

# GENETIC TECHNOLOGIES:

## A Review of Developments in 2003



Briefing Number 26  
February 2004

### Genetic Technologies: a review of developments

During 2003, there has been public debates on GM crops and foods, Government-sponsored reports on the economics and science, and recommendations on how the coexistence of GM and non-GM crops and liability for harm should be managed. The farm-scale evaluations were published and the potential for harm to farmland wildlife caused by using herbicide-tolerant (HT) GM crops was identified. In the light of these developments, the Government has promised to make an announcement on its GM policy early in 2004. Increasing the stakes, the USA has taken action against Europe at the World Trade Organisation because it has failed to approve any new GM crops and foods since 1998.

In the human genetics field, UK Biobank has appointed its staff and is expected to start taking samples of people's genetic material in 2004, despite a continuing lack of safeguards from genetic discrimination and serious questions about the quality of the science. The Government is also considering taking samples of genetic material from all babies at birth. International efforts to ban human cloning have stalled over disputes about whether cloning cells to make tissues should be allowed. Human genetic tests remained unregulated, but the Human Fertilisation and Embryology Authority moved to prevent widespread sex selection of future babies.

In this briefing we review all these developments and set the scene for 2004, when crucial decisions will be made that will shape how wisely we use genetics in the future.

### GM Crops and Foods

#### Commercial growing of GM crops in 2002

During 2003, eighteen countries grew GM crops commercially on 68 million ha, a 15 per cent increase on 2002 (see Table 1). Most of this increase arises from an additional 3.8 million ha of GM crops grown in the USA, and the growing of GM soybean in Brazil for the first time on an

estimated 3 million ha. The USA, Argentina, Canada and China continue to be the major growers with Brazil joining their ranks. The Philippines also grew GM crops for the first time in 2003.

Once again, the only GM traits in commercial use (except for some GM disease resistant papaya in Hawaii) are herbicide tolerance and insect resistance using *Bt* genes. There remains little evidence of innovation or success in developing new traits. In the UK, very few field trials were conducted other than those associated with the farm-scale evaluation, underlining the very difficult position of the industry.

**Table 1: Commercial cultivation of GM crops worldwide in 2003 (in millions of ha)<sup>1</sup>**

COUNTRY	1998	1999	2000	2001	2002	2003
USA	20.5	28.7	30.3	35.7	39.0	42.8
Argentina	4.3	6.7	10.0	11.8	13.5	13.9
Canada	2.8	4.0	3.0	3.2	3.5	4.4
Brazil	0.0	0.0	0.0	0.0	0.0	3.0*
China	<0.1	0.3	0.50	1.5	2.1	2.8
Australia	0.1	0.1	0.15	0.21	0.1	0.1
South Africa	<0.1	0.1	0.20	0.27	0.3	0.4
Mexico	<0.1	<0.1	<0.1	<0.1	<0.1	<0.05
Spain	<0.1	<0.1	<0.1	<0.1	<0.1	<0.05
France	<0.1	<0.1	<0.1	0.0	0.0	0.0
Germany	0.0	<0.1	<0.1	<0.1	<0.1	<0.05
Bulgaria	0.0	0.0	0.0	0.0	0.0	<0.05
Columbia	0.0	0.0	0.0	0.0	<0.05	<0.05
Honduras	0.0	0.0	0.0	0.0	0.0	<0.05
India	0.0	0.0	0.0	0.0	<0.1	0.1
Indonesia	0.0	0.0	0.0	0.0	0.0	<0.05
Philippines	0.0	0.0	0.0	0.0	0.0	<0.05
Portugal	0.0	<0.1	<0.1	0.0	0.0	0.0
Romania	0.0	<0.1	<0.1	<0.1	<0.1	<0.05
Uruguay	0.0	0.0	<0.1	<0.1	<0.1	<0.05
Ukraine	0.0	<0.1	0.0	0.0	0.0	0.0
Total	27.8	39.9	44.2	52.6	58.7	67.7

\*estimated figure

**Table 2: Commercial cultivation of GM crops worldwide in 2003 by trait**  
(% of total GM crops grown).

	<b>HERBICIDE-TOLERANT (%)</b>	<b>Bt INSECT RESISTANT (%)</b>	<b>BOTH TRAITS (%)</b>	<b>Total by crop % (million hectare)</b>
<b>Soybean</b>	61			61 (41.3)
<b>Oilseed Rape</b>	5			5 (3.4)
<b>Maize</b>	5	13	5	23(15.6)
<b>Cotton</b>	3	5	3	11 (7.4)
<b>Total Percentage of GM crops by trait (million hectare)</b>	74 (49.7)	18 (12.2)	8 (5.8)	100 (67.7)

## The GM debate in the UK

***The more people engage in GM issues, the harder their attitudes and more intense their concerns become***

### *The public debate*

In July 2002, the Government announced that it would have a broad public debate on the future of GM crops and food in the UK. This was a novel and welcome step that brought the possibility of a new form of public participation in decision-making. Planning started in the late summer of 2002 and the debate itself ran for six weeks from June 3<sup>rd</sup> to July 18<sup>th</sup> 2003. In parallel, several discussion groups (referred to as the “narrow-but-deep” sample) of randomly selected people were established. Each of these groups met on two separate occasions to debate the GM issue. The findings of the whole exercise were published in September 2003 and GeneWatch has published a review the process and lessons to be learnt<sup>2</sup>.

There were seven key messages from the debate<sup>3</sup>

- 1 People are generally uneasy about GM.
- 2 The more people engage in GM issues, the harder their attitudes and more intense their concerns become.
- 3 There is little support for early commercialisation.
- 4 There is widespread mistrust of government and multi-national companies.
- 5 There is a broad desire to know more and for further research to be done.
- 6 Developing countries have special interests.
- 7 The debate was welcomed and valued.

While the public part of debate was widely welcomed in principle, there were considerable reservations about how it was conducted in practice including:

- whether the Government would listen to the outcome;
- whether the financial resources committed were insufficient - the Netherlands and New Zealand spent four times as much even though they have smaller populations<sup>4</sup>;

- that six weeks was too short a period to extend the discussions to people not already involved;
- whether the quality of the organisation and of the materials were satisfactory

The omission of key pieces of information from the debate - in the shape of the Science and Economics Reviews and the results of the Farm-Scale Evaluations (FSEs) was also a significant shortcoming. Despite these problems, it was clear that many people were keen to try this new form of participation. Estimates of the number of public meetings held ranged from 130 to 500. Some 37,000 feedback forms were returned and 24,609 people visited the website. The two methods used in the debate raised similar concerns, increasing confidence in the reliability of the findings.

The crucial question now is: how will the Government take account of the public debate? Will it take a precautionary approach, which the public prefers, or will it be more sympathetic to the industry?

### ***The economics review***

When Margaret Beckett, Secretary of State for the Environment, announced the public debate, she also said there would be parallel additional strands considering the economics of GM crops, to be conducted by the Prime Minister's Strategy Unit, and a science study by Professor David King, the Government's Chief Scientist<sup>5</sup>.

The findings of the Strategy Unit's study were published in July<sup>6</sup>. Its main conclusions were that the public's attitudes would be central in determining the marketability of GM foods in the future and that there was little evidence that the current generation of GM crops would bring much, if any, economic benefit to the UK. They also pointed to the importance of regulating our ability to deal with any adverse impacts, the potential for future benefits of GM crops, and the importance of how other countries used and managed GM crops.

### ***The science review***

Professor David King appointed a 25-member panel to conduct a review of GM science that was intended to be driven by public concerns. As well as setting out what was known about the science and possible impacts of GM technology, the science review explicitly laid out where the uncertainties remained and what further research was needed<sup>7</sup>. This new approach was refreshing and was more successful than previous attempts in conveying the provisional nature of our scientific knowledge. However, the report was weak in some areas. For example, it relied on the use of "no evidence" of harm as meaning no harm. This approach has been widely criticised, including by the USA's National Academy of Science. Commenting on the use of the phrase by regulators in the USA, the Academy emphasised how little it told people<sup>8</sup> "The term 'no evidence' can mean either that no one has looked for evidence or that the evidence provides contrary evidence. Lack of evidence is not typically useful in making regulatory decisions about risk" (p10).

Because the work was rather rushed and had no formal independent peer review, it had areas where it was weak, such as the lack of evaluation of how the regulations worked in practice and the quality of the risk assessments<sup>9</sup>. Unfortunately there are no plans to correct the original, only to produce a second draft that responds to public comments on the report and the outcome of the farm-scale evaluations. The resignation of one panel member on grounds that the process was not impartial, and underhand efforts to undermine another member, both of whom were critical of GM, also led to some loss of confidence in the Science Review.

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### **Co-existence and liability**

In November, the Agriculture and Environment Biotechnology Commission (AEBC) published its much delayed report considering the issues surrounding coexistence of GM and non-GM farming systems and liability for economic or environmental harm<sup>10</sup>. The AEBC, the Government's strategic advisors on biotechnology, recommended that there should be a legally enforceable set of rules governing how GM crops should be grown to limit contamination of non-GM and organic crops. It also said that there should be a tightly monitored introductory period to ensure the rules worked in practice.

The AEBC also considered that there should be a compensation system established to reimburse farmers if their produce were contaminated and they lost income as a result. Improvements to legislation that would allow the Government to require companies to pay for remediation (when possible) if environmental harm arose through the use of a GM crop, were also recommended. How the Government will respond to the report is not yet known, but is expected to address these issues in its the new policy announcement early in 2004. Many questions were not resolved by the AEBC including the extent to which efforts should be made to limit contamination to 0.9 per cent or effectively zero at 0.1 per cent - and who should be liable to pay for economic harm. Therefore, the Government still has many difficult issues to resolve.

### **The farm-scale evaluations**

The voluntary agreement between the biotechnology industry and the Government not to proceed with the commercialisation of GM crops, rested on the conduct and results of a large-scale study of the impacts of growing GMHT crops on farmland wildlife. The first results from GMHT oilseed rape, beet and maize have now been published<sup>11</sup>. The findings for the crops varied but for oilseed rape and beet, surprisingly dramatic adverse effects were seen. The researchers and scientific steering committee concluded in relation to oilseed rape and beet that<sup>12</sup>:

- “1. Growing GMHT beet and spring oilseed rape on a large-scale may disadvantage wildlife, particularly farmland birds, bees and butterflies...”
2. Growing GMHT beet and spring oilseed rape on a large-scale may exacerbate long-term declines of flowering weeds, including those that are important food resources for seed-eating birds”

For glufosinate-tolerant maize (using a line known as T25 produced by Bayer Crop Science), the outcome was different with greater biomass in the GMHT maize than in the conventionally grown crop with potential biodiversity benefits. The research team summarised the contrasting situations thus<sup>13</sup>:

“If these trends are maintained under widespread GMHT cropping, then the present herbicide regimes associates with GMHT beet and spring oilseed rape might exacerbate long-term declines of dicot\* weeds, that include species that are important food resources for many invertebrates, small mammal and bird species. By contrast, these same weeds might increase in abundance following a shift from conventional to GMHT maize cropping, due to the greater weed control exerted by conventional herbicide regimes compared to those used with the GMHT crops”.

(\*a broad-leafed weed)

On the face of it, the evidence does not support the approval of GMHT oilseed rape and sugar beet. Importantly, the FSE results indicate that the rate of decline in the weed seed bank would increase from the current average of 3 per cent to 7 per cent, if GMHT crops were used as a break crop once every five years in a cereal rotation<sup>14</sup>. The result would be a faster loss of food resources

for farmland wildlife, including birds. Evidence emerging through the late 1980s and 1990s had shown that intensive agriculture was having an adverse impact on biodiversity in arable farming systems<sup>15</sup>. Serious declines in bird and plant populations have been recorded in the UK and other parts of Europe<sup>16, 17, 18</sup>. The later timing of application of herbicide to GMHT crops meant spray drift was greater because the spray boom was higher, leading to more damage to the field margins<sup>19</sup>.

As a result, GMHT oilseed rape and sugar beet should not be grown commercially in Europe because neither of these crops has approval for marketing under the revised Deliberate Release Directive (2001/18), which covers environmental safety aspects of GM organisms. The indirect effects of using a herbicide together with a GMHT crop is now a formal part of that evaluation and, if interpreted in a precautionary way as intended, should mean these two crops are banned. Important decisions will be made on the future of these crops in Europe during 2004.

However, overall the use of glufosinate on GMHT maize appears to be an improvement in biodiversity terms on current practice, and the T25 GMHT maize already has marketing approval under the previous Directive (90/220), when indirect effects were not a part of the assessment. Therefore, Bayer will be seeking regulatory approval for the use of glufosinate on this crop. This will be considered by the Pesticides Safety Directorate in 2004 but it will have to be careful how it interprets the results.

In the FSEs, the comparison (to answer "harmful compared to what?") was made with conventionally farmed maize, where atrazine was the most commonly used herbicide<sup>20</sup>. Because atrazine use is to be banned, whether glufosinate and GMHT maize will perform so well in biodiversity terms compared with the systems that will replace them is not clear. Further research will be required. As Les Firbank, who led the FSE research team commented: "We are confident that our findings would represent what would happen under large-scale growing unless the management regimes altered. For example, if changes in regulations meant that atrazine was banned on maize..."<sup>21</sup>.

In North America, where the same GMHT maize (known as Liberty Link) has been grown commercially for some time, glufosinate alone has not provided adequate weed control for farmers<sup>22</sup> and now atrazine is used in combination with glufosinate and sold as Liberty ATZ<sup>23</sup>. How this would affect farmland wildlife is unclear and, with the ban on atrazine, the same mixture could not be used here. However, it means that any biodiversity benefits may prove to be non-existent unless such mixtures are expressly forbidden or further research is conducted before they are allowed.

Although the FSEs showed that there were more weeds in the GMHT maize than in conventionally produced maize, the weed seed bank was not actually increased. More data are required on this issue, which will be important in determining the extent to which there may or may not be beneficial long-term impacts. GMHT maize may prove to be very similar to conventional maize in the long-term<sup>24</sup>.

### **Other new scientific research**

Research in the UK has revealed that earlier, small-scale research had underestimated the likelihood of gene escape from GM oilseed rape to its relative, wild turnip. It showed 32,000 hybrids between oilseed rape and the

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waterside form of wild turnip could form each year and 17,000 with the weedy populations<sup>25</sup>. If GM oilseed rape were grown, genes from bacteria and virus could be introduced into the gene pool. The first evidence of a transgene escape to a wild relative during commercial growing of a GM crop (herbicide tolerance from oilseed rape, *B. napus*, to weedy *B. rapa*) has now been recorded in Canada<sup>26</sup>.

GM oilseed rape volunteers (where seed shed at harvesting germinates in later crops and is a weed) may remain and act as sources of contamination for more than 1 per cent of non-GM crops up to 16 years if not properly managed<sup>27</sup>. If volunteers were vigorously controlled, it would take five years for contamination levels to fall below 1 per cent.

### Europe

Since 1998 there have been no new approvals for the marketing of GM crops or foods in Europe. This situation did not change despite an application to import one GM variety of maize (Syngenta's *Bt 11*) being taken to a vote of member states. Not enough countries agreed to the application because some remained concerned that although new rules on labelling and traceability were now agreed, these did not come into operation until April 2004 (see below). It has also been revealed that some of the data submitted by Syngenta as part of its application to market the maize, may have come from experimental trials with a different variety of GM maize<sup>28</sup>. This, together with a report commissioned by the Austrian government, which examined nine past applications for placing a GM crop on the market<sup>29</sup>, may continue to undermine confidence in the European regulatory system and signal further delays in GM crop approvals. The Austrian review showed many flaws in the past assessment process including that no direct testing of allergenicity had taken place and that the potential for unintended effects to alter the expression of allergens was not considered at all.

Two new regulations, Regulation (EC) No 1829/2003 on genetically modified food and feed, and Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs (genetically modified organisms) and food and feed produced from GMOs, were agreed. These new rules improve consumer choice greatly and will allow for an appropriate response through the withdrawal of products should adverse effects arise. The food and feed regulations recognise that substantial equivalence is not a sufficient basis of which to evaluate the safety of novel practices, thus ensuring a more robust and scientifically defensible approach.

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### The WTO challenge

The USA, Canada and Argentina upped the GM stakes when they challenged Europe's delays on GM crop and food approvals at the WTO (see GeneWatch Briefing No 25: *The GM dispute at the WTO: forcing GM foods on Europe*). Arguing that the delays have created an unjustifiable barrier to trade, the dispute will form an important backdrop to decision making on GMOs in 2004. Not only may it herald a series of challenges on the GM issues, but it will be used to influence other countries as they make decisions about GM food regulations.

### Human genetics

Most biotech companies continued to do badly financially in 2003. The editor of the journal *Nature Biotechnology*, Andrew Marshall, stated in November: "Biotechs basically lose a lot of money. They don't produce a lot of products..."

They're getting better and better at losing more and more money"<sup>30</sup>. Underlying these financial problems, there continued to be a rising tide of data on genes and proteins with little understanding of their contribution to common diseases<sup>31</sup>.

While many commentators noted that the potential of genetic tests had been over-hyped, Government ministers continued to claim that they would allow an individual's risk of common diseases, such as heart disease, cancer and diabetes to be assessed. However, the Government failed to introduce new regulations to check companies' claims for genetic tests. It also failed to make its own assessment of their usefulness before advocating widespread testing in the health service.

### **Some new gene stories in 2003**

A gene for obesity in worms and a mouse genetically engineered to "eat all you want"<sup>32,33</sup>.

A gene for drunkenness in worms<sup>34</sup>.

A gene for burning the midnight oil<sup>35</sup>.

A gene for longevity<sup>36</sup>.

## **Human Genetic Testing**

Two key publications in 2003 were the Human Genetics Commission's report on direct sales of genetic tests to the public<sup>37</sup> and the Government's White Paper on genetics in the NHS<sup>38</sup>.

In its report, the HGC recognised that genetic test results could "be misused as a powerful marketing tool by unscrupulous companies in support of misleading claims or in order to promote the buying of expensive and unnecessary dietary supplements or medicines". The HGC recommended that the claims made for genetic tests should be assessed by the new Medicines and Healthcare Products Regulatory Agency (MHRA) and that the tests should generally only be available through doctors. But the Commission opposed giving the MHRA the necessary powers to stop misleading tests from being sold. The Government has still not responded to the HGC's report and genetic tests remain unregulated.

The Government's White Paper considered the future of genetic testing in the NHS. It made numerous misleading claims about the potential for genetic tests to predict future disease or response to medicines (see *pharmacogenetics* section below) and failed to put in place new safeguards to prevent genetic discrimination by insurers or employers.

The White Paper also included a highly controversial proposal for genetic screening of all babies at birth genetically ("barcoding babies"). This plan would waste precious NHS resources and would tear up existing rules about the need for counselling prior to testing, consent to tests and the evidence of benefit that is normally required before introducing screening programmes. Screening every baby could also lead to a society where people were categorised according to their genes, increasing the likelihood of genetic discrimination. The proposal appears to be a way for genetic testing companies to make a profit from a captive market at taxpayers' expense. The database of genetic samples might also become a backdoor forensic database on every citizen, with potential for the erosion of civil liberties.

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The barcoding babies proposal will be considered by the HGC in 2004 and is expected to be widely opposed.

The White Paper also included claims that genetic tests will allow people with certain profiles to avoid foods, chemicals or environmental factors, such as smoking, which are particularly risky and that it may be possible in future to test for genes that increase susceptibility to exposures such as cigarette smoke. Such claims wrongly imply that only a minority of individuals with so-called “bad genes” need to stop smoking, eat healthily or live and work in unpolluted environments.

Attempts to offer genetic screening to smokers are more likely to benefit the tobacco industry than to be good for health<sup>39,40</sup>. Attempting to identify those susceptible to cancer caused by hazardous chemicals or radiation in the workplace or environment could lead to the exclusion of such individuals from jobs and/or insurance, rather than an obligation to improve the environment for all. Genetic screening for susceptibility to workplace hazards is widely opposed by the TUC and others as a false alternative to cleaning up the workplace<sup>41</sup>.

Misleading comments about the potential of genetic testing were repeated in the Labour Party's consultation *The Big Conversation*, which stated: “Individuals can inherit diseases as varied as heart conditions, diabetes and dementia...Within a decade, genetic screening will be widespread. By 2015 the practical use of gene therapy may be able to treat one in three life threatening diseases”<sup>42</sup>. In fact, although genetic factors may contribute to these diseases, only in a small minority of cases are these inherited, and environmental factors (including diet and lifestyle) are much more important in most cases<sup>43</sup>. Gene therapy has been successful in treating only a few children suffering from one rare genetic disorder. In 2003, it was sadly confirmed that two of these children had developed leukaemia as a side effect of treatment<sup>44,45</sup>.

## Pharmacogenetics

“Research in pharmacogenetics should help make medicines usage more effective. It should allow doctors to identify patients who could suffer adverse reactions as well as those who may not respond to a particular drug at all. And it should help them tailor the dose according to a person's individual needs”. White Paper, para 5.18.

“Much of the policy debate on pharmacogenetics appeared to assume that the new products (i.e. genetic tests and test-drug combinations) would have high levels of precision, both for predicting safety and efficacy. This view, however, can be seriously questioned in the light of increasing evidence that genetic tests for complex traits do not perform well in practice”. University of Cambridge, 2003<sup>46</sup>.

The White Paper also promoted the concept of “pharmacogenetics” described as using genetic tests to choose “the right drug for the right patient”. However it made no assessment of the growing evidence that genetic tests are often poor at predicting drug efficacy or safety<sup>47</sup>. This is because so many other factors (including age, diet, general state of health, other genes and use of other medicines) are important in influencing how someone responds to a medicine.



A University of Cambridge report highlighted that misleading tests linked to drug selection could cause serious harm; that there is currently no independent regulation of such tests; and that the smaller clinical trials proposed by some pharmaceutical companies (testing medicines only in a group of people with the "right" genetic make-up) could make it harder to detect safety problems with a drug. None of these problems were recognised, let alone addressed, in the policy proposals.

## Cloning

In November, the United Nations voted to suspend negotiations on a treaty banning human cloning. Although the majority of governments and scientists agree that producing a cloned baby should be banned, discussions became deadlocked on the issue of non-reproductive or therapeutic cloning, which some countries want to see included in the ban.

The dangers to the mother and child of attempting reproductive cloning has long been one major reason to oppose it, with the majority of cloned animals dying before or shortly after birth or suffering significant deformities. The premature death of Dolly the cloned sheep from a lung disease in February highlighted possible additional dangers, with suggestions that the cloning process meant she did not age normally<sup>48</sup>. Claims by the company Clonaid, linked to the Raelian sect, to have cloned five human babies in 2002, were widely disbelieved when it refused to allow scientists access to the children<sup>49</sup>. However, some scientists continued to state that they were moving closer to producing the first cloned baby<sup>50</sup> whilst others argued that this might prove technically impossible<sup>51</sup>.

In December, the US company Advanced Cell Technology (ACT) announced that it had successfully repeated its previous attempt to clone an embryo for medical research, growing it to the stage where it consisted of 16 cells<sup>52</sup>. The aim of therapeutic cloning is to try to treat diseases by growing cloned embryos to a stage where they produce genetically matched cells and tissues for the patient. However, developing the technology may make attempts to clone babies more likely. The large numbers of donated eggs required would limit future treatments, if they work, to a rich minority of patients and could also lead to a commercial trade in human eggs which would be harmful to women. Many people also object to using embryos in this way on religious grounds. ACT has suggested that a process of artificially stimulating eggs to divide, called parthenogenesis, might both require fewer eggs and avoid the need for cloning. Other options, such as using adult stem cells, would not raise any ethical concerns. It remains unclear which approaches, if any, would be technically successful<sup>53, 54</sup>.

In the UK, scientists at the Roslin Institute who cloned Dolly the sheep have been granted a licence by the HFEA to undertake parthenogenesis<sup>55</sup>. They will need a further licence to attempt to clone an embryo for research purposes. Allowing the embryo to grow in a woman's womb to produce a cloned baby is illegal in Britain, but the deadlock in the UN negotiations means that attempts could still be made legally elsewhere.

## Sex Selection

In November, the Human Fertilisation Authority (HFEA) recommended that selecting the sex of a child using a new sperm sorting technique should be allowed only for serious medical reasons and should be strictly regulated in licensed clinics<sup>56</sup>. The widely welcomed recommendation was a response to widespread public concern. If adopted by the Government, it will be an

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important step towards preventing companies from marketing technologies that encourage parents to select the genetic make-up of their child for trivial or non-medical reasons.

**UK Biobank**

Plans for the UK Biobank genetic research project progressed slowly with the appointment of new staff and the publication of a draft ethical framework. Pilot recruitment is now planned to start in 2004, with collection of DNA samples and lifestyle data from 500,000 volunteers now scheduled to take place from 2005-2010.

In March, the controversial proposals were strongly criticised by the House of Commons Science and Technology Committee, which stated: "It is not clear to us that Biobank was peer reviewed and funded on the same basis as any other grant proposal. Our impression is that a scientific case for Biobank has been put forward by the funders to support a politically driven project"<sup>57</sup>. An article in the medical journal, *The Lancet*, and a BBC report also highlighted continuing concerns amongst scientists that the project was poorly designed and based on false assumptions about the role of genes in common diseases<sup>58, 59</sup>.

Despite the scientific criticisms, the Biobank moved ahead with appointing staff and publishing a draft ethical framework<sup>60</sup>. GeneWatch continues to argue that such a framework is premature first there is a need for an independent scientific peer review of the proposals; an assessment of the Biobank's likely value for money; and democratic debate of its assumptions about health<sup>61</sup>. The framework also side-stepped key issues such as the relationship between the Biobank and commercial companies (including whether gene patenting would be allowed) and the lack of legal safeguards to prevent genetic discrimination and protect privacy.

**The call for caution and reluctance to see GM crops grown in the UK must be acted upon by Government if it is to gain any confidence in its willingness to manage GM in the public interest**

**Conclusions**

Having a public debate was an important step. It should help establish whether or not, or under what conditions we use GM foods or grow GM crops in the UK. Although it was limited in its funding and timing, its conclusions meshed with earlier studies of public attitudes. The call for caution and reluctance to see GM crops grown in the UK must be acted upon by Government if it is to gain any confidence in its willingness to manage GM in the public interest. The clear findings of the FSEs, that GMHT oilseed rape and sugar beet would damage farmland wildlife if grown here commercially means that Europe should reject these crops. Other countries should also consider whether their environments would suffer in a similar way. If we decide to allow the growing of GM maize or any GM crops, it should not take place before enforceable rules are in place to prevent contamination of non-GM farmers' produce and compensation should be available if this did happen.

In human genetics, public health research and policies continue to be undermined by misleading claims that the key to preventing diseases such as heart disease and cancer lies in testing people's genes. Health and research policies continue to be based on meeting commercial needs to market products, rather than on assessing the best approach for public health.

## References

- 1 James (2003) Preview: *Global status of commercialised transgenic crops: 2003*. ISAAA Briefs No. 30. ISAAA: Ithaca, NY.
- 2 Mayer. S. (2003) *GM Nation? Engaging people in real debate?* GeneWatch UK: Tideswell.
- 3 *GM Nation? The findings of the public debate*. Department of Trade and Industry: London. September 2003.
- 4 *Debate, what debate?* Editorial in Nature, 12<sup>th</sup> June 2003.
- 5 *Public dialogue on GM*. Government response to AEBC advice submitted in April 2002. July 2003.
- 6 Strategy Unit (2003) *Field work: weighing up the costs and benefits of GM crops*. Cabinet Office: London.
- 7 GM Science Review Panel (2003) *GM science review. First report*. Department of Trade and Industry: London.
- 8 National Academy of Sciences (2002) *Environmental impacts of transgenic plants: the scope and adequacy of regulation*. National Academy Press: Washington.
- 9 See: Comments on GM Science Review from Econexus, *The Five Year Freeze*, Friends of the Earth, GeneWatch UK, Greenpeace, the Soil Association, and Dr Michael Antoniou October 14th 2003. Available on [www.gmsciencedebate.org.uk](http://www.gmsciencedebate.org.uk)
- 10 AEBC (2003) *GM crops? Coexistence and liability*. Available on [www.aebc.gov.uk](http://www.aebc.gov.uk).
- 11 *The Farm Scale Evaluations of spring-sown genetically modified crops*. Papers of a Theme Issue. Philosophical Transactions of the Royal Society of London, Series B 358: 1773-1913.
- 12 Burke, M. (2003) for Farmscale Evaluations Research Team and Scientific Steering Committee GM crops. *Effects on farmland wildlife*.
- 13 Firbank, L.G. *et al* (2003) *The implications of spring-sown genetically modified herbicide-tolerant crops for farmland biodiversity. A commentary on the Farm Scale Evaluations of spring sown crops*.
- 14 Heard, M.S. *et al* (2003) *Weeds in fields with contrasting conventional and genetically modified herbicide-tolerant crops. II. Effects on individual species*. Philosophical Transactions of the Royal Society of London, Series B. 358:1833-1846.
- 15 Robinson, R.A. & Sutherland, W.J. (2002) *Post-war changes in arable farming and biodiversity in Great Britain*. Journal of Applied Ecology 39: 157-176.
- 16 Gibbons, D. *et al* (1994) *The New Atlas of Breeding Birds in Britain and Ireland:1998-1991*. London: T&A Poyser.
- 17 Preston C.D. *et al* (2002) *The changing flora of the UK*. London: DEFRA.
- 18 Andresen, C. *et al* (1996) *Decline of the flora in Danish arable fields*. Journal of Applied Ecology 33: 619-626.
- 19 Roy, D.B. *et al* (2003) *Invertebrates and vegetation of field margins adjacent to crops subject to contrasting herbicide regimes in the Farm Scale Evaluations of genetically modified herbicide-tolerant crops*. Philosophical Transactions of the Royal Society of London, Series B. 358: 1879-1898.
- 20 Champion, G.T. *et al* (2003) *Crop management and agronomic context of the Farm Scale Evaluations of genetically modified herbicide-tolerant crops*. Philosophical Transactions of the Royal Society of London, Series B. 358:1801-1818.
- 21 Burke, M. (2003) for Farmscale Evaluations Research Team and Scientific Steering Committee. GM crops. *Effects on farmland wildlife*. ISBN 0-85521-035-4.
- 22 Bean, B. & Rowland, M. (2000) *Weed Control in Liberty Link Corn. 1996 to 1999*. Texas Agricultural Extension Service. Texas A&M University System. Result demonstration report. [Http://soilcrop.tamu.edu/publications/pubs/demo.pdf](http://soilcrop.tamu.edu/publications/pubs/demo.pdf) .
- 23 See: <http://www.ag.uiuc.edu/cespubs/pest/articles/199901g.html> for details of Liberty ATZ and its use.
- 24 Heard, M.S. *et al* (2003) *Weeds in fields with contrasting conventional and genetically modified herbicide-tolerant crops. II. Effects on individual species*. Philosophical Transactions of the Royal Society of London, Series B. 358:1833-1846.
- 25 Wilkinson M.J. *et al* (2003) *Hybridization between Brassica napa and B. rapa on a national scale in the United Kingdom*. Science. [October 2003]
- 26 Warwick S.J. *et al* (2003) *Hybridisation between transgenic Brassica napus L. and its wild relatives : Brassica rapa L., Rhanus raphanistrum L., Sinapsis arvensis L., and Erucastrum gallicum (Willd.) O.E. Schulz*. Theoretical and Applied Genetics 107: 528-539.
- 27 Squire, G.R. & Askew, A. (2003) Final Report - DEFRA project RG0114: *The potential for oilseed rape feral (volunteer) weeds to cause impurities in later oilseed rape crops*.
- 28 *Europe split over safety of GM corn*. The Independent on Sunday 21 December 2003.
- 29 Spök A. *et al* (2002) *Toxicological and allergological safety evaluation of GMO. (Toxikologie und Allergologie von GVO-Produkten. Empfehlungen zur Standardisierung der Sicherheitsbewertung von gentechnisch veränderten Pflanzen auf Basis der Richtlinie 90/220/EWG (2001/18/EG) Wien, 2002. (Monographien; Band 109)* .

- 30 *Journal editor offers sobering picture of struggling biotech sector.* The Business Review. 3 November 2003.
- 31 *Data swell refocuses biotech on systems.* EE Times. 31 October 2003.
- 32 *From Worm Genes, Human Obesity Clues,* The New York Times, 16 January 2003.
- 33 *How to Eat All You Want,* Health 24, January 2003. [www.health24.co.za](http://www.health24.co.za) .
- 34 *Scientists Find Drunkenness Gene in Worms.* 11 December 2003. <http://news.yahoo.com> .
- 35 *Late Nights in the Genes.* The Telegraph, 16 June 2003.
- 36 *Cholesterol Gene Linked to Longevity.* Newsday.com , 15 October 2003.
- 37 Human Genetics Commission (2003) Genes direct. March 2003.
- 38 Department of Health (2003) *Our inheritance our future: realising the potential of genetics in the NHS.* June 2003.
- 39 GeneWatch UK (2003) *Securing Good Health for the Whole Population: Submission to the Wanless Review.* November 2003.
- 40 Hall, W., Madden, P., & Lynskey, M. (2002) *The Genetics of Tobacco Use: Methods, Findings and Policy Implications.* Tobacco Control 11: 119-124.
- 41 [www.hazards.org/genescreen](http://www.hazards.org/genescreen) .
- 42 <http://www.bigconversation.org.uk/index.php?id=704> .
- 43 Willett, W.C. (2002) *Balancing Life-Style and Genomics Research for Disease Prevention.* Science 296: 685-698.
- 44 *Cancer Case Raises Gene Therapy Fears.* BBC Online. 15 January 2003.
- 45 *Gene Therapy 'Caused Leukaemia'.* BBC Online. 16 October 2003.
- 46 Melzer, D. *et al* (2003) *My Very Own Medicine: What Must I Know?* University of Cambridge, 2003.
- 47 GeneWatch UK. (2003) *Pharmacogenetics: Better, Safer Medicines?* Briefing Number 23. July 2003.
- 48 *Goodbye Dolly.* BBC Online. 14 February 2003.
- 49 *Company shows 'cloned baby'.* BBC News Online, 25 March 2003.
- 50 *Scientist publishes "world first" cloned human embryo claim.* Reuters. 3 June 2003.
- 51 *Human cloning currently 'almost impossible'.* New Scientist. 10 April 2003.
- 52 *Human clone experiment repeated successfully.* Reuters. 16 December 2003.
- 53 *Has one cell fooled them all?* New Scientist. 17 May 2003.
- 54 *Differentiating hope from embryonic stem cells.* The Scientist. 15 December 2003.
- 55 *Go-ahead for stem cell research.* BBC Online, 6 October 2003.
- 56 Human Fertilisation and Embryology Authority (2003) *Sex Selection: Options for Regulation.* November 2003.
- 57 <http://www.publications.parliament.uk/pa/cm/200203/cmselect/cmsctech/132/1320> .
- 58 Barbour, V. (2003) *UK Biobank: A Project in Search of a Protocol?* The Lancet 361: 1734-1738.
- 59 Ghosh, P. (2003) *Will Biobank pay off?* BBC Online. 24 September 2003.
- 60 UK Biobank (2003) *UK Biobank Ethics and Governance Framework.* 24 September 2003.
- 61 Wallace, H.M. (2003) *UK Biobank: Good for Public Health?* [Http://www.opendemocracy.net/debates/article-9-79-1381.jsp](http://www.opendemocracy.net/debates/article-9-79-1381.jsp) .



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