000, 19 research projects have been allowed and 14 refused.[41] The requests revealed that stored DNA samples have been used for genetic studies of the male Y-chromosome, without the consent of the people involved, as part of a controversial attempt to predict ethnicity from DNA. This type of research could also inadvertently reveal other genetic characteristics such as a man's risk of infertility. E-mails supplied to GeneWatch UK also showed that the commercial company LGC, which analyses some DNA samples for the police, had retained its own
'mini-database' of DNA records, despite claims that access to the DNA Database is carefully restricted and controlled.

The existence of secret Home Office guidance on the extension of criminal investigations to make routine use of medical databases and health information of family members was also reported.[42] Concerns that blood spots taken from babies for medical tests at birth might be used to make a 'back-door' forensic database were exacerbated when a senior police officer advocated this approach.[43,44]

In November, the Home Office held a consultation about oversight of the DNA Database and the use of forensic information, in which it admitted there was a 'regulatory gap'.[45] The Nuffield Council on Bioethics launched a broader consultation which seeks people's views about whose DNA and fingerprints should be kept on forensic databases.[46]

UK Biobank

UK Biobank aims to collect blood and urine samples from 500,000 volunteers between the ages of 40 and 69.[47] Genetic data, and results of other tests, will be linked with lifestyle information from an initial questionnaire and follow-up data from medical records. After years of delay and scientific criticism,[48] UK Biobank appears set to finally begin recruitment in early 2007.

The biobank's main pilot study was launched in March 2006. Some former scientific critics changed their minds about the project after being told it no longer planned to focus on genetics.[49] UK Biobank's new Director told the Guardian newspaper: 'It's not a genetic study, it's not a DNA study.[50] However, UK Biobank's website still claims that it 'will be a unique resource for ethical research into genetic and
environmental factors that impact on human health and disease'. A new scientific protocol for the biobank, which could clarify the role of genetics in the study, has still not been published.

Scientists continued to criticise the UK Biobank for its emphasis on size and genetic factors, rather than detailed measurements

Despite positive comments from a scientific panel which reviewed the project in August 2006, other scientists continued to criticise the UK Biobank for its emphasis on size and genetic factors, rather than detailed measurements. They argued that failure to measure environmental exposures throughout a person's life would bias the results, making the study a waste of money.[51] Others pointed out that the UK Biobank depended for its support on 'backing from the powerful genetics lobby'[52] and that genetic studies are not likely to be useful to predict or prevent the kind of diseases to be studied in the biobank.[53,54]

Millions of personal medical records loaded onto the new computer database could be accessible by the police and security services as well as NHS staff

UK Biobank will rely on the implementation of electronic medical records in the NHS, as a means of tracking individuals' health. Indeed, the pharmaceutical industry's desire to access medical records is one of the drivers behind computerising them – the idea for the biobank began with a 1999 proposal for a public–private partnership to use NHS records as a research resource, by scientists from the pharmaceutical company SmithKline Beecham (now GlaxoSmithKline).[55] At the time, the biobank was seen by the Department of Health as the first step towards a national genetic database, by linking people's DNA samples to electronic medical records.[56] However, in November 2006, concerns about privacy led to a call for a boycott of the new NHS electronic patient records system.[57] Millions of personal medical records loaded onto the new computer database could be accessible by the police and security services as well as NHS staff.[58] The police will also be able to access genetic profiles and DNA samples held by UK Biobank, provided they can get an access order granted by a court.[59] The role of commercial companies in UK Biobank is still unclear, as its policy on access and intellectual property has still not been finalised. However, companies will be allowed to apply to use the data for research and to patent their discoveries, including genes.

Gene tests for sale

The FDA agreed that the tests being offered 'are not grounded in scientific evidence' and 'appear both largely medically unproven and meaningless

In July 2006, the US Federal Trade Commission issued a warning to consumers about purchasing at-home genetic tests.[60] A report published by the US Government Accountability Office (GAO) concluded that genetic tests marketed via four websites (Sciona, Genelex, Market America and Suracell) mislead people by making
predictions that are medically unproven.[61] At Senate hearings on the report the Food and Drug Administration (FDA) agreed that the tests being offered 'are not grounded in scientific evidence' and 'appear both largely medically unproven and meaningless'.[62] The report also highlighted that the first three websites were in fact selling the same genetic tests, developed by Sciona, the former UK company which relocated to the USA in January 2005. Sciona abandoned its attempt to sell genetic tests in the UK, via the Body Shop, in 2001, following criticism from scientists, Which? and GeneWatch UK, but subsequently received venture capital investment from the food industry, which wishes to use the tests to market expensive new 'personalised' diets.[63] After a five year absence, Sciona is again seeking pharmacists to market its genetic tests in Britain.[64]

A new UK company called Genetic Health began marketing via its Harley Street clinic

The UK company G-Nostics continued marketing its NicoTest genetic test, via its website and selected pharmacists, despite being forced to withdraw claims that it included a 'nicotine addiction gene' and significantly improved quit rates.[65] At the end of the year, a new UK company called Genetic Health began marketing via its Harley Street clinic.[66] The company makes the dubious claim that it can 'improve the quality of your life, extend the active period of your life, and most possibly enable you to live longer', based on unregulated and unproven genetic test results.

Genetic discrimination by insurers and employers

The voluntary moratorium on the use of most genetic test results by insurers

continues until 2011; however it remains unclear what will happen after this date. The Association of British Insurers (ABI) wrote to the Department of Health on 15 February 2006 to say it 'will not be submitting any applications to use predictive genetic tests, including for breast cancer during 2006 and 2007'.[67] However, it still plans to develop a methodology that the Genetics and Insurance Committee (GAIC) can use to assess future applications. During the moratorium, the results of GAIC-approved tests can be requested only when someone applies for a high-value insurance policy, but people taking genetic tests now still do not know whether they will affect any insurance they apply for after 2011. Currently only tests for Huntington's Disease (a rare genetic condition) have been approved by GAIC.

Employers in Britain, unlike the USA, do not yet appear to be using genetic tests in the workplace, or as part of pre-employment checks.[68] However, there is still no legislation in place to prevent this happening in future. The Government has made a commitment to consider the issue of legislating against the use of genetic tests in employment and insurance as part of its Discrimination Law Review.[69]

Embryo selection, embryonic stem cells, cloning and chimeras

Pre-implantation genetic diagnosis (PGD) was used for the first time to select an embryo free of an inherited form of eye cancer known as retinoblastoma

In May, the Human Fertilisation and Embryology Authority (HFEA) decided to permit pre-implantation genetic diagnosis (PGD) for the selection of embryos free from mutations associated with inherited predisposition to breast, ovarian and bowel cancers.[70] This decision represented an expansion in the use of PGD, because many people with an inherited mutation in these genes will not develop cancer, or will do so relatively late in life, and better methods of prevention and treatment may be developed in the meantime.

Also in May, pre-implantation genetic diagnosis (PGD) was used for the first time to select an embryo free of an inherited form of eye cancer known as retinoblastoma.[71] Embryos created using in-vitro fertilisation (IVF) were tested for a mutation in the RB1 gene. People with the mutation have about a 90% chance of developing eye cancer, usually during early childhood. The clinic using the test had been licensed by the HFEA, which had also already licensed the use of PGD for other forms of largely inherited childhood cancer.

In December, the Government published a White Paper containing proposals for a new regulatory body, the Regulatory Authority for Tissue and Embryos (RATE) to replace the HFEA and the Human Tissue Authority (HTA).[72] The White Paper also included proposals to:

- set explicit criteria for embryo selection; these will allow the testing of embryos to screen out genetic or chromosomal abnormalities which may lead to serious medical conditions or disabilities or miscarriage, but ban the deliberate selection of an embryo affected by a disease or disorder;
- allow embryos to be selected to provide a tissue match for a brother or sister suffering from a life-threatening illness;
- ban sex selection for non-medical reasons;
- allow the creation of genetically modified human embryos, eggs and sperm for research purposes, but ban their use for reproduction;
- allow research cloning but ban the creation of animal–human hybrids (chimeras).

Cloning people from embryos (reproductive cloning) is banned in the UK. However, cloning experiments on embryos up to 14 days old are allowed and

licences have been granted to Newcastle University (in 2004) and the Roslin Institute in Scotland (in 2005). Despite the discovery in 2005 that claims by South Korean researchers to have cloned stem cell lines from human embryos were false, some researchers continue to hope that it will one day be possible to produce personalised tissues through so-called 'therapeutic cloning'.

A key issue was where the human eggs would come from that are needed to do this type of research

In 2006, a key issue was where the human eggs would come from that are needed to do this type of research, and whether making future medicines from eggs would really be a good idea. Concerns arise because of the large numbers of eggs that would be needed, the dangers to women's health of donating eggs, and the risks to women in poor countries if a trade in eggs develops (already an issue for eggs for IVF).[73] In 2006 the HFEA approved reduced-cost IVF for women willing to donate some of their eggs for research[74] and held a consultation on whether women should be able to donate eggs purely for research.[75]

Researchers from Newcastle University and King's College London asked for a licence to create embryos by fusing human DNA with cow eggs

In November, researchers from Newcastle University and King's College London asked the HFEA for a licence to create embryos by fusing human DNA with cow eggs.[76] The embryos would be used for research and not allowed to develop for more than a few days. The aim would be to carry out research on therapeutic cloning by using eggs from animals instead of women. However, human–animal hybrids, known as chimeras, raise ethical concerns about blurring the distinction between humans and animals. The researchers oppose the ban on creating chimeras proposed in December's White Paper, and the HFEA has now decided to hold a public consultation on the issues before granting any application.[77]

Conclusions

The European Commission is conducting a mid-term review of its "Life Sciences and Biotechnology – A Strategy for Europe" programme.[78] Although the political driver of the review concerns the question of whether enough has been done to promote biotechnology, a realistic assessment of what has been achieved is needed to counterbalance the hype that has always surrounded this technology.

Some 10 years after they were first commercialised, only two traits have been used in GM crops on any scale

The claims for benefits from GM crops and the potential for individualised diets and medicines based on genetic testing continues. However, some 10 years after they were first commercialised, only two traits have been used in GM crops on any scale. This is not the revolution that was promised. No reliable genetic tests for susceptibility to common late-onset diseases have been developed and most adverse drug reactions cannot be predicted from a person's genes. A massive expansion in Britain's DNA Database has not helped to tackle crime.

A massive expansion in Britain's DNA Database has not helped to tackle crime

Even in the drug production sector progress has been slow and, of 48 biopharmaceuticals evaluated between January 1986 and April 2004, none gave a 'major advance' and only 16 gave an 'important' or 'some' advance over pre-existing treatments.[79] Progress has been slow, not revolutionary.

Whilst the benefits of the vast investments in biotechnology compared to other areas of science have been limited, the potential for harm and abuse continues. Contamination by GM crops, threats to privacy, and the potential for genetic discrimination remain.

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