GENETIC TECHNOLOGIES: a review of developments in 2005

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In 2005, the fortunes of GM crops and foods remained stagnant. As in previous years, there has been an increase in the area of GM crops being grown, but largely in Brazil. No new GM traits have come to the market. Major shortcomings in the management of GM crops were exposed when it was revealed that Syngenta had 'muddled up' one variety of GM maize with another, leading to an unapproved GM crop being grown and exported from North America undetected for four years. As companies' efforts to turn crops into drug factories continue, the implications of such failures could be very serious.

In the field of human genetics, much continues to be promised, but little has been delivered. Considerable investment is being made in the search for genes linked to susceptibility to common complex diseases, despite evidence that environmental, social and economic factors are much more important. However, the most dramatic development was in cloned human embryonic stem cells. In May, South Korean researchers had a paper published documenting how they had produced individualised human embryonic stem cell lines, raising hopes of new treatments for degenerative diseases (see GeneWatch Briefing No 32: Human cloning and stem cells). Later it was revealed that women researchers on the team had been paid to donate eggs and, in December, that the lead scientist, Woo-Suk Hwang, had fabricated the evidence, sending shock waves through the stem cell community.

2005 also saw a major expansion in Britain's police DNA database and increasing concerns about the permanent retention of data and DNA samples from innocent people.
This briefing examines the major issues in genetic technologies that emerged in 2005.

GM CROPS AND FOOD

Commercial growing of GM crops in 2005

During 2005, 21 countries grew GM crops commercially on 90 million hectares, an 11% increase on 2004 (see Table 1). The majority of this arises from increased acreage in Brazil. In Europe, Romania, Spain, 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 71%; Bt insect resistance, 18%; and the two traits 'stacked', 11% of the area of GM crops grown. Soybeans (60%), cotton (11%), oilseed rape (4%) and maize (24%) are the only GM crops grown commercially on a large scale.

Experimental GM trials in Europe

During 2005, there were no field trials with GM crops in the UK. Table 2 gives a breakdown of where GM crop trials that were notified to the European Commission in 2005 took place and with which crops. Table 3 gives details of the traits introduced into these crops. Maize is the most commonly modified crop and stacked herbicide tolerance and insect resistance the most common trait. GM maize with tolerance to two herbicides (glyphosate and glufosinate) is now being trialled. Other traits include maize to produce a dog gastric lipase (an enzyme for therapeutic use), maize to produce a human anti-cancer antibody, and potatoes producing a spider silk protein which has great strength.

Table 1: Commercial cultivation of GM crops worldwide in 2005
(in millions of hectares)[1]

COUNTRY	1998	1999	2000	2001	2002	2003	2004	2005
USA	20.5	28.7	30.3	35.7	39.0	42.8	47.6	49.8
Argentina	4.3	6.7	10.0	11.8	13.5	13.9	16.2	17.1
Canada	2.8	4.0	3.0	3.2	3.5	4.4	5.4	5.8
Brazil	0.0	0.0	0.0	0.0	0.0	3.0	5.0	9.4
China	<0.1	0.3	0.5	1.5	2.1	2.8	3.7	3.3
Paraguay	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.8
India	0.0	0.0	0.0	0.0	<0.1	0.1	0.5	1.3
South Africa	<0.1	0.1	0.2	0.3	0.3	0.4	0.5	0.5
Australia	0.1	0.1	0.2	0.2	0.1	0.1	0.2	0.3
Uruguay	0.0	0.0	<0.1	<0.1	<0.1	<0.05	0.3	0.3
Mexico	<0.1	<0.1	<0.1	<0.1	<0.1	<0.05	0.1	0.1
Philippines	0.0	0.0	0.0	0.0	0.0	<0.05	0.1	0.1
Romania	0.0	<0.1	<0.1	<0.1	<0.1	<0.05	0.1	0.1
Spain	<0.1	<0.1	<0.1	<0.1	<0.1	<0.05	0.1	0.1
France	<0.1	<0.1	<0.1	0.0	0.0	0.0	0.0	<0.1
Germany	0.0	<0.1	<0.1	<0.1	<0.1	<0.05	<0.05	<0.1
Columbia	0.0	0.0	0.0	0.0	<0.05	<0.05	<0.05	<0.1
Honduras	0.0	0.0	0.0	0.0	0.0	<0.05	<0.05	<0.1
Iran	0.0	0.0	0.0	0.0	0.0	0.0	0.0	<0.1
Portugal	0.0	<0.1	<0.1	0.0	0.0	0.0	0.0	<0.1
Czech Republic	0.0	0.0	0.0	0.0	0.0	0.0	0.0	<0.05
Bulgaria	0.0	0.0	0.0	0.0	0.0	<0.05	0.0	0.0
Indonesia	0.0	0.0	0.0	0.0	0.0	<0.05	0.0	0.0
Ukraine	0.0	<0.1	0.0	0.0	0.0	0.0	0.0	0.0
Total	27.8	39.9	44.2	52.6	58.7	67.7	81.0	90.0

Table 2: Field trials with GM crops notified in 2005 according to crop and country[2]
(Some of these trials may take place in 2006 and/or continue for several years.)

State	Maize	Potato	Rice	Sugar beet	Cotton	Grape /plum	Apple	Birch	Pea	Total
Czech Republic	1	1								2
Denmark				1						1
Finland								1		1
France	14									14
Germany	2	4							1	7
Hungary	10									10
Netherlands		4					1			5
Poland	2									2
Portugal	4									4
Spain	18	2	1		2	1				24
Sweden		2								2
Total	**51**	**13**	**1**	**1**	**2**	**1**	**1**	**1**	**1**	**72**

TRAIT	Number of trials	Percent
Insect resistance (Bt)	7	9.7
Herbicide tolerance	14	19.4
Herbicide tolerance and insect resistance	29	40.3
Starch modification	7	9.7
Other	15	20.8
Total	72	100

There were also six trials with GM organisms other than plants notified to the European Commission in 2005 (see Table 4).

Table 4: Field trials with GM organisms other than crops notified in 2005[2]
(Some of these trials may take place in 2006 and/or continue for several years.)

State	GM organism	Description of trials
Netherlands	GM rats and mice modified to be more sensitive to air pollutants	Holding GM animals in mobile laboratories to explore the health effects of exposure to air pollution
Netherlands	GM adenoviral vector intended to be used as gene therapy for lipoprotein lipase (LPL) deficiency	A clinical trial with LPL deficient patients
Spain	GM myxoma virus intended as a vaccine against myxomatosis	To determine whether there is any effect on rapacious birds and European lynx associated with ingestion of rabbits inoculated with the GM vaccine strain. Animals will be confined in compounds, not free-ranging
Spain	GM vaccinia virus intended as a dog vaccine	Field trial of a vaccine against canine Leishmaniasis
Sweden	GM vaccinia virus intended as vaccine against HIV	A clinical trial of the HIV vaccine with human volunteers
Sweden	GM bacteria, Pseudomonas fluorescens	To conduct a risk assessment of using non-resident micro-organisms for biocontrol of fungal pathogens in wheat

In Europe, there is continuing confusion and disagreement over the regulation of GM crops and foods

GM regulation and approvals in Europe

The European Commission remains anxious to promote GM crops and, spurred on by the US case against Europe at the World Trade Organisation (WTO), has given approval for the importation of GM crops into Europe under environmental safety rules despite lack of member state agreement (see Table 5). However, the approval of Monsanto's GM insect-resistant maize line, MON863, has been particularly controversial because public access to Monsanto's data from its 90-day rat-feeding trial was denied. It was only made public following a court case brought in Germany by Greenpeace. Evidence of some adverse effects has led to calls for the GM crop to be banned, although these were considered not to be biologically relevant by the European Food Safety Authority.[3] Other approvals for hybrids of MON863 are pending but are likely to be delayed as a result of the controversy.

How individual countries manage GM crops has also remained problematic with the Commission unable to enforce a uniform approach. Since 1998, several EU countries (Austria, France, Germany, Greece and Luxembourg) have had bans on certain GM crops and foods which had been given marketing approvals in Europe before the *ad hoc* moratorium came into place. These bans were part of the US case at the WTO, the outcome of which is expected in February 2006. The European Commission, keen to appease the USA at the WTO, made a proposal to the Council of Ministers that the bans be overturned, arguing that there was no scientific justification for them. However, in June, the Council rejected the proposal and the bans remain in place.[5]

The European Commission made a surprise move, publishing proposals for an allowable accidental GM contamination threshold of 0.9% in organic produce

Courting further controversy in December, the European Commission made a surprise move, publishing proposals for an allowable accidental GM contamination threshold of 0.9% in organic produce.[6] Current European organic regulations do not allow GM to be used in organic production systems and do not state whether there is any allowable level of contamination.

The proposal is likely to prove intensely controversial with organic farmers being placed in a difficult position. If no accidental contamination is allowed, they risk losing their organic status and livelihood if GM crops are grown nearby. Equally, consumers may be angry if they find a product considered completely non-GM to be contaminated up to 0.9% without their knowledge. The lack of Europe-wide coexistence rules and a community mechanism for compensation for economic losses as a result of GM contamination further compromise the organic movement. Currently, each country in the European Union is developing its own rules with varying approaches. The UK Government will be starting a consultation in 2006 on the UK's approach.

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Table 5: GM crop, food and feed approvals in Europe in 2005[4]

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	European Commission approved under Deliberate Release Directive (2001/18) for environmental safety despite lack of member state agreement, 8/8/05. Still requires approval under Food and Feed Regulation, 1829/03
Oil seed rape – herbicide resistant GT73 (Monsanto)	For import and uses in feed and industrial processing, not for cultivation	European Commission approved under Deliberate Release Directive (2001/18) for environmental safety despite lack of member state agreement, 31/8/05. Oil from GT73 oilseed rape has previously been approved for human consumption
Maize line 1507 CRY1F – herbicide and insect resistant (Pioneer/Mycogen)	For import and processing, not for cultivation	European Commission approved under Deliberate Release Directive (2001/18) for environmental safety despite lack of member state agreement, 3/11/05. Still requires approval under Food and Feed Regulation, 1829/03

Final results of the farm-scale evaluations

The final results of the farm-scale evaluations with spring-sown GM herbicide-tolerant oilseed rape were published in March.[7] The results show that broad-leaved weed numbers were reduced whereas grass weeds increased. Numbers of some bees and butterflies were also lower in the GM crop. Because broad-leaved weeds are the most important plants for bird species, if GM herbicide-tolerant spring oilseed rape were grown it would be detrimental to wildlife. The poor control of grass weeds would also pose problems for farmers.

GM contamination

GeneWatch and Greenpeace launched a website which records all the known incidents of GM contamination since GM crops started to be grown on a large scale in 1996

In 2005, GeneWatch and Greenpeace launched a website (www.gmcontaminationregister) which records all the known incidents of GM contamination since GM crops started to be grown on a large scale in 1996:

- when food, feed or a related wild species have 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 GM Contamination Register contains 113 incidents to the end of 2005: 88 cases of contamination, 17 illegal releases and eight reports of negative agricultural side-effects. The data from the GM Contamination Register show that GM contamination can arise at every stage of development – from the laboratory, to the field, to the plate.

In 2005, there were seven cases of contamination, eight illegal releases and three cases of negative agricultural side-effects. The most damaging case of contamination, in 2005, concerned a line of GM maize, Bt10, that does not have regulatory approval anywhere in the world but had been grown accidentally for four years.[8] The Bt10 maize was produced by the agricultural biotechnology company Syngenta, and was 'mistakenly identified' as its approved commercial GM maize line, Bt11, and used in commercial maize breeding lines. This case and its implications are considered in the Box.

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A total of 39 countries on five continents have been affected by an incident of GM contamination, illegal planting or adverse agricultural side-effect since 1996. In 2005, 11 countries and Europe as a whole were affected by a new contamination incident, illegal release or report of a negative agricultural side-effect: USA (two); Australia (four); Brazil (one); Germany (one); New Zealand (one); Japan (one); Romania (three); India (one); Ireland (one); China (one); and Serbia (one).

Over 90% of the 113 incidents were associated with the four major GM crops grown commercially: maize (39, or 35%); soybean (26, or 23%); oilseed rape (20, or 18%); and cotton (10, or 9%). The incidents involving other GM organisms, except for GM papaya which is grown commercially in Hawaii, involved illegal releases (grass, plum, potato and rice) and unintended contamination of GM crops to be used in field trials (sugar beet), or they arose from poor record keeping or 'mistakes' (pig, tomato and zucchini cases). In 2005, GM maize was associated with five incidents; soybean, four; oilseed rape, three; and cotton, plum, potato, zucchini and rice, one each.

Although the majority of contamination cases are not fully investigated, cross-pollination appears to be the major cause in the majority of seed contamination incidents. With food, feed and seed contamination, poor quality control and failure of post-harvest segregation also play an important role.

Seventeen illegal releases included in the register are associated with research and development or black-market growing (in India, Brazil and Romania). Mistakes and errors in handling are one apparently common cause of illegal releases associated with research and development.

Eight reported and verified cases of adverse agricultural side-effects have been reported with GM crops, affecting the USA, Argentina, Canada, India and Australia. These include the emergence of herbicide-tolerant weeds in the USA and Argentina, unreliable performance of Bt cotton in India, and the first field case in Australia of cotton bollworm resistance to a toxin, Cry1Ac, used in GM cotton.

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Syngenta's Bt10 maize contamination incident

'This incident points to fundamental problems with the regulatory framework for agricultural biotechnology in the United States. And the response of the agencies involved gives little confidence that these problems are being seriously addressed.'
Nature, Editorial, 14 April 2005[9]

The mix-up between Bt10 and Bt11 arose because Syngenta's quality control procedures were not sufficiently rigorous and did not differentiate between Bt10 and Bt11

The journal *Nature* first revealed that Syngenta had inadvertently produced and distributed a variety of GM maize, Bt10, which did not have regulatory approval, in March 2005.[8] Between 2001 and 2004, several hundred tonnes of the Bt10 maize were distributed and grown commercially as if it were Bt11 maize in the USA and, to a lesser extent, in Canada. As a result, the maize was exported to other countries. Bt10 maize was also mistakenly used in field trials in Spain, Chile, Canada and Argentina and in a contained growing system (phytotron) in France in 2001. The breach was reported by the company to the US authorities in December 2004, but was not made public until three months later.

The mix-up between Bt10 and Bt11 arose because Syngenta's quality control procedures were not sufficiently rigorous and did not differentiate between Bt10 and Bt11. The company had relied upon field observations and testing for Bt proteins rather than looking at the specific DNA construct inserted.[10] As a result, Bt10 lines were mistakenly used in breeding. The error was detected after four years, when one of the seed companies developing Bt11 varieties, Garst seeds, used more sophisticated DNA-based techniques.

When the mix-up between Bt10 and Bt11 first came to light, Syngenta emphasised the similarity between the two GM maize varieties. Both include insecticidal Cry1Ab toxins as a result of the introduction of a gene from the soil micro-organism *Bacillus thuringiensis* and a gene (the PAT gene) which gives herbicide tolerance to glufosinate, also from a soil micro-organism. The company simply said that the new proteins produced by the maize were the same in Bt10 and Bt11. However, later it emerged that Bt10 also contains a gene that gives resistance to the antibiotic ampicillin.[11]

The Bt10 contamination incident shows that it may prove impossible to prevent a much more serious and possibly life-threatening contamination incident taking place. This is because of the extent and nature of the research that is taking place using GM that may either deliberately (e.g. by engineering food crops to produce drugs) or unintentionally (e.g. by introducing a new allergen) lead to harmful compounds being produced. Because the external appearance of the plant may not give any information about its changed nature, there are no simple safeguards against human error.

The situation is made more complex because of the commercial confidentiality that surrounds GM crops. Therefore, the problems for other countries or third parties wishing to ensure imports are not being contaminated are enormous.

International news in GM crops and foods

Because of the serious social and economic consequences of Terminator technology, there is an ad hoc international moratorium on its development

Terminator technology tries to make a come back

Terminator technology is a name give to a genetic modification which results in the seed of a crop being sterile. It has been developed by the biotechnology industry as a way of preventing seed being kept and resown (see GeneWatch Briefing No 33). Because of the serious social and economic consequences of Terminator technology, especially on farmers who would not be able to follow their current practice of saving seed, there is an *ad hoc* international moratorium on its development under the Convention on Biological Diversity (CBD). However, in February 2005, during a meeting of the CBD, a leaked memo revealed that the Canadian government was seeking to reverse this position.[12, 13, 14]

South Africa

Research conducted by Biowatch in South Africa has shown that GM Bt cotton being grown in the Makhathini Flats, in northern KwaZulu Natal, is not living up to the claims being made for it.[15] The area of Bt cotton has declined by about 80% since it was first grown in 2000/1. Small South African farmers are reported to have acquired massive debts from buying the expensive GM seed together with the impacts or droughts and an international market in cotton which is heavily stacked against them through subsidies paid to farmers in the USA, China and Europe.

GM Bt cotton being grown in the Makhathini Flats, in northern KwaZulu Natal, is not living up to the claims being made for it

The official South African view on GM crops has been generally supportive, with several varieties of GM maize as well as GM cotton being approved. However, in a surprise move, all decisions concerning applications for licences to import GM commodity crops into South Africa have been halted pending a study by the Department of Trade and Industry into their economic consequences.[16]

India

Research published in the journal *Current Science* has confirmed reports from farmers in India that Monsanto's GM Bt cotton does not give reliable protection against the cotton bollworm.[17] The research revealed that the Bt cotton hybrids sold in India show seasonal changes in the amount of the insecticidal protein, Cry 1Ac, produced and also between plants and in different parts of the plant. There is a decline in levels of the toxin over the growing season so there is insufficient to kill the cotton bollworm late in the season and farmers have to spray with insecticides to kill the pests. The research also found that the levels of the toxin were lower in the parts of the cotton that the bollworm feed upon than in leaves, increasing the vulnerability.[18]

Australia

Two important pieces of biosafety research were published from Australia in 2005. First came a report that a strain of the cotton bolloworm, *Helicoverpa armigera*, has developed resistance to one of the Bt toxins (Cry1Ac) used in GM insect-resistant crops.[19] The Cry1Ac toxin gene comes from the soil organism *Bacillus thuringiensis*, and the toxin it codes for kills the cotton bollworm when it feeds on GM cotton containing the gene. The evolution of resistance to the Bt toxin would limit its usefulness for farmers. The scientists isolated the strain of the bollworm, known as the 'silver strain', from fields where the growing of GM cotton was being monitored. In the laboratory, they found the strain was resistant to the Cry1Ac toxin and considered this was due to a newly discovered mechanism that allowed the insects to break down the toxin. Companies are producing new strains of insect-resistant GM crops that contain two Bt toxins to delay the emergence of insect resistance. Bollgard II, a GM cotton grown in Australia since 2003, also contains the Cry2Ab toxin, and the silver strain of the bollworm was still killed by this toxin.

The next piece of research was with peas genetically modified with a gene from a bean which coded for a protein, alpha-amylase inhibitor, that gives protection against insects.[20] Research in mice showed that although the protein isolated from the bean did not cause immune reactions, the version of the protein in the GM peas did cause allergic reactions in the mouse model used. This means that the protein in the GM pea was changed in some way which led to it being reactive. The tests employed are not a part of normal GM food safety evaluation, raising concerns that such possibly harmful modifications may have gone undetected in other GM crops.

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Switzerland

In December, the Swiss voted for a five-year moratorium on the commercial growing of GM crops.[21] There was 55.7% in favour of the moratorium with a majority across all 26 cantons, a situation which was unprecedented.

GM AND CLONED ANIMALS

The increase in use of animals in research is because of the dramatic rise in the use of GM animals

In December, the Home Office published its figures for the use of animals in research in the UK in 2004.[22] The total number of procedures conducted on animals rose by 2.3% to 2.85 million compared to 2003. This is the highest figure since 1992. The increase in use of animals in research is because of the dramatic rise in the use of GM animals. GM animals were used in 32% of procedures (914,000) in 2004, compared to 16% in 1995. The Home Office explains the need for GM animals in research by saying 'Advances in genetics research means that the trend of increased production and use of genetically altered animals has continued. It allows a more precise study of physiological studies and disease mechanisms.'[22]

One of the main approaches is the production of 'knockout mice'. A gene which is thought to play a role in biology or disease is identified and a non-functional copy of the gene engineered into mice at the embryonic stage. The effect on the behaviour of the animal is then followed. Making knockout mice is becoming big business, with many companies, such as the Jackson Laboratory,[23] Deltagen,[24] GeneTargeting Labs,[25] Xenogen[26] and GenOway,[27] offering custom-made knockout mice or mice from existing lines. These knockout mice may be promoted as models of complex disorders in a manner which reinforces a probably false genetically determined view of the illness. For example, a mouse with a gene knocked out that codes for a protein, stathmin, found in certain regions of the brain, was much less fearful than normal mice. It is being proposed as a model for anxiety states in humans even though whether stathmin is important in such human disorders is not known.[28]

In the USA and Japan, interest continues in the production of cloned pigs and cattle to improve agricultural productivity. Researchers in the USA and Japan studied the composition of meat and milk taken from cloned animals and showed there was no difference between clones and non-clones in milk composition.[29] Differences in some meat characteristics (amount of fat and fatty acids) were attributed to their genetic inheritance as they were cloned from a bull with such (desirable) characteristics. The US Food and Drugs Administration is expected to publish guidance soon.[30]

There were 120 failed pregnancies and over 1,000 cloned embryos used to produce Snuppy

With pets, the first cloned dog was produced.[31] Called 'Snuppy' (after the Seoul National University puppy), it came from the South Korean team that has now been discredited over stem cell research (see below). US companies, such as Genetics Savings & Clone and Allerca, continue to push cloned and GM pets.[32] Allerca presents its efforts to genetically modify cats to be non-allergenic as 'developing lifestyle pets' and 'improving the ownership experience'.[33] GS&C will offer dog cloning when it has developed an 'efficient procedure'. There were 120 failed pregnancies and over 1,000 cloned embryos used to produce Snuppy.

HUMAN GENETICS

Stem cell research 'fabricated'

In the first half of 2005, South Korean researchers were being feted for their work in developing embryonic stem cell lines from cloned human embryos tailored to individual patients. Their research, published in the prestigious journal *Science*,[34] was seen as a crucial breakthrough in efforts to grow personalised tissues to treat degenerative diseases. Scientists were 'champing at the bit' to visit and learn from the lead scientist, Huang Woo-Suk.[35] However, first there were revelations that the human eggs used to produce the stem cell lines had to be obtained by paying female researchers, something which contravenes international medical guidelines.[36] Then came accusations that the embryonic stem cell lines were not personalised lines at all, and a University of Seoul investigation confirmed this.[37]

The implications of such a high-profile piece of research being fabricated are enormous. The work has been used to whip up excitement about stem cell research even before it had been repeated. Speaking about the South Korean work in May, George Daley, a stem-cell researcher at Harvard Medical School in Boston, Massachusetts, told the journal *Nature* that 'this is spectacular work. It just moves the field forward so quickly. It really convinces you that this is practical and feasible.'[38]

The atmosphere of hype that pervades science today is partly responsible for creating the scale of the collapse. As Jack Price, a developmental neurobiologist at the Institute of Psychiatry in London, told *Nature* in December: 'I guess we should have been suspicious given the speed with which he overcame problems that were holding back other labs. I guess in the end the pressure to succeed was too great. So much had been invested in him by the state. This is a spectacular collapse.'[39]

DNA databases expanding

DNA databases and biobanks (which link DNA samples with medical and other information) continued to expand in 2005. The UK Home Office published a report detailing the rapid expansion of the National DNA Database (NDNAD), used by the police, between 2000 and 2005.[40] At the end of March 2005, the database held more than 3 million DNA profiles. This is the largest DNA database in the world and 5.2% of the UK population is now on it, compared with 0.5% of the population in the USA.

750,000 juveniles have been added to the database in the last ten years and it now contains over a third of the black male population

Since April 2004, the law in England and Wales has allowed the police to take DNA samples routinely on arrest for all recordable offences (including begging, being drunk and disorderly, or taking part in an illegal demonstration) and to keep data and samples permanently, even if a person is acquitted or never charged. The rapid expansion of the database has resulted from this and earlier changes in the law, and is expected to continue, reaching an estimated 4.2 million by 2008. DNA samples from innocent people are not retained in other countries and this practice is being challenged in the European Court of Human Rights.[41] However, the Scottish Executive held a consultation in 2005 on introducing similar legislation, which if adopted would also allow permanent retention of the DNA profiles and samples of people arrested in Scotland.[42]

The National DNA Database now contains DNA profiles from 140,000 people whose DNA was taken on arrest but who were subsequently not charged. 750,000 juveniles have been added to the database in the last ten years[43] and it now contains over a third of the black male population.[44] Although people's right to removal from the database on acquittal or when charges are dropped has been denied, the Home Office has recently stated that chief constables have the discretion to destroy the data. This resulted in the record of one 14-year-old being removed in early 2006.[45]

A report by the House of Commons Science and Technology Committee in March 2005 highlighted the increasing use of the National DNA Database for research purposes, including by commercial companies.[46] Genetic research has been undertaken without consent and without any ethical oversight – no public information is available on the projects undertaken. At least one controversial research project has attempted to predict ethnicity from DNA profiles on the database. The Committee also expressed concern at the lack of parliamentary debate about 'familial searching' (which seeks to identify individuals via their relatives on the database); the process of seeking 'irrevocable' consent from volunteers included on the database; and the lack of independent oversight.

Genetic research has been undertaken without consent and without any ethical oversight

The Government's 2003 proposal to take a DNA sample from every baby at birth and store the genetic information in its electronic patient record was, however, rejected in March 2005.[47] The Government's advisers, the Human Genetics Commission (HGC), concluded that genetic profiling of every baby, although technically feasible, is unlikely to be publicly affordable within 20 years. The HGC and the National Screening

Committee (NSC) also found that such a programme would not meet health screening criteria; its possible future usefulness for health could not yet be judged; and there are problems with the fact that newborn babies cannot give their consent. Steps would also need to be taken to preclude any future misuse of information (such as genetic discrimination by insurers or employers). The HGC recommended that the proposal be revisited in five years.

Nevertheless, concerns remained that a similar system might be introduced through the back door without adequate justification or safeguards. In autumn 2005, the Medical Research Council consulted on proposals to permanently retain the blood spot cards taken from every newborn baby in the National Health Service (NHS).[48] The blood spots are currently used for a limited number of important medical tests, with the mother's consent, and retained for five years for quality assurance and future test development. The proposals would allow permanent retention of the blood spots from every baby, for future medical (including genetic) research. Although the individual's NHS number would be separated from their blood after five years, appointed staff would be able to link the blood spots back to the NHS number and to medical records. Permanent retention could therefore lead to a genetic database of the whole population in the future.

Plans to recruit half a million adults to the genetic research project UK Biobank progressed only slowly, amid continued scientific controversy about the usefulness of the proposals

Plans to recruit half a million adults (aged 40 to 69) to the genetic research project UK Biobank progressed only slowly, amid continued scientific controversy about the usefulness of the proposals. In May 2005, the Medical Research Council finally published the scientific peer reviewers' comments on the Biobank's original scientific protocol (published in 2002), following a Freedom of Information request from GeneWatch.[49] Many of the reviewers raised concerns about the design and statistical assumptions behind the study; the likely poor quality of much of the data; and the plans for a broad form of consent and access to the data by commercial companies.

The Biobank now plans to publish a new scientific protocol, and to undertake a new scientific review process, following a large-scale pilot project in 2006 (more than three years behind the original schedule). However, the issue of whether the project is a good priority for health has largely been excluded from public consultation and debate.[50, 51] The UK Biobank's Ethics and Governance Council was also appointed in 2005,[52] but many issues within its remit also remain to be resolved. For example, a draft policy on intellectual property and access to the data by researchers from universities and industry was published in January 2005.[53] However, this policy remains controversial because it would allow researchers or their institutions to patent gene sequences that they had linked with diseases using Biobank research.

Patenting and commercial exploitation

A paper published in the journal *Science* in 2005 revealed that nearly 20% of human genes have now been patented, mainly by commercial companies.[54] Gene patents allow companies to claim monopolies on future genetic tests and treatments, and may restrict and distort research.

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An article in the *British Medical Journal* expressed disappointment that only a small proportion of new biotech treatments were truly innovative; they were not always rigorously assessed; side-effects were often no better than ordinary drugs; and they were often more expensive.[55] New clinical trial results for the breast cancer drug Herceptin (trastuzumab), which is suitable only for treating about 25% of cancers that involve a particular genetic change, increased enthusiasm for this genetically targeted approach to treatment, but also highlighted concerns about costs and access to the drug.[56, 57] A report from the Royal Society also warned that it is likely to be at least 15 to 20 years before a patient's genetic make-up is a major factor in determining which drugs they are prescribed (known as 'pharmacogenetics') because so many complex genetic and environmental factors are usually involved.[58]

A drug for heart failure called BiDil became the first drug ever approved in the USA for exclusive use in African-Americans, reigniting a debate about genetics, ethnicity and race.[59] Critics pointed out that BiDil is an example of 'third time lucky', having failed to gain regulatory approval following two previous clinical trials. The original patent expires in 2007, but the company obtained an extra 13 years of market exclusivity by filing a later, racially targeted patent on the drug. The journal *Nature Biotechnology* pointed out that skin colour is unlikely to determine drug response, and suggested that a more likely reason for its increased effectiveness in black people was that the black population studied is more prone to die of heart disease at a younger age: probably due to a combination of factors, including social and economic ones.[60]

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Continued lack of regulation

In March 2005, the Government published a new agreement with the insurance industry (the 'Concordat') on genetic testing.[61] The agreement includes a five-year extension of the existing voluntary moratorium on insurers' use of predictive genetic test results, until 1 November 2011. However, the moratorium remains partial, temporary and not legally binding.[62] The Concordat also accepts that insurers will have the right to use genetic test results in underwriting decisions in the future, provided the use of each test is approved by the Genetics and Insurance Committee (GAIC).

The insurance industry is preparing an application to GAIC to seek access to the results of tests for mutations in the BRCA genes, which indicate a high risk of a largely inherited form of breast cancer, and an increased risk of ovarian cancer, in some women with a strong family history of these cancers. If approved, test results would initially be used only when an individual applies for a high-value insurance policy (for example, over £500,000 of life insurance). However, once the moratorium has ended, the industry could seek GAIC-approved genetic test results for any value policy.

Research by the charity Breakthrough Breast Cancer, published in September 2005, found that many women with a family history of breast cancer might not take the BRCA genetic tests if they had to reveal the results to insurers, and that most women disagree with the use of genetic test results to set insurance premiums.[63]

There is also still no legislation in the UK to prevent employers using genetic test results to decide who gets a pension or a job. The health claims made for genetic tests remain unregulated; however, the Human Genetics Commission has re-established its Genetic Services subgroup[64] and is committed to a meeting to discuss direct-to-consumer genetic tests in 2006.

There is still no legislation in the UK to prevent employers using genetic test results to decide who gets a pension or a job

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