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# GENETIC ENGINEERING:

A Review of Developments in 2000



Briefing Number 13 January 2001

During 2000, GM crops and foods continued to hit the headlines with opposition gradually spreading around the world. At the same time, an uncertain and anxious debate began about human genetics and how we might benefit whilst avoiding the potential for genetic discrimination and eugenics.

This briefing reviews the major developments in the regulation, science and politics of gene technology in 2000 and considers their implications.

# **GM Crops and Foods**

# The global position

During 2000, no new GM foods were given approval for growing, importation or consumption in Europe. The vast majority of GM crops grown in Europe were for experimental purposes (see below for details of trials in the UK) with very small areas of GM maize being grown commercially in France, Spain and Germany.

Globally, the area of GM crops grown increased by about 11% to 44.2 million hectares in 2000 compared to 1999, a considerable slowdown in the rate of expansion which had been 44% in 1999¹. The area planted with GM soybean increased by almost 20% in 2000 and accounted for 95% of Argentinean and 54% of US soybeans.

Growing of GM maize decreased by 0.8 million hectares (7%) partly due to uncertainty over markets and partly because of low levels of corn borers, the insect pest GM maize is engineered to resist. Similarly, GM oilseed rape cultivation fell by about 0.6 million hectares (11%). However, the area of GM cotton planted grew by 40% from 3.7 million

hectares in 1999, to 5.3 million hectares in 2000, mainly in the USA where GM cotton now makes up 72% of the total crop.

North America and Argentina remain the major growers of GM crops (see Table 1). 68.5% of all GM crops were grown in the USA, 22.6% in Argentina; 6.8% in Canada and 1% in China. Herbicide tolerance was again the most predominant trait (see Table 2).

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

COUNTRY	1998	1999	2000
USA	20.5	28.7	30.3
Argentina	4.3	6.7	10.0
Canada	2.8	4.0	3.0
China	<0.1	0.3	0.50
Australia	0.1	0.1	0.15
South Africa	<0.1	0.1	0.20
Mexico	<0.1	<0.1	<0.1
Spain	<0.1	<0.1	<0.1
France	<0.1	<0.1	<0.1
Germany	0.0	<0.1	<0.1
Portugal	0.0	<0.1	<0.1
Rumania	0.0	<0.1	<0.1
Bulgaria	0.0	0.0	<0.1
Uruguay	0.0	0.0	<0.1
Ukraine	0.0	<0.1	0.0
TOTALS	27.8	39.9	44.2

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

HERBICIDE TOLERANT	Bt INSECT RESISTANT	BOTH TRAITS	Total % by Crop
59%			59%
6%			6%
5%	15%	3%	23%
5%	3%	4%	12%
75%	18%	7%	
(32.7 million hectares)	(8.4 million hectares)	(3.1 million hectares)	
	59% 6% 5% 5% 5% 75%	TOLERANT     RESISTANT       59%        6%        5%     15%       5%     3%       75%     18%       (32.7 million     (8.4 million	TOLERANT         RESISTANT         TRAITS           59%            6%            5%         15%         3%           5%         3%         4%           75%         18%         7%           (32.7 million         (8.4 million         (3.1 million

### **GM** crop trials in the UK

There were 146 GM crop trial sites planted in the UK in 2000 that required a consent from the DETR<sup>2</sup>. Of these, 13% were conducted by the public sector and 87% by the private sector. Aventis (including AgrEvo) and Monsanto are the main companies conducting field trials. Of the trials, 73 (50%) involved sugar or fodder beet; 64 (44%) oilseed rape; 6 (4%) potato; and 3 (2%) wheat. There was also one other release of a GM organism (not a crop) which involved a GM virus for use as an insecticide.

Most of the trials were conducted on a small scale but farm-scale trials (FSTs) with GM herbicide tolerant oilseed rape, sugar and fodder beet accounted for 40% (59 sites)of these sites. There were also 12 additional FST sites of GM herbicide tolerant maize which do not need a consent because they already have marketing consent (see GeneWatch Briefing No 8 and Farm Scale Trial fact sheets).

94% of GM crop trials in the UK were of herbicide tolerant crops 94% (137) of the trials were of herbicide tolerant crops and there were individual trials on altered oil content (oilseed rape); disease resistance (potato); nematode resistance (potato); chemical switch (potato); increased protein content (wheat); delayed pod shatter (oilseed rape); altered starch content (potato); altered sugar content plus nematode resistance (potato).

The striking emphasis on herbicide tolerance in the trials mirrors the commercial dominance of this GM crop trait. Undoubtedly, this is because the companies involved are anxious to use herbicide tolerance as widely as possible because it makes economic sense. Once the investment has been made in isolating the relevant genes and making their use routine, the costs of using that same genetic trait in new varieties or new crop species drops dramatically and profits increase in parallel<sup>3</sup>.

#### The UK Government's position on GM foods

During 2000, Prime Minister Tony Blair felt it necessary to stress the UK Government's impartial position on GM foods to clear up any misunderstandings. In February, on the eve of an OECD conference on GM food safety in Edinburgh, he wrote in *The Independent on Sunday* that: "*There is no doubt that there is potential for harm, both in terms of human safety and in the diversity of the environment, from GM foods and crops...... Nothing has puzzled me more than claims that this government is an unquestioning supporter of GM food. We are not pro or anti-GM food. We are pro-safety, pro-environment and pro-consumer choice*" <sup>4</sup>.

However, at the G8 Summit in Okinawa in July, Mr Blair appeared somewhat less impartial when he supported Bill Clinton in defending the importance of the biotechnology industry against the other European countries who want to take a more precautionary approach to the possible dangers. Mr Blair said: "What is essential is that we recognise that this process of science and biotechnology is perhaps going to be for the first half of the 21st century what information technology was to the last half of the 20th century. It is important for a country like Britain, which is a leader in science and biotechnology, that we proceed according to the facts and the science." 5

Tony Blair's impartiality was further called into question during a speech to the European Bioscience Conference in London in November: "This is an industry

to improve life<sup>41</sup>. Such concern is not confined to Europe as opposition to GM foods is rising in other countries including the United States<sup>42</sup>. The use of genetics for improving human health has much more support than GM foods although there are anxieties about cloning and GM animals.

- In November, Novartis and AstraZeneca spin off and merge their agrochemical divisions to form Syngenta, now the world's largest GM crop developer.
- In the wake of the StarLink debacle in the USA (see *StarLink Maize in the USA* above), Aventis announces it is looking for a buyer for its agrochemical and seeds section under the name Agreva<sup>43</sup>.
- At the end of November, Monsanto apologises for being arrogant and dismissive of public concerns in the past and announces that its attitude had changed and that it had formally pledged to be 'honourable, ethical and open' 44.
- Monsanto's new contract for farmers using its patented GM crops in the US is revealed. Farmers must waive any rights to sue Monsanto if the GM crops do not perform as advertised and agree to be bound by the findings of an American Arbitration Association hearing. Dennis Howard, Oklahoma's Secretary of Agriculture, is quoted as saying: "Not only does this contract severely limit the options of the producer, it also limits Monsanto's liability. Marketing agreements and contracts are only effective if they serve to protect the interests of all parties involved. The protection of the Monsanto contract is strictly one-sided and I would encourage producers to carefully consider this before entering into this agreement." 45
- McDonald's in the UK announces that it will not use GM ingredients in its animal feeds.
- In December, the Canadian National Farmers' Union calls for a moratorium on the commercial use of GM crops and food<sup>46</sup>.

## **Conclusions**

The fortunes of GM foods have suffered further in 2000 and the question of most concern to industry is whether this backlash will now have an effect on human applications of genetics. The economic stakes are much higher in the human field - not only do the big pharmaceutical companies stand to make enormous profits but the insurance industry hopes to cash in too. Hyping up the benefits and ignoring the dangers of human genetics has become the industry's PR strategy.

For the public, the question is whether their interests will be taken into account in the 'gene profit dash' but the evidence of recent months does not inspire confidence. Governments have already failed to ensure fair regulation and enforcement with GM crops and foods, as the Advanta seed contamination and StarLink fiascos illustrated, and Tony Blair's increasing promotion of the financial interests of the biotechnology industry in 2000 does not bode well for the future as we continue the complex task of attempting to distinguish between the benefits and threats of human genetics.

Monsanto
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Hyping up the benefits and ignoring the dangers of human genetics has become the industry's PR strategy

500,000 people aged between 45 and 64. The scheme would be administered through GP practices and would involve taking DNA samples, lifestyle data and medical records.

Will the UK's biocollection amount to putting our genes up for sale? Experiences elsewhere suggest that 'gene prospecting' is high on the agenda of pharmaceutical companies where gene banks are concerned. DeCODE Genetics are involved in gene banks in Iceland and Estonia<sup>32,33</sup>. In November 2000, the Australian biotech company Autogen Limited secured exclusive rights to the entire gene pool of the 110,000 population of Tonga<sup>34</sup>. An American company, DNA Sciences, has put out a call on the Internet for DNA donations (www.DNA.com) and are reported to have had a very good response so far, with over a thousand people signing up in the first week<sup>35</sup>. In a different twist, you can pay the GeneLink company up to £230 to have a sample of DNA taken from a deceased person and kept in cold storage – perhaps for cloning if it becomes possible in the future<sup>36</sup>.

As well as the concerns about commercial exploitation, collections of this type raise numerous social and ethical questions including those relating to security, privacy, and the misuse of information leading to discrimination.

## The Biotechnology Industry's Year

In the mid 1990s, the fashion was to build giant 'life-sciences' corporations following mergers between pharmaceutical and agrochemical companies and the acquisition of smaller biotechnology specialist companies, seed companies and so on. However, in 2000 the move was in the opposite direction and companies started to dispose of their agrochemical sectors so that their flagging GM crop interests would not taint the much more lucrative uses of genetics in human pharmaceuticals. The GM crop industry's fortunes suffered further in the UK as a result of an increasing number of food producers refusing to use GM ingredients in animal feeds. Since these are the major uses of GM soybean, oilseed rape and maize, this will hurt the industry economically. The highs and lows of the biotech industry year include:

- In March, Monsanto merges with Pharmacia-Upjohn<sup>37</sup> but the Monsanto name is relegated to use with the agrochemical division only.
- In April, Monsanto does the decent thing and announces that it will share its rice genome sequence information freely<sup>38</sup>.
- In May, AstraZeneca (now part of Syngenta) buys the rights to 'golden rice' which has been hailed by GM food supporters as a cure for vitamin A deficiency in developing countries (see GeneWatch Briefing No 10). The company will license the non-commercial rights back to the inventors who will make it freely available to public institutes in developing countries where farmers earning below \$10,000 (£7,000) a year will not have to pay royalties<sup>39</sup>. The acquisition of the commercial rights fits nicely with AstraZeneca's R&D interests in the 'functional food' market in the developed world.
- In August, the top GM crop producer, Novartis, announces that it will no longer use GM ingredients in its foods including Ovaltine and Gerber baby foods<sup>40</sup>.
- Published in September, the most recent Eurobarometer results from 1999 confirm the trend of decreasing optimism about the ability of biotechnology

whose market in Europe alone is expected to be worth over \$100billion (about £67billion) by 2005.... The giants of British biotechnology, like Celltech, dominate the continent. I want to make it clear that we don't intend to let our leadership fall behind and we are prepared to back that commitment with investment".6

European policy has long been dominated by a commitment to biotechnology as a key driver of industrial competitiveness. A taken-for-granted attitude that GM foods and crops are unquestionably desirable and that there is no alternative has undermined confidence in the UK Government's ability to make judgements about safety in the public interest.

European policy has long been dominated by a commitment to biotechnology

# Failures in the regulatory system

Two incidents in 2000 have exposed failings in the risk management systems both here and in the US. Whilst neither may result in any actual physical harm arising, they both serve to demonstrate how little attention has been paid to the effectiveness of controls. The first case was the contamination of non-GM oilseed rape seed with GM seed in the UK and the rest of Europe. The second case was in the US when GM maize was found in the human food chain which was only intended to be used for animal consumption.

#### Advanta's seed contamination

On 17th May, the Government admitted that Advanta Seeds had imported the seed of an oilseed rape variety known as Hyola, which was contaminated with around 1% of GM glyphosate and glufosinate tolerant seed<sup>7</sup> and that this had been sown on approximately 4,700 hectares8. The contaminated seed had been identified as a result of checks in Germany and the company informed the UK Government about the problem on 17th April. Although it is illegal to grow GM oilseed rape commercially in the UK, the Government took no action to prevent planting during the month before it made the announcement and resisted demands that the crops be destroyed saying that the GM crop posed no risk to human health or the environment. However, farmers who had inadvertently planted the seeds found they had no market for their oilseed rape when the Seed Crushers' and Oil Producers' Association announced they would not accept it for food use<sup>9</sup>. Two weeks later, in an extraordinary aboutturn, the Agriculture Minister, Nick Brown, advised farmers to plough up the contaminated crop, long after farmers would have been able to reseed their fields and leaving them facing huge losses<sup>10</sup>. Advanta was eventually forced into paying compensation to affected farmers in June<sup>11</sup>.

As well as revealing a lack of scrutiny of imported seed purity, this incident also highlights how scientists have underestimated the potential for non-GM crops to be contaminated by GM crops grown nearby. The seed was produced in Canada and, according to evidence given by Advanta to the House of Commons Agriculture Select Committee<sup>12</sup>, was produced from plants grown over 4 kilometres from the nearest GM crop. Because the seed Advanta was importing was a hybrid, it was produced by planting male sterile plants interspersed with a few (usually about 20%) male fertile plants to pollinate them. Under these growing conditions, known as varietal associations, because there is less pollen than normal in the field, pollen transported into the field has a greater chance of pollinating the crop. The incident has led to a review of separation distances between GM and non-GM oilseed rape crops in the UK which is currently 50 metres under normal conditions or 200 metres if a seed crop is involved. These distances will now be increased when varietal

Scientists have underestimated the potential for non-GM crops to be contaminated by GM crops

The top GM crop producer,
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Biobanks raise

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GeneWatch UK Briefing Number 13

January 2001

GeneWatch UK Briefing Number 13

10 January 2001 January 2001

The British Government's reaction was both slow and secretive associations are being grown in the vicinity of a GM crop. Whilst this may be manageable under experimental conditions, enforcing and policing separation distances between GM and non-GM crops may not be practical or possible under normal farming practices.

The British Government's reaction to this incident was both slow and secretive and showed little inclination to enforce the law. In contrast, in other European countries such as Sweden, France and Germany, the contaminated crop was removed more quickly and compensation negotiated. British farmers were left to face the consequences and the UK Government lost even more trust in its ability to arbitrate fairly.

#### StarLink maize in the USA

In September, sampling by Friends of the Earth and the Genetically Engineered Food Alert (GEFA - a coalition of public interest groups in the US), showed that a variety of GM maize known as StarLink was present in taco shells being sold for human consumption even though it was not approved for this use and should only have been used for animal feed<sup>13,14</sup>. The StarLink maize, produced by Aventis, is genetically modified to contain a gene from the bacterium *Bacillus thuringiensis* coding for an insecticidal Bt toxin known as Cry9C. This particular type of Bt toxin is not found in other GM insect resistant crops and there are concerns that it could be a human allergen because (unlike the Cry1A and Cry3A Bt toxins used in other GM crops) it is heat stable and does not break down in gastric acid – characteristics shared by many allergens<sup>15</sup>. Because Cry9C is not found in Bt preparations used directly as an insecticide, there is no experience with its use and safety.

The contamination appeared to have been caused by a combination of two factors. Firstly, post-harvest segregation between StarLink and other maize varieties was not maintained and, secondly, cross contamination of other non-GM maize varieties occurred because farmers were not aware or, or did not observe, separation distances to prevent cross pollination.

As a result of the discovery, Kraft, Safeway and Western Family rapidly recalled their StarLink contaminated taco shells, an action which is estimated to have cost them millions of dollars. Exports are also threatened as the StarLink maize has also been found in maize exported to Japan<sup>16</sup> - the largest importer of US maize - and as a result, it is reportedly cutting back on its imports.

The StarLink fiasco revealed a lack of monitoring and enforcement in the USA

Aventis has been forced to remove StarLink from sale and a formal recall order was issued by the US Department of Agriculture on October 9th for all 350,000 acres of StarLink corn planted across the US in 2000. However, Aventis is now pushing the US Environmental Protection Agency for a four year approval for human consumption. Although the EPA's panel found the probability of allergic reactions to be 'low', it has asked for further data on people claiming to have suffered allergic reaction and for more data on residues<sup>17</sup>. It seems unlikely that Aventis will get approval for StarLink in human food in the short term if at all.

The StarLink fiasco revealed a lack of monitoring and enforcement in the USA similar to that seen with the Advanta seed contamination case in the UK. The commercial pressure to facilitate GM crops has had the upper hand. Exactly who will be liable for the huge economic losses both in the US and abroad is unclear, although companies and farmers affected by the fiasco in the US are expected to sue Aventis.

In October, it was disclosed that a couple in the US had used PGD to select an embryo which did not carry the genetic disorder, Fanconi's anaemia. Their first child, Molly, had the disease and needed cells from an unaffected sibling to cure her condition. Umbilical cord cells were taken from their next baby, Adam (selected via PGD), at birth to treat Molly<sup>26</sup>. Later the same week, a couple in Scotland attempted to use human rights legislation to allow them to use PGD to select the sex of their child. They had lost a baby girl in a tragic accident and wanted to ensure that their next child was also a girl<sup>27</sup>.

These examples raise very difficult questions. Whilst most people would agree that choosing the sex of a baby should not be allowed (and was refused in the Scottish case), whether a baby should be selected to be of use to another person is far more contentious. Similarly, the fact that PGD could also be used to select against different types of disabilities also raises questions about where the ethical line should be drawn.

## Insurance and genetic testing

In 2000, Britain became the first country to officially sanction genetic testing for insurance purposes<sup>28</sup>. In October, the Department of Health's Genetics and Insurance Committee gave an official seal of approval to insurance companies asking to see the results of two genetic tests for Huntingdon's chorea. The Committee are also looking at 6 other tests – breast cancer, early onset Alzheimer's disease, familial adenomatous polyposis, myotonic dystrophy, multiple endocrine neoplasia, and motor and sensory neuropathy type 1. A decision on these is expected by June 2001. The insurance industry are currently emphasising that they will only ask to see the results of tests already taken and will not require people to undergo tests before taking out insurance. However, they would not be acting illegally if they did so. In the same way, the Genetics and Insurance Committee's judgement has no legal status and, in practice, companies can ask to see the results of tests that do not have its official approval<sup>29</sup>. In any event, whilst Britain has no anti-discrimination legislation in place, and as genetic tests become increasingly reliable, the insurance industry are likely to make more and more use of them if they can.

In the USA, public organisations are banned from using genetic tests to discriminate in employment and there are moves afoot to extend this to private employers and the insurance industry<sup>30</sup>. In the meantime, various sources of evidence are indicating a growing problem of genetic discrimination in the USA. For example, a recent American survey<sup>31</sup> uncovered 582 cases of people who were refused jobs or health insurance because of 'flaws' discovered in their genes. The Council for Responsible Genetics have also recorded more than 200 cases of genetic discrimination in the USA<sup>31</sup> and believe these are the tip of the iceberg. Disturbingly, the US Department of Labour has also found that: "many women are avoiding breast cancer screening because they believe a positive finding would go on their medical records and become available to employers or insurers." <sup>31</sup>

#### **Biobanks**

To find out what genes do, scientists need to make comparisons between the genes in different people and how these relate to the kinds of diseases they do or do not get. This requires access to large collections of individuals' DNA and, in the UK, numerous DNA collections already exist in both the public and private domains. In addition, this year has seen the development of a Wellcome/MRC/NHS proposal to set up a country-wide collection involving

Britain became the first country to officially sanction genetic testing for insurance purposes

Various sources of evidence are indicating a growing problem of genetic discrimination in the USA

#### **Issues in Human Genetics**

Developments in human genetics are posing many difficult questions for society. A Human Genetics Commission opinion poll in November 2000 found that 7 out of 10 people had no confidence that Government controls would be able to keep pace with the speed of developments in the science of human genetics<sup>24</sup>. GeneWatch UK will be looking more closely at the issues involved in human genetics during 2001 and how well the Government is dealing with them. Below are some of the main areas we will be investigating.

## Cloning

Cloning involves making identical copies of something. This can be genes or whole organisms. Breakthroughs in animal genetics (such as the cloning of Dolly the sheep) have raised the spectre of cloning human beings. To clone a human, the nucleus of a cell from an early embryo would have to be replaced with a nucleus from a cell of the person to be cloned. (Theoretically, an adult cell could be used instead of an embryo cell although this is more difficult because it has to be re-programmed to develop into an embryo). The single embryonic cell would then have to be grown into a multi-celled embryo and implanted in a woman's womb and carried to term. In animal experiments, the whole process often goes very wrong with very few embryos surviving, and many that do survive die just before or after birth. The whole process would be technically difficult in humans, but a survey by The Independent of 32 British scientists and doctors<sup>25</sup> showed over half believed human cloning would be achievable within 20 years although many emphasised that they did not want this to happen.

In December, Parliament voted to allow human embryo stem cells (unspecialised cells which have not yet differentiated into any specific type of tissue) to be used for any type of research if approved by the Human Fertilisation and Embryology Authority. Until then, embryos could only be used for research on reproduction and fertility. The new laws will allow 'therapeutic' but not 'reproductive' cloning. Embryos used in research have to be destroyed at the 14 day stage so a whole human cannot be reproduced (reproductive cloning) but with 'therapeutic cloning', stem cells could be multiplied and used to produce new tissues such as nerve cells or bone for use in the treatment of diseases. Whilst many medical scientists welcomed the liberalisation of the laws and believe it will help in the search for new disease treatments, other people have voiced deep-seated concerns. Some have moral or ethical misgivings about embryo research whatever the intention because they believe that destruction of the embryo amounts to taking a life. Others believe that knowledge gained in this country using human embryo stem cells could be used elsewhere to enable human reproductive cloning - a procedure for which there is currently no global ban. Because there have been significant advances in the use of adult stem cells in producing tissues, others think the use of embryos may not be necessary at this stage.

## Pre-implantation genetic diagnosis

When an embryo is created in the laboratory through the fertilisation of an egg by sperm (using *in vitro* fertilisation), its genetic make-up can be examined before the embryo is placed in the woman's womb and grows into a baby. The genes of the embryo can be tested for disease-causing genes and the embryo could be discarded if it is not thought suitable. This process is known as pre-implantation genetic diagnosis (PGD).

## **Human Genetics**

## **Genome Mapping**

The most dramatic scientific development during 2000 was the rapid advance in the sequencing of the genomes of many different organisms. Sequencing is the process of working out the order of the chemical letters making up the genomes (the hereditary information an organism contains). The speed of sequencing has been made possible by parallel developments in computing power (to analyse the data) as well as those in genomics.

On 23rd June, President Clinton and Prime Minister Blair announced that the first draft of the human genome was complete. Scientists and politicians vied with each other to hail the publication of the draft genome in glowing terms. For Clinton, it was: "the most wondrous map ever produced by mankind". For Blair, it was: "a breakthrough that opens the way for massive advancement in the treatment of cancer and hereditary diseases, and that is only the beginning." Mike Dexter of the Wellcome Trust said: "A few months ago, I compared the project to the invention of the wheel. On reflection, it's more than that...this code is the essence of mankind." 18

Before 2000, only one multi-cellular organism, a worm known as *Caenorhhabditis elegans*, had been sequenced. Now, complete sequences have been obtained for two other important experimental species, the fruit fly, *Drosophila melanogaster*, and thale cress, *Arabidopsis thaliana*. Many more microorganisms were sequenced in 2000 including *Vibrio cholerae* (which causes cholera), *Pseudomonas aeruginosa* (a common organism that sometimes causes disease) and *Xylella fastidiosa* (which causes disease in citrus fruits) bringing the total to about 60 microorganisms whose gene sequences are now known<sup>19,20</sup>. In the near future, the genomes of the mouse, zebrafish, rat, and two species of pufferfish are expected to be completed.

Although an amazing achievement, in many ways determining the DNA sequence of an organism is relatively easy. More difficult is understanding what the genes do and how they interact with each other and the environment – known as 'functional genomics'. There are huge gaps in our knowledge and we still do not even have a clear idea of how many genes there are in the human genome - the current consensus is between 30,000 and 100,000<sup>19</sup>. Furthermore, if we are to understand genetic variation between human beings, we clearly need to understand what it is that makes us different from other organisms. At the moment, however, even this is poorly understood: "Sheep are human, basically. Ninety-eight per cent of our genes are the same" (Sue Galloway, University of Otago)<sup>21</sup> and "We share half our genes with the banana" (Robert May, ex-UK Chief Scientist)<sup>22</sup>.

Freedom of access to sequencing data to facilitate research has continued to cause furious rows between scientists. Determining the sequence of an organism and checking its accuracy depends on sharing information between laboratories but private companies, which rely on public data to verify their results, have been criticised for being reluctant to reciprocate freely. The row erupted again at the end of the year when it was revealed that Celera Genomics had submitted a paper to the journal Science on the condition that the raw human sequence data it referred to remained in its own database to which the company would control access<sup>23</sup>. Normal practice would be for the data to be entered on the public database, GenBank.

"We share half our genes with the banana" (Robert May, ex-UK Chief Scientist)

7 out of 10

people had no

confidence in

Government

controls

# The Rush to Patent Life

The control of, and access to, genetic information is causing controversy not only because it raises concerns about fairness and how the best use of basic research can be made in the public interest. but mainly because whoever controls the information will reap the highest financial rewards. The greedy scramble to cash in on genetics is nowhere more obvious that in the rush to patent genes. In October 2000, GeneWatch UK was commissioned by The Guardian to discover the extent to which patents are being applied for and granted on genes and partial gene sequences. The research revealed that a race is on to control the genomes of almost all living organisms and the number of patents which include gene sequences is growing exponentially as progress in genetic research becomes more rapid. During the one month period of the research, the number of human gene sequences claimed in patents rose by 27% from 126,672 to 161,195.

The majority of patents are being applied for by companies based in the US, Japan and Western Europe. As the tables below show, specialist genomic companies are gaining control over the human genome and the agrochemical companies are mopping up the staple crops. The concentration of control in the hands of very few companies is particularly striking.

Table 3: Top 10 human gene sequence patent applications

	applications			
	COMPANY/ INSTITUTE	NUMBER OF SEQUENCES CLAIMED	% OF TOTAL (126,672)	
1	GENSET (France)	36,083	28.5	
2	RIBOZYME (US)	15,863	12.5	
3	GENETICS INSTITUTE (Subsidiary of American Home Products)	9,876	7.8	
4	GENZYME (US)	8,546	6.7	
5	HYSEQ (US)	6,147	4.9	
6	HUMAN GENOME SCIENCES (US)	3,964	3.1	
7	US DEPT OF HEALTH	2,991	2.4	
8	AFFYMETRIX (US)	2,079	1.6	
9	GENENTECH (US)	1,955	1.5	
10	INCYTE (US)	1,755	1.4	
		TOTAL	70.4	

To obtain a copy of The Guardian supplement on patenting genes, send a self-addressed A4 envelope with a 33p stamp to GeneWatch UK.

## **Top Crop and Gene Sequence Patenters**

These data are based on the genes and gene sequence patents claimed by the companies listed and include those held by their main subsidiaries.

Table 4: Top 5 oilseed rape gene patenters

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	COMPANY/ INSTITUTE	SEQUENCES	%OF TOTAL (184)
1	MONSANTO	45	24.5
2	ZENECA	24	13.0
3	CARGILL	23	12.5
4	DU PONT	22	12.0
5	UNIVERSITY OF MICHIGAN STATE	11	6.0
		TOTAL	68.0

Table 5: Top 5 wheat gene patenters

	COMPANY/ OF TOTAL		
	INSTITUTE	SEQUENCES	(288)
1	DU PONT	117	40.6
2	MONSANTO	78	27.1
3	AVENTIS	14	4.9
4	NOVARTIS	12	4.2
5=	CSIRO	8	2.8
5=	GOODMAN FIELDER	8	2.8
5=	LIMAGRAIN	8	2.8
		TOTAL	85.2

Table 6: Top 10 rice gene patenters

	COMPANY/ INSTITUTE	SEQUENCES	%OF TOTAL (537)
1	DU PONT	115	21.4
2	MITSUI	77	14.3
3	UNIVERSITY OF CALIFORNIA	49	9.1
4	MONSANTO	30	5.6
5	NORIN	22	4.1
6	TAKEDA	17	3.2
7	JAPAN TOBACCO	16	3.0
8	NOVARTIS	15	2.8
9	AVENTIS	15	2.8
10	MITSUBISHI	14	2.9
		TOTAL	69.2

Table 7: Top 5 maize gene patenters

	COMPANY/ INSTITUTE	SEQUENCES	% OF TOTAL (2181)
1	DOW **	655	30.3
2	AFFYMETRIX	418	19.2
3	DU PONT	587	26.9
4	MONSANTO	102	4.7
5	ZENECA	83	3.8
		TOTAL	84.9

<sup>\*\*</sup> Ribozyme hold 604 maize patents jointly with Dow

 Table 8: Top 5 soybean gene patenters

	COMPANY/ INSTITUTE	SEQUENCES	%OF TOTAL (523)
1	DU PONT	253	48.4
2	MONSANTO	146	27.9
3	UNIVERSITY OF IOWA	12	2.3
4	CANADIAN MIN AG	10	1.9
5	DOW/AGRI- GENETICS	10	1.9
		TOTAL	82.4

Table 9: Top 5 potato gene patenters

	COMPANY/ INSTITUTE	SEQUENCES	%OF TOTAL (1110)
1	RIBOZYME	796	71.7
2	MONSANTO	62	5.6
3	DANISCO	40	3.6
4	ZENECA	36	3.2
5	NATIONAL STARCH	24	2.2
		TOTAL	85.7

Table 10: Top 3 cotton gene patenters

	COMPANY/ INSTITUTE	SEQUENCES	%OF TOTAL (228)
1	MONSANTO	203	89.0
2	SHANGHI BEITI BIOTECH	6	2.6
3	NOVARTIS	2	0.9
		TOTAL	91.5

As well as patents being applied for on human and crop genes, gene sequences from animals, bacteria and viruses are all being claimed as inventions at an alarming rate. Almost anything that lives is now being patented. For example, US patent 5641669, owned by ICOS Corp, covers a platelet activating factor gene from a dog; Genelabs Technologies own patent US 5578444 on a gorilla foetal alpha gamma globulin gene; Lilly & Co have a European patent pending (EP 764722) on gorilla, chimpanzee and orang-utan leptin genes which they hope to use in the treatment of obesity and diabetes; the US Brigham & Womens Hospital wants to patent (WO 942160) gene sequences from the dolphin involved in red blood cell production; and Florigene is attempting to patent (WO 9732023) a flavenoid gene from the rose to alter flower colour.

GeneWatch believes that gene sequences are not inventions and should not be patentable. By allowing the control of genetic information to be privatised, research into new cures for diseases will be compromised because complex licence agreements will have to be sought to use genes patented by others who often did not understand exactly how the gene functioned or how it could be used in disease treatments.