

GENETIC TECHNOLOGIES: A Review of Developments in 2002



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During 2002, the UK Government announced that there would be a public debate to inform the decision on whether genetically modified (GM) crops should be grown commercially in the UK. However, there was no clear indication of how the Government would respond to outcomes of the debate, which has been inadequately funded. Questions therefore remain about the UK's position on GM crops and the extent to which the Government takes public concerns seriously. Lobbying by the Food Standards Agency (FSA) against European plans for comprehensive GM food labelling further undermined confidence in the impartiality of the Government during 2002. Added to this were several contamination incidents, creating anxiety about whether non-GM and organic farming systems could co-exist alongside GM farming.

In the human genetics field, the year ended with unconfirmed claims by the Raelian sect to have cloned a human baby. During the year, the direct over-the-counter selling of genetic tests began and plans to develop a UK population genetic 'biobank' gathered momentum. There was no equal momentum behind safeguards to protect people against the abuse of genetic information or to ban human cloning. As with GM foods, the interests of the biotechnology and pharmaceutical industries are being given disturbing priority.

This briefing reviews the major developments in the science, regulation and politics of genetic technologies in 2002 and considers their implications.

GM Crops and Foods

Commercial Growing of GM Crops in 2002

In 2002, four countries accounted for 99% of the GM crops grown commercially - the USA

(66%), Argentina (23%), Canada (6%), and China (4%) (see Table 1)¹. The dominant traits continued to be herbicide tolerance (75%), insect resistance (17%) and both traits (8%) in four major crops – soybean (62%), maize (21%), cotton (12%) and oilseed rape (5%) (see Table 2). India was the only new country to start growing GM crops (*Bt* cotton), although Columbia and Honduras are said to be in 'pre-commercial' production of *Bt* cotton and maize respectively.

As in 2001, there is no evidence of new GM traits on the market. Research and development is stagnant, due partly to the contraction of the industry and partly the difficulties of achieving complex changes. The commercial strategy is to extend cultivation into developing countries and to increase the number of varieties of GM herbicide tolerant and insect resistant crops.

Table 1: Commercial cultivation of GM crops worldwide (in million of hectares)¹

n.a. = cultivation areas not available at time of publication.

COUNTRY	1998	1999	2000	2001	2002
USA	20.5	28.7	30.3	35.7	39.0
Argentina	4.3	6.7	10.0	11.8	13.5
Canada	2.8	4.0	3.0	3.2	3.5
China	<0.1	0.3	0.5	1.5	2.1
Australia	0.1	0.1	0.15	0.21	n.a.
South Africa	<0.1	0.1	0.2	0.27	n.a.
Mexico	<0.1	<0.1	<0.1	<0.1	n.a.
Spain	<0.1	<0.1	<0.1	<0.1	n.a.
France	<0.1	<0.1	<0.1	0.0	n.a.
Germany	0.0	<0.1	<0.1	>0.1	n.a.
India	0.0	0.0	0.0	>0.1	n.a.
Portugal	0.0	<0.1	<0.1	0.0	n.a.
Rumania	0.0	<0.1	<0.1	>0.1	n.a.
Bulgaria	0.0	0.0	<0.1	>0.1	n.a.
Uruguay	0.0	0.0	<0.1	>0.1	n.a.
Ukraine	0.0	<0.1	0.0	0.0	n.a.
TOTALS	27.8	39.9	44.2	52.6	58.7

Table 2: Commercial cultivation of GM crops worldwide in 2002 by trait (% of total GM crops grown)¹

	HERBICIDE TOLERANT	Bt INSECT RESISTANT	BOTH TRAITS	Total % by Crop
Soybean	62%			62%
Oilseed Rape	5%			5%
Maize	4%	12%	5%	21%
Cotton	5%	5%	3%	12%
Total % of GM Crops by Trait	75% (44.2 million hectares)	17% (10.1 million hectares)	8% (4.4 million hectares)	

Regulations in Europe

Environmental safety - The Deliberate Release Directive (2001/18/EC) was implemented in Europe on October 17th 2002. This has brought improvements to the environmental safety assessments, which now include the evaluation of indirect as well as direct effects, monitoring requirements, and time-limiting consents to 10 years. More negatively, the Directive still allows the use of some antibiotic marker genes, has no provision for socio-economic impacts to be considered and no provision for liability. However, the *de facto* moratorium on marketing consents for GMOs remained in place as several member states wish to see agreement on labelling and traceability before allowing marketing consents for new GM crops in Europe. Meanwhile, the US continued to threaten action at the World Trade Organisation (WTO), arguing that proposals for labelling and traceability were not scientifically justifiable and that they discriminated against US products. Whether the US will follow the threat through is unclear, but action at the WTO would most likely harden public attitudes against GM foods across Europe.

Labelling and traceability – Two regulations were discussed in Europe which would considerably improve labelling to include GM derivatives and introduce traceability (important both for choice and to allow product removal if problems arise). Controversy exists on the level of adventitious contamination that should be allowed without labelling. Environment and Agriculture Ministers have proposed 0.9% - higher than the 0.5% suggested by the European Parliament and fractionally lower than the Commission's 1%. The UK continues to oppose extension of labelling to derivatives on the FSA's advice, who say the system would be subject to fraud. This is counter to moves in all other areas of food production where traceability has become a cornerstone of policy for safety and choice. However, the UK is very isolated in Europe. Final agreement should be reached in the Spring of 2003.

Seeds - The GM seeds regulation is currently stalled in the expert committee considering the issue. The intention was to set standards for seed purity in relation to GM contamination but the levels proposed have been very contentious. Some have argued that a low percentage of GM contamination in seed should be acceptable (0.3% has been proposed for oilseed rape). Even at this level, however, the large numbers of plants involved and the fact that they will multiply would lead to an increasing degree of contamination. English Nature are arguing that levels of contamination must be zero or a build-up of herbicide tolerant weeds will arise and environmental protection will suffer².

Liability – There is a proposal for a European Directive on environmental liability to determine who should be responsible for any damage caused by

The UK continues to oppose extension of labelling to derivatives

growing GM crops and to repair any damage (when possible). This includes GMOs but is restricted in its scope to effects on specified species and habitats and thereby excludes most of the UK's agricultural land. It is in the early stages of negotiation and is unlikely to be agreed quickly. Currently, complying with regulations is a defence against being held liable for harm, so unforeseen impacts are not covered – the cause of most public concern. There is also no legislation relating to economic liability to protect farmers whose crops are contaminated by GM and so lose their market.

Environmental Impacts – Scientific Research

Gene flow to non-GM crops and weeds. There have been several recent papers which consider gene flow, data from which are crucial for informing decisions on co-existence between GM and non-GM crops and what separation distances are required. These studies have tended to show that pollen can travel further than previously predicted and is strongly influenced by landscape, insect movement and local environmental conditions. In Australia, non-GM herbicide tolerant oilseed rape, which was grown commercially for the first time in 2000, was found to cross-pollinate oilseed rape up to 3km from the source fields³. The levels of contamination were low (up to 0.07%) but levels did not decline with distance as predicted by small-scale experimental trials. Studies in Canada show similar results, with levels of 0.07% cross-pollination at 800 metres from GM oilseed rape⁴. Similarly, French researchers have shown that the likelihood of gene flow between GM beet and weed beet has been underestimated in the past⁵.

Research in the US has shown that genes passed from crops to related weeds can persist for generations and become permanent, possibly leading to the evolution of problem weed populations⁶. Other research from the same group has shown that weeds can become stronger and fitter through the acquisition of genes from GM crops. Wild sunflowers that acquired insect resistance genes from GM sunflowers became hardier and produced up to 50% more seed⁷.

A review of gene flow studies, published by the European Environment Agency⁸, concluded that the frequency of gene flow from:

- oilseed rape to other oilseed rape and wild relatives is *high*;
- sugar beet and fruits such as apples, strawberries, blackberries, etc. is *medium to high*;
- potatoes, wheat and barley is *low*;
- maize carries a medium to *high* frequency of gene flow to non-GM maize *but there are no wild relatives* with which it could cross in Europe.

Data are still being gathered about gene flow and many assumptions are being overturned, particularly as experimental trials are a poor predictor of gene flow when GM crops are grown commercially. Current UK separation distances from non-GM crops will need to be reviewed in the light of this new knowledge. A UK report, only published on Christmas Eve, underlined this for oilseed rape – levels of over 0.5% contamination were detected at 200 metres in one farm-scale evaluation⁹. Again, small-scale trials were shown to be poor predictors of larger-scale releases and gene flow from GM oilseed rape to wild turnip, a species related to oilseed rape, was detected in trial fields for the first time in the UK.

Unexpected effects. One concern about GM crops is that the GM process could result in unintended impacts as other genes and biochemical pathways in the plant may be affected. One example of this has been seen in GM

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potatoes which were genetically modified to contain a lectin gene to make them insect resistant (in the same way as the infamous GM potatoes at the centre of the Pusztai controversy – see GeneWatch Briefing No 9). There was an unexpected drop in levels of chemicals, known as glycoalkaloids, normally found in potatoes and which act as natural insecticides^{10,11}. This was unexpected and attributed to the GM process and could have had implications for vulnerability to other insect pests. The potential for unintended effects and unforeseen impacts tends to be downplayed, but these findings are an important reminder that the introduction of one gene does not always only have one effect.

About 75% of Canadian oilseed rape is currently herbicide tolerant and weed oilseed rape that is resistant to up to three herbicides is becoming commonplace

Chemical use on GM crops. The US Department of Agriculture (USDA) has reported on the use of GM crops in the USA and the associated changes in chemical applications¹². Their studies show an overall decline in the frequency of application of herbicide and insecticide for Bt cotton, and herbicide for herbicide tolerant soybeans, cotton and maize. However, the overall weight of herbicide used on soybeans increased and 13.4 million pounds of Roundup (glyphosate) substituted for 11.1 million pounds of other synthetic herbicides.

There is an argument that herbicides like *Roundup* are more benign than other weedkillers and should therefore be welcomed. It is not clear, however, whether this is true for the UK where the more efficient removal of weeds could lead to further declines in wildlife populations (c.f. the USA where nature conservation focuses on wilderness preservation). Furthermore, other studies are suggesting that the move to supposedly environmentally ‘safer’ chemicals may be short-lived. A report by English Nature¹³ revealed the widespread emergence of ‘volunteer’ oilseed rape plants which were resistant to several herbicides following the growing of GM herbicide tolerant oilseed rape in the Canadian prairies. The problem has arisen because some seed is shed at harvest time, remains in the ground, and germinates in future years. When the plants emerge in subsequent crops of a different species, they are then unwanted weeds (‘volunteers’) which have to be removed by the farmer. About 75% of Canadian oilseed rape is currently herbicide tolerant and weed oilseed rape that is resistant to up to three herbicides is becoming commonplace. This resistance to more than one herbicide is known as ‘gene stacking’ and arises through pollination of one herbicide tolerant variety by another.

The emergence of these weeds is causing an increase in the use of other, more toxic chemicals. Both 2,4-D and paraquat (grammoxone) are being recommended by government agencies to control herbicide tolerant oilseed rape volunteers in Canada. English Nature consider that if herbicide tolerance gene stacking arose in the UK, more paraquat and diquat may be used, which could harm an already threatened species, the hare, which is extremely sensitive to their toxic effects.

The use of herbicide tolerant maize in the US is not giving the weed control advantages that had been anticipated

It has also been revealed by the BBC’s *Newsnight* programme¹⁴ that the use of herbicide tolerant maize in the US is not giving the weed control advantages that had been anticipated. As a result, the herbicide to which some maize is made tolerant - *Liberty* (glufosinate) - is now being sold in a package with the persistent chemical, atrazine. This is particularly relevant to the UK because the GM maize in the farm-scale trials is tolerant to *Liberty* and so questions are being raised about the relevance of the trials to how the crop is likely to be managed in practice.

Only *Bt* cotton gives a clear reduction in the massive use of insecticides on conventionally grown cotton, which accounts for 20% of all insecticide used globally. However, a GeneWatch report for Pesticide Action Network has shown that the reductions may be short-lived as pests not killed by *Bt* are on

the increase and farmers are not following the management plans needed to avoid resistance emerging¹⁵.

Overall, these results give a complex picture. The only crop where there have been clear declines in chemical use is *Bt* cotton, but questions remain about how long such advantages will be maintained. The picture is more mixed in relation to herbicide tolerance, and it is herbicide tolerant GM crops which would be grown first in Britain (insects are not an agronomic problem here). Even if the herbicides used are more 'environmentally friendly', any such benefits may be short-lived and farmers could revert to old-fashioned, toxic chemicals. To avoid the problem of herbicide tolerant gene stacking, the Government should give a clear signal that only one herbicide tolerant variety of a crop will be approved (whether produced by GM or conventional means).

Contamination Incidents

Cases where non-GM or organic crops are found to contain genes from GM crops continue to be reported. The most controversial case has been in Mexico. A paper published in *Nature* in 2001 reported GM contamination in native landraces of maize even though no GM maize should have been grown there commercially¹⁶. The findings of the study came under considerable attack (orchestrated, it seems, by the biotechnology industry) and, in 2002, the journal published some critical reviews and indicated that it should not have published the original paper^{17,18}. However, it is not the basic finding of contamination that is contested but a claim that foreign genes spread in the genome of the maize. What is disturbing is that maize originated in South America, so it is a centre of diversity, and GM maize was not authorised to be grown there. It seems that farmers may have kept and sown maize imported for food (possibly as aid). This exposes the consequences of the loophole in the Biosafety Protocol (negotiated in the interests of the USA and other commodity crop exporting countries) where GMOs intended only for food and feed use – not for growing – are not required to have advance informed consent.

One of the most embarrassing contamination incidents was the revelation in August 2002 that GM oilseed rape grown in the UK's farm-scale evaluations was contaminated with another GM variety which had not been approved for growing¹⁹. Rather than enforce the law, the Government asked for a *post hoc* evaluation by the Advisory Committee on Releases to the Environment (ACRE), who concluded that there was no environmental risk and no consequences for the trials themselves.

In a contamination incident which did not involve cross-pollination on November 12th 2002 in the USA, the Department of Agriculture (USDA) announced that it had quarantined over \$2.7 million worth of soybeans (500,000 bushels) destined for human consumption at a Nebraska grain elevator after finding stalks of ProdiGene's GM maize mixed with the soybeans²⁰. They later ordered their destruction. The field where the soybeans were grown had been used previously by ProdiGene to grow GM maize which contained genes to produce an experimental vaccine against a pig disease, transmissible gastroenteritis virus (TGEV). The US Food and Drug Administration has fined Prodigene £2 million²¹.

Two days later, on 14th November, the Soil Association revealed that organic soybeans intended for animal feed had been found to be contaminated with GM soybeans. The Soil Association is now calling for the biotechnology industry to pay for testing to detect contamination so the costs are not passed on to organic farmers²².

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These reports suggest that contamination incidents are becoming more frequent and underline the need for high quality traceability systems for GM crops and foods. These should be statutory in nature with proper policing if they are to be effective. Unless the costs of traceability systems are to be passed onto the consumers of non-GM and organic food, there is a good argument that the biotechnology industry should be required to pay, perhaps through some kind of levy system.

Co-existence of GM with Non-GM and Organic Farming

The contamination incidents, general pressure for non-GM food streams to be preserved, and controversy about the impacts of GM on organic farmers have led to co-existence becoming a key issue in 2002. There have been two important reports in recent months. In May 2002, the European Commission's Joint Research Centre published a report examining co-existence scenarios between GM, conventional and organic crops in Europe²³. Using scenarios where 10% or 50% of the area of a crop grown is GM, the report concluded that low levels of contamination (<0.1%) would be very difficult, even impossible, to achieve for most GM crops. The costs of any systems to prevent contamination were predicted to fall mostly on the organic sector. This raised important questions for the commercialisation decision in the UK. Is it possible to commercialise GM crops and maintain a non-GM market?

In September 2002, the Soil Association published a report on the situation in North America and the problems that organic farmers were experiencing as a result of contamination²⁴. Organic standards do not allow the use of GM products or processes, and because of high levels of GM contamination it is no longer possible to produce organic oilseed rape in Canada. There are many court cases being brought by organic farmers against the biotechnology industry because their ability to sell products as organic is being harmed.

Food Safety

In November, the British Medical Association made a submission to the Scottish Parliament's Health and Community Care Committee, which is investigating the safety of field trials in Scotland²⁵. They recommended that field trials be suspended because of uncertainties over the safety of GM foods and the lack of adequate monitoring of the impact of trials on the health of local communities.

The BMA recommended that Scottish GM field trials be suspended because of uncertainties over safety

GM Crops and the Developing World

Commercial growing of GM crops - particularly insect resistant *Bt* cotton - is increasing rapidly in parts of the developing world. Monsanto's GM *Bt* cotton is now grown commercially in both South Africa and India. In South Africa, the GM seed is sold under a loan system²⁶ in the same way that chemical pesticides are, raising the potential for debt and excluding poor farmers. In India, experiences have been mixed during the first year of commercial growing. Whilst some farmers have had good experiences with improved yields, there have been losses in other areas as GM varieties appear to have been more susceptible to some viral diseases, particularly in drought situations. It is eerily reminiscent of the industry's reaction to agrochemical poisonings that they are blaming farmers, their lack of knowledge and failure to follow the 'rules'²⁷. At the end of the Earth Summit in South Africa, Monsanto announced its plans to extend its GM cotton sales into Uganda and then Kenya²⁸. Columbia is also said to be undertaking 'pre-commercial' production of *Bt* cotton²⁹.

The argument over the potential for GM food to 'feed the world' has reached a peak recently with the importation of GM maize as food aid into drought-hit Africa. Zambia has been insistent that it does not want GM food aid because of concerns about safety, contamination and effects on trade in the longer term. Greenpeace has produced the most detailed critique on this subject³⁰ and revealed the US Agency for International Development's policy to "*integrate GM into local food systems*" and "*spread agricultural biotechnology through regions of Africa*".

Human Genetics

"I made a million dollars the hard way. I started with a billion dollars and worked my way down." Craig Venter, founder of Celera Genomics³¹.

In 2002, the biotech bubble began to burst, with investors beginning to make a much more realistic assessment of the prospects of a 'genetic revolution' in healthcare. Companies feeling the pinch included PPL Therapeutics³² producers of Dolly the cloned sheep - and Corixa³³, one of the US companies exposed by GeneWatch and the Guardian in 2001 as having sold exclusive licences for its future biotech lung cancer vaccines to a tobacco company.

Far from speeding up the process of drug discovery, the sequencing of the human genome appeared to have actually slowed it down, as industry wrestled with how to use the information³⁴. One paper has argued that the failure to innovate is partly because companies' high-throughput screening and genomics programmes "*seem to have lost all sense of biology and the complexity of living things*"³⁵. Others warned of increasing medicalisation as global pharmaceutical companies seek to expand their markets for existing medicines³⁶, including the prospect that "*Genetics could drive a new wave of medicalisation if genetic tests are accepted without appropriate clinical evaluation*"³⁷.

Gene therapy experienced a major setback as two children in France - thought to have been treated successfully for the rare immune disorder X-SCID - developed leukaemia as a result of the treatment³⁸.

The world's best-selling biotech drug, EPO - a protein used to stimulate red blood cell production in kidney patients - also came under scrutiny when a version of the drug manufactured by Johnson & Johnson triggered a dangerous immune response in some patients. The adverse reaction, in which the body started to attack its own red blood cells, "*raised doubts about not just the company but about a whole class of drugs that are a cornerstone of biotechnology*", according to the New York Times^{39,40}.

Human Genetic Testing

The US genetic testing company, Myriad Genetics, which owns patents on the BRCA1 and BRCA2 genes that have been associated with an increased risk of breast cancer, is seeking to monopolise genetic testing for mutations in these genes. The company is advertising these tests to the general public in the USA (see Myriad's website⁴⁶) but the advertisements fail to inform women that the tests have a relatively poor predictive value in women who do not have a strong family history of breast cancer. They also encourage women to visit their doctors for a test by stating that there are "*effective medical options*" to reduce breast cancer risk without explaining that the options are either surgical removal of both breasts or taking the cancer drug tamoxifen, which has serious side-effects. The San Francisco group, Breast Cancer Action, declared they

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were “*outraged*” about the potential for generating fear and unnecessary surgery, and some scientists warned that the risk of breast cancer for women with these genes has been exaggerated^{47,48}. There is nothing to prevent Myriad from advertising their genetic tests in Britain once the Government has reached an agreement with them regarding the costs of providing the tests within the NHS.

The first unregulated human genetic tests appeared in High Street stores in Britain in 2002, following a deal between UK company Sciona and The Body Shop. Sciona gives dietary advice which is supposedly tailored to an individual's genetic test results despite a lack of evidence to back their claims. The tests were criticised by leading scientists as meaningless and unethical⁴⁹ and have now been withdrawn from sale on the Internet and in the High Street⁵⁰. Following a campaign by GeneWatch and the Consumers' Association, most High Street retailers stated that they would not sell the tests^{51,52}, although Sciona is still trying to market them via ‘healthcare professionals’.

The US company Great Smokies Diagnostics Laboratory (GSDL) is now also marketing genetic tests in the UK. The tests, called ‘Genovations’ make dubious claims to predict people's genetic risk of heart disease, asthma, osteoporosis, and some cancers^{53,54}. In the UK, they are being marketed by a company called Health Interlink, mainly through alternative healthcare practitioners. They include recommendations for supplements and medicines to ‘treat’ common genetic variations. Future tests are planned, including predictions of susceptibility to mental illness and obesity.

The Government's advisors, the Human Genetics Commission, whilst expressing concerns about Sciona's tests, have so far failed to act to stop their sale or that of the Genovations tests. Following a consultation, their preliminary view was to favour industry ‘self-regulation’ of genetic testing⁵⁵. But public concern about the issue now looks likely to lead to a welcome recommendation that the new Medicines and Healthcare Products Regulatory Agency makes an independent assessment of companies' marketing claims and requires most tests to be sold only through doctors. A key issue in 2003 will be whether ministers accept this recommendation and how it is then implemented. A genetic privacy law and legislation to prevent genetic discrimination are also critical.

No action has been taken to legislate to prevent genetic discrimination by insurers or employers

The voluntary moratorium preventing the use of most genetic test results by the insurance industry remains in place but no action has been taken to legislate to prevent genetic discrimination by insurers or employers. The Government has also still not signed the European Convention on Human Rights and Biomedicine, which prohibits genetic discrimination.

Sex Selection, Cloning and ‘Designer Babies’

Sex selection of babies via a new ‘sperm sorting’ technique is being sold by The Genetics & IVF Institute in the USA. They claim to have ‘produced’ around 300 babies so far. About 15% of parents using the Institute to date have reportedly been trying to avoid the birth of a child with a serious sex-linked disease, but the majority wanted to select a gender for ‘family balancing’ reasons⁵⁶.

The prospect that the company might begin selling sperm sorting in Britain prompted a consultation by the Human Fertilisation and Embryology Authority. Companies involved in selling sex selection technologies are actively seeking to expand their markets. If sex selection remains unregulated, or is regulated purely on the basis of ‘individual choice’, it will not be possible to prevent or

address the serious social implications – including the possibility of a growing gender bias in certain sectors of society (towards boys or girls). Allowing widespread sex selection would also establish a new precedent that parents should be allowed to select the genetic make-up of a child, even for trivial or non-medical reasons, increasing the likelihood of pre-natal genetic testing being used increasingly in future as a way to select a ‘perfect child’.

Claims by the Italian fertility specialist, Severino Antinori, and by Clonaid (a company with links to the Rael religious sect) to be cloning human babies caused widespread concern. Although the claims of success are probably untrue, any attempt to clone a human baby would cause significant suffering to mother and child as well as raising wider ethical concerns. Many failed attempts are likely to involve serious birth deformities and spontaneous abortions. Even if an apparently healthy baby is born, there are questions over whether he/she would age normally.

Many failed attempts at cloning are likely to involve serious birth deformities and spontaneous abortions

Gene Patenting

“There should be no patenting of gene sequences, period. They were invented by nature.” US biotech company Affymetrix, March 2002⁴¹.

This statement was just one sign that parts of the biotech industry itself are starting to question the wisdom of patenting gene sequences, influenced by the costs of legal challenges and by concerns about the negative impacts on research and development⁴². Even Craig Venter, the founder of Celera Genomics who led the commercial attempt to sequence the human genome, recognised that with most gene patents “...only the patent lawyers got rich”⁴³.

Two influential reports on patenting were also published in the UK in 2002. The Nuffield Council on Bioethics questioned whether patents on gene sequences were stifling, rather than stimulating, innovation⁴⁴. The UK Commission on Intellectual Property Rights (CIPR) concluded that the patenting system may sometimes be detrimental to developing countries and stated that: *“Developing countries may not be sharing appropriately in the benefits from commercialisation of their knowledge or genetic resources when they are patented in developed countries”*⁴⁵.

Unfortunately, the UK Government, backed by its research councils such as the Medical Research Council, continues to regard gene patenting as an essential part of supporting the UK biotech industry. The UK is one of only five Member States of the European Union which had implemented EC Directive 98/44/EC by mid-2002, which allows the patenting of DNA, including the patenting of human DNA sequences without the individual’s knowledge.

The UK Biobank

In April 2002, funding was announced for the UK Biobank genetic research project. In addition to £5 million from the Department of Health, The Medical Research Council (MRC) and the Wellcome Trust are contributing £20 million each. The project aims to identify the links between genetic and environmental factors in common diseases such as heart disease and cancer by studying DNA samples taken from 500,000 participants between the ages of 45 and 69, linked with their lifestyle and medical data⁵⁷. However, the Biobank’s aims are controversial, its science is questionable, and there is a lack of legal safeguards to prevent misuse of genetic information.

The main aim of the project is to be able to identify individuals who are ‘genetically susceptible’ to common diseases so that medication or advice on lifestyle changes can be targeted at them. However, many scientists have argued that this approach is unlikely to contribute significantly to reducing the

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GeneWatch believes that legal safeguards need to be in place before volunteers are asked to donate their samples to the UK Biobank

incidence of these diseases and may even be damaging to health^{58,59}. Underlying these concerns are serious question-marks about the scientific validity of the Biobank, including the danger of identifying spurious links between genetic and environmental factors and diseases^{60,61}.

There are also concerns about confidentiality – particularly potential access to the data by the police – and the need to control commercial conflicts of interest and patent claims⁶². The head of the MRC recently confirmed to the House of Commons Science and Technology Committee that companies would be allowed to patent gene sequences identified using the Biobank.

GeneWatch believes that legal safeguards need to be in place before volunteers are asked to donate their samples to the UK Biobank. This is particularly important because the Biobank is seen as a pilot study for a national genetic database, potentially including all NHS patients⁶³. There is also a need for an independent scientific peer review of the proposals⁶⁴ (in which the peer reviewers are not selected by the funders); an independent assessment of its likely value for money; and a House of Commons debate of all the issues.

Genetics and World Health

“...it is vital that the more conventional approaches of epidemiology and public health, particularly as they relate to tobacco-induced diseases and other aspects of lifestyle, continue to be pursued with vigour. This is particularly important as there are still major uncertainties about the predictive role and cost of genomics for controlling common diseases.”
World Health Organisation, 2002⁶⁵.

The impacts of genetics on global health continued to be debated and the World Health Organisation published its report on “Genomics and World Health”. GeneWatch argued that genetic ‘prediction and prevention’ would not address the growing epidemic of cancer and heart disease in low- and middle-income countries, and that tackling poverty, infections, smoking, poor diets, lack of exercise and pollution remain key to improving health worldwide⁶⁶. The growing incidence of obesity is caused by an increase in unhealthy diets and Western lifestyles, not by an increase in ‘genes for obesity’, and developing countries are increasingly being targeted as a growth market by tobacco companies.

Conclusions

Public concerns about genetic technologies will be high on the political agenda in Britain in 2003. Two key Government decisions will be taken. Will GM crops be grown commercially in the UK and, if so, under what conditions? Will human genetic tests be regulated and, if so, what controls will be put in place? The impacts of genetic technologies on human health, human rights and the environment must be central to these decisions.

Technological developments continue to run ahead of public safeguards and there is a real danger that the potential health benefits of some human genetic technologies will be lost if research and development are driven purely by commercial interests without adequate controls.

The promotion of GM crops as a solution to world hunger and of genetic ‘prediction and prevention’ as a solution to the growing global epidemic of cancer and heart disease could exacerbate existing inequalities and lead to a failure to tackle the socio-economic factors underlying global hunger and disease.

Potential health benefits of some human genetic technologies could be lost if research and development are driven purely by commercial interests without adequate controls

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GM Public Debate

The Government has announced that it will ask the public for its views before making a decision on whether to allow GM crops to be grown commercially in the UK.

For details, see www.genewatch.org and the official Government site at www.gmpublicdebate.org.

GeneWatch



The Mill House, Manchester Road, Tideswell, Buxton, Derbyshire, SK17 8LN, UK
Phone: 01298 871898 Fax: 01298 872531 E-mail: mail@genewatch.org

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