

**ADVISORY COMMITTEE ON  
GENETIC MODIFICATION**

**THIRD ANNUAL REPORT  
(March 2002)**

## **ADVISORY COMMITTEE ON GENETIC MODIFICATION THIRD ANNUAL REPORT – TO MARCH 2002**

### **1 Background/Introduction**

In last year's annual report, the 1999 governmental review of the advisory and regulatory framework for biotechnology was explained. Its main outcome was the determination that the advisory system should be as open and transparent as possible. It is this emphasis on openness which inspired the first ACGM Open Meeting held in October 2001. Preparations and planning for this major event occupied a large part of ACGM's work in 2001 and consequently is one of the main items covered by the Third Annual Report. It was decided that maximum effort would be put into making the Open Meeting informative to enable the public to find out more about ACGM's members and their work.

A further development in the life of ACGM arose in 2000 when the Health and Safety Commission (HSC) began an internal review of its own advisory committees. It may be recalled that because of that review, ACGM was reconstituted for one year temporarily and its members were appointed for one year in the first instance in a bid to focus firmly on the best way forward for ACGM. The Third Annual Report will describe the outcome of HSC's review and the resultant continuation of ACGM membership and constitution.

This report will also aim, for the first time, to bring to the attention of readers not only information concerning the membership of ACGM's Technical Sub Committee (TSC) but also an outline of the work that it has carried out between April 2001 and March 2002. While ACGM is required to look at the broad issues concerning the contained use of genetically modified organisms and micro-organisms (GMOs and GMMs), TSC's remit is to look at and advise on the more detailed scientific aspects.

Finally, as we are all too well aware, the year 2001 will be remembered as the one in which the world was rocked by the September 11 attacks on the World Trade Centre. The consequences of that momentous event have been far-reaching. Indeed, the resultant ripple effect has extended as far as the world of genetically modified organisms in containment. It led to the temporary closure of the Public Register of premises and activities involved in contained use of GMOs. This was followed by an amendment to the Genetically Modified Organisms (Contained Use) Regulations 2000 and the reopening of a modified Register excluding certain sensitive information in accordance with wider Government policy on the question of national security. This report explains what has been happening in this field and ACGM's and TSC's important input. Both ACGM and TSC members have given their invaluable advice on these difficult issues as matters have unfolded. ACGM continues to be kept informed and consulted.

## **2 Genetic Modification (GM) and Genetically Modified Organisms, (GMOs)**

In order to clarify for the wider public who may read this Annual Report, it is important to explain what is meant by genetic modification.

Genetic modification (GM) occurs where the genetic material of an organism (either DNA or RNA) is altered by use of a method that does not occur in nature and the modification can be replicated and/or transferred to other cells or organisms. Typically, GMM involves the removal of DNA, its manipulation outside the cell and reinsertion into the same or another organism. The aim of GM is often to introduce a new or altered characteristic to the target organism.

The organism which has been modified is referred to as a genetically modified organism (GMO). GMOs may be plants, animals or (most commonly) micro-organisms (including bacteria, viruses parasites and fungi). Where the GMO is a micro-organism it is typically referred to as a genetically modified micro-organism (GMM).

An important point to note about GMOs is that in the case of humans, even if they have undergone genetic modification as a result of, for example, gene therapy, they are never GMOs. This is because humans are specifically excluded from the definition of an organism. The result is that the contained use legislation (the Genetically Modified organisms (Contained Use) Regulations 2000 (GMO(CU)) does not apply to humans.

## **3 Contained Use**

It is similarly important to clarify what is meant by 'contained use'. ACGM's remit is limited to consideration of 'contained use'. Contained use is where control measures are used to limit contact between GMOs and humans and the environment so as to provide a high level of safety. In practice, this involves work in laboratories, animal houses, plant growth facilities (including growth rooms in buildings and suitable glasshouses) and large scale production facilities on industrial sites. All of these activities are regulated under GMO(CU). There are also controls on the environmental aspects of GM animals and plants under the Environmental Protection Act 1990.

Matters that do not fall under contained use and are hence outside of the remit of ACGM include:

- Deliberate release of GMOs into the environment (e.g. crop plants in fields):
- Food safety aspects;
- Product approval/marketing approval.

ACGM also does not get involved in some areas closely related to contained use, but for which there are other specific advisory bodies. These include matters of animal welfare and patient safety (e.g. in relation to gene therapy). Whilst ACGM does not advise on patient safety with regard to gene therapy, where the therapy administers GMMs, this has usually constituted a contained

use activity although ACGM or TSC could be asked to advise on safety in relation to the medical safety of staff, patients' relatives and other close contacts of the patient.

#### **4 Outcome of HSC's internal review of its Advisory Committees**

In mid-September 2000, the Health and Safety Commission began a major review of all of its advisory committees, of which ACGM is one. The review was to provide the Commission with the opportunity to reflect on the scope and coverage of its advisory committees. However, that review was overtaken by the Commission's own more strategic review of its ways of working and the sort of advice and information it needs for the future. In practice this meant that the discussion document envisaged in the original advisory committee review plan was not considered necessary.

On November 15, 2001, Bill Callaghan, Chairman of HSC, wrote to all advisory committee members confirming that the Commission had reached a clear understanding about its future needs. In it he concluded that in recognition of the changing world of work, the present system of advisory committees should be allowed to evolve in a flexible way and that the arrangements as they existed at that time were perhaps too restrictive to allow that to happen quickly or effectively. The Commission therefore recognised the need to take a first step to free up the system so that it could begin the process of change. On this basis, it has taken the view that, while it wishes to retain contact with advisory committees, it should direct HSE to appoint and reimburse members of advisory committees, review current work plans and appointment of members to existing committees and arrange the reconstitution of existing committees and the creation of any new ones. At the same time, the Commission will continue to receive information from committees about progress towards achieving outcomes in HSC's Strategic Plan and will continue to expect advisory committees to draw to its attention matters of concern. HSC may also seek a direct dialogue with committees on specific issues from time to time. In line with the Commission's wish, HSE will retain the current tripartite (i.e. employer, employee and independent) nomination arrangements for members who will continue to be selected on merit.

One of the things the Commission will need in the run-up to its consideration of the next strategic plan in the early part of 2003 is a horizon-scanning review of future science and health issues. The aim is to ensure that the next HSC Strategic Plan is informed by the best available view of the future from a scientific and technological perspective. HSC will be looking to ACGM to take the leading role in developing this advice in relation to the contained use of GMOs.

## **5 ACGM's Terms of Reference (from April 2000)**

**To advise the Health and Safety Commission and Executive, the Secretary of State, the First Minister of the National Assembly for Wales and Scottish Ministers on all aspects of human and environmental safety of the contained use of genetically modified organisms. In developing its advice, ACGM shall take account of the work of the Food Standards Agency (FSA), the Human Genetics Commission (HGC) and, in particular, the Agriculture and Environmental Biotechnology commission (AEBC).**

These Terms of Reference have not changed other than to exclude reference to the MAFF Minister since MAFF no longer exists as a Ministry (its function having been absorbed by the Department for the Environment, Food and Rural Affairs (DEFRA)).

## **6 Extension of Existing Constitution and Membership**

The reconstituted Committee, appointed in December 2000, was originally appointed for one year (until the end of December 2001). This short initial period of office, together with the appointment of an HSE officer, Mrs Sandra Caldwell, as Chair, was made in order not to pre-empt the concomitant HSC review of its advisory committees. The Committee reflected the minor but significant changes brought about by the reconstitution which took place in April 2000. These minor changes namely of introducing, in addition to the usual employee and employer representatives and independent members (reflecting the tripartite nature of the Committee), the appointment of an expert in the social science field of risk perception and also an additional lay member. The Committee also continued to reflect, among its newly appointed independent members, the vital contingent of independent scientific and technical expertise in virology, bacteriology, industrial production, safety management, ecology, GM animals and plants as well as the newly introduced field of public perception.

Following the advisory committee review, HSC made clear its expectations that HSE would look closely at simplifying considerably the procedures for constitution, reconstitution, planning and monitoring progress as well as inheriting HSC's duties to appoint, reappoint and reimburse committee members. In ACGM's case, HSE took the decision for the time being simply to extend members' appointments in order to enable the committee to run for a full three years with the same membership thus providing committee continuity, identity and cohesion. In the same manner and in order to provide that same continuity, the extension of the HSE Chair seemed most appropriate and practical. HSE wrote to members to this effect early in 2002 extending their term of office until the end of December 2003. Towards the end of that period of ACGM office, HSE will reflect on the nature of ACGM, its membership, its Technical Sub Committee and the future and best way forward to provide HSC with advice on matters relating to the contained use of GMOs.

## 7 This year's membership of ACGM

Member	Nominated by / Independent	Employer
Mrs Sandra Caldwell (Chair)	HSE, Director of Health	HSE
Dr Gary Burns	CBI <sup>1</sup> (employer organisation)	AstraZeneca
Dr Jonathan Butler	Independent	MRC
Mrs Dot Carey	TUC <sup>2</sup> (employee organisation)	Retired, formally of NERC Centre for Ecology and Hydrology, Oxford
Dr Robert Dalziel	Independent	University of Edinburgh
Mr Spyros Elia	Independent	Thomas Tallis School
Dr Lynn Frewer	Independent	Institute of Food Research
Dr Penny Hirsch	Independent	Rothamsted Research
Dr John Keddie	CBI (employer organisation)	GlaxoSmithKline
Prof. Julian Kinderlerer	TUC (employee organisation)	University of Sheffield
Dr Tom Loeffler (appointed from April 2001)	TUC (employee organisation)	BBSRC
Mr Robert Osborne	CVCP <sup>3</sup> (employer organisation)	University of Glasgow
Professor Bert Rima	Independent	Queens University Belfast
Dr Brian Robertson	Independent	Imperial College
Mr Roger Spiller	TUC (employee organisation)	MSF Union
Prof. Anthony Trewavas FRS	Independent	Institute of Cell and Molecular Biology, Edinburgh
Dr Bruce Whitelaw	Research Councils (employer organisation)	Roslin Institute
Professor David Wynford-Thomas	Independent	University of Wales College of Medicine

1 <sup>1</sup>CBI - Confederation of British Industry

2 <sup>2</sup>TUC - Trades Union Congress

3 <sup>3</sup>CVCP - Committee of Vice Chancellors and Principals

Dr Janet Radcliffe-Richards who was initially a member has since expressed her wish to stand down and so there are now 18 members including the Chair. The Register of Members' Interests is given at Annex 1.

## 8 Technical Sub Committee

The Technical Sub Committee was set up to provide detailed technical advice to ACGM and to HSE on scientific developments involving GM. During the year it continued in this role, providing advice on a number of emerging topic areas, as well as giving detailed comments on a number of notifications made under the Genetically Modified Organisms (Contained Use) Regulations. The membership of the TSC is primarily drawn from independent experts selected to reflect current developments in the field. There is also a nominee from the TUC, and a nominee from the CBI, and up to 10 independent experts. The current membership is shown below:

Member	Nominated by / independent	Employer
Mr Steve Vbranch (chair)	Independent	Jacobs Engineering
Dr Gary Burns	Independent	Astra Zeneca
Dr Iain Cooper	Independent	Institute for Virology and Environmental Microbiology
Mr Steve Eley	Independent	DERA, Porton Down
Dr Penny Hirsch	Independent	Rothamstead Research
Dr Julian Kinderlerer	TUC (employee organisation)	University of Sheffield
Dr Mike Mackett	Independent	Paterson Institute
Dr Joanna Marshall	Independent	Oxford University
Dr Sue Mayer	Independent	GeneWatch
Dr Phil Minor	Independent	National Institute for Biological Standards and Control
Professor Tony Minson	Independent	Cambridge University
Professor Rick Randall	Independent	University of St. Andrews
Mr John Thorley	CBI (employer organisation)	Consultant
Professor Douglas Young	Independent	St. Mary's Hospital, London

There have been several changes in membership during the year. Professors Tony Minson and Douglas Young have both resigned due to workload commitments. Dr Mike Mackett has taken up a new post, and cannot continue as a member of the TSC. Dr Peter Searle (Birmingham University)

and Dr Peter Coyle (Royal Victoria Hospital, Belfast) have agreed to join the TSC. Other appointments will be made as appropriate to reflect current developments in the field.

The TSC met twice during the year, and covered a range of topics, including genetic modification of picornaviruses, cloning of immune modulating genes, developments in gene therapy, genetic modification of mycobacteria, and genetic modification of RNA viruses. Advice from the committee was fed into the notification process, and is also being used to draft new guidance to be circulated to GM centres, and disseminated in ACGM Newsletters.

The TSC was also consulted over the development of emergency legislation following the terrorist attacks on September the 11<sup>th</sup>. Further details are given in section 10 of this report.

## **9 First Annual Report (April 2001 - Mar 2002) to the Competent Authority on notifications processed under the Genetically Modified Organisms (Contained Use) Regulations 2000 as amended**

For the first year the Competent Authority (CA) has formally collected figures on the numbers/types of notifications for information on trends and also in order to assist in resource management.

### **Numbers and types of notifications**

At the beginning of the year, HSE cleared the outstanding renotifications (England 510/ Scotland 37/ Wales 22) made under the transitional arrangements. Concurrently, we were processing completely new notifications . These new notifications break down as:

<b>For the period 1/April/ 2001 to 31/March/2002</b>			
<b>Notification</b>	<b>Number in England</b>	<b>Number in Scotland</b>	<b>Number in Wales</b>
Class 2 (first) Reg 10	54	11	6
Class 2 (subsequent) Reg 10	131	23	3
Class 3 (first) Reg 11	12	2	0
Class 3 (subsequent) Reg 11	17	1	0
Class 4 (first) Reg 11	1	0	0
Class 4 (subsequent ) Reg 11	0	0	0
Premises (for Class 1 only) Reg 9	29	7	1
Premises (for other classes ) Reg 9	15	2	0
Significant change Reg 15	16	0	0
Compliance with conditions of consent	0	1	0
Compliance with imposed conditions	6	0	0
Derogation after notification Reg 18	12	1	0
Confidentiality claim after notification	0	1	0
<b>Total</b>	<b>293</b>	<b>49</b>	<b>10</b>

There is a continuing upward trend in the overall numbers of notifications. For comparison, numbers for previous years are given below:

## Notifications under the Genetically Modified Organisms (Contained Use) Regulations 1992

Year April 1- Mar 31	Notifications processed					
	Reg 8 consent premises	Reg 8 no consent premises	Reg 9 no consent activity	Reg 9 consent activity	Reg 10(4) change	Total
93*	2 <sup>1</sup>	4	1	0	0	6 +1 <sup>1</sup>
93-94	127 <sup>2</sup>	20	73	0	1	101 + 120 <sup>2</sup>
94-95	28 <sup>3</sup>	25	84	0	50	163 +24 <sup>3</sup>
95-96	8	12	80	0	62	162
96-97	16	18	64	0	42	140
97-98	16	19	100	0	45	180
98-99	14	23	93	0	75	205
99-00	12	28	109	0	88	237
00- end**	5	20	68	0	50	143**

\* came into force on 1st Feb 93

1 1 was a re-notification from the 82 Regs

2 120 were re-notifications from the 82 Regs

3 24 were re-notifications from the 82 Regs

\*\* Genetically Modified Organisms (Contained Use) Regulations 1992 as amended ceased on 14/11/2000. Numbers in this row should be added to those for the remainder of the year under the 2000 Regs

4 1289 were re-notifications from the 92 Regs

## Notifications under the Genetically Modified Organisms (Contained Use) Regulations 2000

Year April 1st-31 March	Notifications processed											
	Premises		Activities									Total
	Class 1/ non notifiable non- GMMs	Class 2/3/4/notifi able non- GMMs	Class 2 first	Class 2 subsequ ent	Class 3 first	Class 3 subsequ ent	Class 4 first	Class 4 subse quent	Notifia ble non- GMMs	Significa nt changes	Deroga tions	
Start - 2001	10	5	33	20	5	8	1	0	0	6	1	89**+ 1289 <sup>4</sup>
01-02	37	17	71	157	14	18	1	0	0	16	13	344

### 10 Open Meeting

The first ACGM Open Meeting was held on October 30 2001 as a direct response to the Government's 1999 Review and 'The Advisory and Regulatory Framework for Biotechnology Report' calling for openness and transparency to ensure that the public can engage with the work of advisory

committees. In addition, it was a response to the HSC's Code of Practice for Advisory Committees, which encourages the holding of an annual open meeting for members of the public to attend.

In addition to ACGM members and Secretariat devoting a great deal of 'behind-the-scenes' time and effort towards the Open Meeting, members attended four meetings this year: on 2 October, a special 'Pre-meeting' on the morning of 30 October, the main Open Meeting on the afternoon of 30 October, and a February meeting. These meetings were largely taken up with preparations for and planning of the Open Meeting and a review afterwards.

It was felt that for this new venture, a special effort would be made. Rather than simply opening up an 'ordinary' meeting for the public to view as onlookers, it was agreed that the meeting would take on a format specifically devised to inform the public about contained use of GMOs – what it is and what it is not; the legislation that governs it; and ACGM's role and current work plan (December 2000 – December 2003). A further aim was to give the public a glimpse of the types of GM activities that are now taking place in containment and of the issues surrounding them. Finally, it was necessary to explain to the public that ACGM, like all other HSC advisory committees was under review and was not itself static but was flexible and subject to change/develop as new needs and biotechnological progress might dictate. Coincidentally, shortly after the ACGM event, the Office of Science and Technology (OST) published the 'Code of Practice for Scientific Advisory Committees', in December 2001, to promote good practice in the operation of committees and their relationship with government. It advises that committees should aim to hold open meetings on a regular basis (or provide equivalent opportunities for direct public access) and that Open meetings may need to be organised in a different way from a committee's normal meetings.

The Secretariat looked at the best mechanism for advertising the event. Discussion with another government department had indicated that use of the national press may not yield results. Clearly, the contained use of GMOs is a very specialised subject and the extent of interest which the lay public might have is likely to be small. On the other hand, the GM community (both academic and business) were likely to be very interested in attending an open meeting. It was therefore decided to send out a flyer, advertising the event to 850 addressees covering a range of people. Roughly half comprised GM centres known to HSE because of their obligation to register premises and notify GM contained use activities. The rest was made up of environmental groups e.g. Friends of the Earth, GeneWatch, Greenpeace; employer and employee organisations; associations; professional bodies; societies; women's groups; educational establishments and similar organisations.

The venue, timing and details of the meeting format was discussed at length with ACGM members. Views were sought and much planning ensued. In order to remain within budgetary constraints, HSE's London headquarters was chosen to host the meeting. The final meeting plans included an invitation to four external experts to come and join 'counterpart' ACGM members and take part in four twenty-minute 'dialogue sessions' to be held in front of the

audience. For each dialogue session a topic area (GM animals, GM plants, GMMs and environmental issues) was chosen. It was also decided to hire a professional facilitator to lead and encourage audience debate/ discussion since this constituted a major part of the event and two 50 minute slots were allotted to allow the audience to participate fully in them.

Within two weeks of sending out the flyer, 'full house' status had been reached. Invitations had been issued on a strictly first-come-first-served basis. A total of 85 seats were filled, 60 of whom represented the GM community.

Some of the issues which seemed to be of particular interest to the GM community and environmental groups were:

- waste disposal;
- risk assessment;
- notification fees;
- public perception of risks associated with GM;
- horizontal gene transfer.

These were not unexpected areas of discussion and they will continue to provide 'food for thought' for ACGM in the future.

In the information packs issued to each member of the audience were evaluation sheets. The Secretariat also sought comment from members after the event. The general consensus was that the event had been a success. Certainly, the provision of discussion/question time for the audience was appreciated and regarded as important to the point that some felt even more time should have been allowed for this. There was an indication that while those with a scientific background would have liked more detailed/in depth discussion, some lay members of the audience found some of the language/issues difficult to understand. Clearly, wherever a public audience is involved this is bound to be an issue which is difficult to resolve.

Special thanks for participation in the dialogue sessions must go to the visiting experts namely: Professor Douglas Young of Imperial College; Dr Stephen Harris of GlaxoSmithKline's Medicines Research Centre, Dr Chris Gliddon of the University of Wales, Bangor and Dr Sue Mayer of GeneWatch UK (also a member of TSC) and to their ACGM counterparts: Dr Jo Butler, Dr Bruce Whitelaw, Dr Penny Hirsch and Dr Gary Burns who gave extra time, above and beyond their normal duties as ACGM members, in preparation for this special contribution to the Open Meeting. Mrs Sandra Caldwell and the Secretariat especially appreciate their individual contributions.

Having embarked on the route of open meetings with this special meeting, it was concluded by members at the ACGM meeting on February 12 2002, that although this had been a very good start to openness and transparency of meetings and it had clearly attracted a full audience, it was not a sustainable format for every open meeting in the future. It had been a very useful way of introducing ACGM and its work into the public eye but it was decided that it could now be followed by simpler and less time consuming open meetings in

the future. It was also agreed that wherever possible future ACGM meetings would be open.

## **11 The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002**

Shortly after the terrorist attacks of September 11, enquiries were made to HSE about the location of a particular GM pathogen. As guardian of the Public Register of notified premises and activities involving GM contained use work, HSE was faced with a dilemma. The dilemma was that of openness versus national security. In order to act quickly and decisively in the unusually sensitive political climate which followed in the wake of the attacks on the World Trade Centre, HSE closed the Register temporarily. This was a practical short-term step since, if it were deemed necessary, sifting through the Register to remove certain dangerous pathogens which might be of interest to terrorists would take time, scientific and political consultation and manpower (the Register is held in a number of hard copies up and down the country). HSE, informed other members of the Competent Authority (DEFRA and the Scottish Executive) who oversee the administration/enforcement of GMO(CU).

The Public Register was withheld temporarily from public scrutiny on 18 October and at the ACGM Open Meeting on 30 October, the Chair announced this unprecedented step to the audience. It was explained that HSE had, in the meantime, however, made arrangements for access to the Register to be continued on a case-by-case basis in order to meet the public's expectation of and the Competent Authority's commitment to openness, as far as possible, in these unforeseen circumstances.

It should be explained that provision and maintenance of the Register is a requirement of GMO(CU). After seeking legal advice and the views of other government departments, HSE, on behalf of the Competent Authority set about the task of drawing up draft amending regulations which would allow the Secretary of State to require certain information to be kept confidential in the interests of national security and for him to give directions to the Competent Authority to exclude certain information for national security reasons.

Readers may be aware, that at the same time that HSE was dealing with this particular matter, the Government was drawing up the Anti-terrorism Crime and Security Bill with broad sweeping provisions relating to national security. This became law in December 2001 as the Anti-terrorism, Crime and Security Act 2001 (the 2001 Act).

ACGM members were consulted on the draft amending regulations. The unprecedented circumstances which had given rise to the Amending Regulations had meant that ACGM members were consulted as individuals rather than as a committee. The urgency of the circumstances and the speed with which matters developed lent no time to hold an extra ACGM meeting to

discuss the matter. However, individual member responses provided a mix of views which the Secretariat took into consideration.

A long list of consultees were also asked to consider the draft amending regulations. The broad majority response was in favour of the amending regulations and, as a result, the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002 were signed by the Minister on 16 January 2002 and laid before Parliament.

In the meantime, ACGM Secretariat had also asked for the specialist scientific advice of ACGM's Technical Sub Committee at its meeting on 23 January 2002. TSC were asked to consider which GM pathogens and toxins, if any, should be listed in the Secretary of State's Direction (arising from the Amending Regulations) and so excluded from the Register. TSC members expressed their concern for openness and some members had difficulty with the idea of withdrawing information from the Register which is already in the public domain through academic papers and the research network. There was, however, a degree of understanding of the difficulty facing HSE on behalf of the Competent Authority in maintaining a central, Government-sponsored, comprehensive and concise list of all GM activities, including dangerous pathogens and their locations - in the light of the 11 September and its aftermath. TSC were also informed that there are plans to make the presently held hard-copy information available on the internet, which would allow more anonymous access to such information in the future.

Members of TSC made clear the scientific difficulties in defining a comprehensive list of pathogens/toxins about which information should be withheld from the Register. Some members were understandably concerned that withdrawal of certain information would do little to build confidence in relation to biological weapons control. (This matter was, in fact also raised by a few respondents to the Amending Regulations Consultation exercise. As a consequence HSE contacted the Ministry of Defence (MOD) on this issue and were informed that such action would not cut across the Biological and Toxin Weapons Convention.)

There was much debate among members, after they were presented with various options for a way forward on this matter. The options ranged from reopening the Register unabridged, to compiling their own considered list of pathogens/toxins for removal, to employing the 2001 Act's Schedule 5 (a list of human pathogens and toxins to which increased security measures, in terms of premises and personnel, had been introduced) either alone or together with an additional list compiled by members, as the basis for exclusion of information from the Register. The Committee concluded and recommended that, for the present, the Secretary of State should authorise the withholding from the Register of information concerning the location and GM activities relating to the pathogens listed in Schedule 5 of the 2001 Act. By so doing, TSC's decision provided consistency with the Government's new anti-terrorism legislation.

To underline their concern for openness, TSC members did however recommend that the Register should make clear that work is taking place in Great Britain on the pathogens/toxins excluded from the Register. TSC requested that they be listed in the Register but that no details of the activities taking place or of their location be included and it was felt that this would go some way to alleviate the concerns of some, namely that the public have a right to know which pathogens/toxins are being used in genetic modification work in Great Britain.

As a result, of the foregoing, the Amending Regulations came into force on 8 February 2002 and the Direction was signed by the Minister on 9 February 2002. The Register was sifted to exclude relevant items and reopened to the public on 11 February.

TSC also recommended that the matter of exclusion of information from the Register be kept under annual review. As a consequence, a review for 2002/2003 is planned and is already underway.

## **12 ACGM Meeting of 12 February 2002**

At ACGM's final meeting of the year, the Secretariat updated members on the position relating to the Register and explained that a brief guide to the Amending Regulations was in preparation and near publication.

In addition to other matters already covered by this Annual Report, it was concluded at this final meeting of the year that ACGM members would value more information on other biotechnological committees which advise government. The Committee also wished to forge closer links with its own Technical Sub Committee. The Secretariat took note of these requests and have since produced a paper mapping out the external biotechnology environment of ACGM and the responsibilities of other biotechnology Advisory Committees. It has also included a summary of TSC's work in this year's Annual Report. In addition, a joint horizon-scanning exercise is planned to include ACGM, TSC and the Advisory Committee on Releases into the Environment (ACRE).

Identification of the need for closer links and joined-up working where appropriate with other Advisory Committees and the wider biotechnology arena should prove both interesting and useful in the coming year.

## **GLOSSARY**

<b>ACGM</b>	Advisory Committee on Genetic Modification
<b>ACRE</b>	Advisory Committee on Releases into the Environment
<b>AEBC</b>	Agricultural & Environmental Biotechnology Commission
<b>CBI</b>	Confederation of British Industries
<b>CVCP</b>	Committee of Vice Chancellors and Principals
<b>DNA</b>	Deoxyribonucleic acid – present in almost all living cells and contains information coding for cellular structure, organisation and function
<b>DEFRA</b>	Department for the Environment, Food and Rural Affairs
<b>FSA</b>	Food Standards Agency
<b>GM</b>	Genetic Modification
<b>GMM</b>	Genetically Modified Micro-organism
<b>GMO</b>	Genetically Modified Organism
<b>GMO(CU)</b>	Genetically Modified Organisms (Contained Use) Regulations 2000
<b>HGC</b>	Human Genetics Commission
<b>HSC</b>	Health and Safety Commission
<b>HSE</b>	Health and Safety Executive
<b>MAFF</b>	Ministry of Agriculture, Fisheries and Food
<b>MOD</b>	Ministry of Defence
<b>RNA</b>	Ribonucleic acid – the alternative reservoir of genetic information to DNA
<b>TSC</b>	Technical Sub Committee (of ACGM)
<b>TUC</b>	Trades Union Congress

## ANNEX 1

## REGISTER OF ACGM MEMBERS' INTERESTS

ACGM members have declared the following commercial and non-commercial interests deemed relevant to their appointment to the ACGM.

**Note:** Share holdings only declared if over £25,000

Member's Name	Interest
<b>Chair</b>	
Mrs Sandra Caldwell	<b>Employer:</b> <input checked="" type="checkbox"/> Health and Safety Executive <b>Commercial Interests:</b> <input checked="" type="checkbox"/> None <b>Non-commercial Interests:</b> <input checked="" type="checkbox"/> None
<b>Employer Nominees</b>	
Dr Gary Burns	<b>Employer:</b> <input checked="" type="checkbox"/> AstraZeneca <b>Commercial Interests:</b> <input checked="" type="checkbox"/> None <b>Non-commercial Interests:</b> <input checked="" type="checkbox"/> None
Mr Robert Osborne	<b>Employer:</b> <input checked="" type="checkbox"/> University of Glasgow <b>Commercial Interests:</b> <input checked="" type="checkbox"/> None <b>Non-commercial Interests:</b> <input checked="" type="checkbox"/> None
Dr C Bruce A Whitelaw	<b>Employer:</b> Roslin Institute (Edinburgh) <b>Commercial Interests:</b> <input checked="" type="checkbox"/> None <b>Non-commercial Interests:</b> <input checked="" type="checkbox"/> Most research is funded by the BBSRC. Currently some research is funded through a consortium of Pharmaceutical Companies (AstraZeneca; Aventis; Cyclacel; GlaxoSmithKline; Novartis; Novo Nordisk; Pharmacia; Pfizer; Schering Plough and Wyeth) - approx funding 200K per annum. <input checked="" type="checkbox"/> Editor of internationally peer reviewed scientific journal, Transgenic Research, published by Kluwer (Netherlands).
Dr John R Keddie	<b>Employer:</b> <input checked="" type="checkbox"/> GlaxoSmithKline <b>Commercial Interests:</b> <input checked="" type="checkbox"/> GlaxoSmithKline Shares held by Dr Keddie and his spouse. <b>Non-commercial Interests:</b> <input checked="" type="checkbox"/> None
<b>Employee Nominees</b>	
Mrs Dot Carey	<b>Employer:</b> Retired (Formerly of MEM of Oxford) <b>Commercial Interests:</b> <input checked="" type="checkbox"/> None <b>Non-commercial Interests:</b>

Member's Name	Interest
	<input checked="" type="checkbox"/> None
Mr Roger Spiller	<b>Employer:</b> <input checked="" type="checkbox"/> MSF(Management, Science, Finance) <b>Commercial Interests:</b> <input checked="" type="checkbox"/> None <b>Non-commercial Interests:</b> <input checked="" type="checkbox"/> None
Dr Julian Kinderlerer	<b>Employer:</b> <input checked="" type="checkbox"/> University of Sheffield <b>Commercial Interests:</b> <input checked="" type="checkbox"/> Occasional consultancy to UNEP and UNIDO re GMOs. <b>Non-commercial Interests:</b> <input checked="" type="checkbox"/> Adviser to UNEP, UNIDO and various governments including Namibia and South Korea on safe use of GMOs.
Dr Tom Loeffler	<b>Employer:</b> <input checked="" type="checkbox"/> Biotechnology and Biological Sciences Research Council (BBSRC) <b>Commercial Interests:</b> <input checked="" type="checkbox"/> None <b>Non-commercial Interests:</b> <input checked="" type="checkbox"/> None
<b>Independent Members</b>	
Dr Lynn Frewer	<b>Employer:</b> <input checked="" type="checkbox"/> Consumer Science Section, Institute of Food Research <b>Commercial Interests:</b> <input checked="" type="checkbox"/> None <b>Non-commercial Interests:</b> <input checked="" type="checkbox"/> BBSRC - CASE award with Unilever - in the area of food risk communication.
Professor Anthony Trewavas FRS	<b>Employer:</b> <input checked="" type="checkbox"/> Institute of Cell and Molecular Biology <b>Commercial Interests:</b> <input checked="" type="checkbox"/> None <b>Non-commercial Interests:</b> <input checked="" type="checkbox"/> Helps administer a grant from AKFADIX (California) to five plant science academic staff in the University of Edinburgh. No payment or research support is received from this grant. The grant is for a gene discovery programme. <input checked="" type="checkbox"/> On the Governing Council of the John Innes Centre
Dr P. Jonathan G. Butler	<b>Employer:</b> <input checked="" type="checkbox"/> The Medical Research Council, Laboratory of Molecular Biology <b>Commercial Interests:</b> <input checked="" type="checkbox"/> None <b>Non-commercial Interests:</b> <input checked="" type="checkbox"/> Acts as Biological Safety Officer in MRC Laboratory of Molecular Biology and as Biological Safety Adviser to several MRC units

Member's Name	Interest
	<p>in Cambridge (and occasionally MRC Safety Section).</p> <p><input checked="" type="checkbox"/> Acts as paid consultant in biological safety to the Sanger Centre, Hinxton, Cambridge. (This is a non - commercial laboratory established and supported by the Wellcome Trust and MRC).</p>
Dr Robert G Dalziel	<p><b>Employer:</b></p> <p><input checked="" type="checkbox"/> University of Edinburgh.</p> <p><b>Commercial Interests:</b></p> <p><input checked="" type="checkbox"/> None</p> <p><b>Non-commercial Interests:</b></p> <p><input checked="" type="checkbox"/> Project Grant."Characterisation of a model of Post Herpetic Neuralgia", GlaxoSmithKline - £200,000 until 30/07/03.</p>
Dr Brian D. Robertson	<p><b>Employer:</b></p> <p><input checked="" type="checkbox"/> Imperial College of Science, Technology and Medicine.</p> <p><b>Commercial Interests:</b></p> <p><input checked="" type="checkbox"/> None</p> <p><b>Non-commercial Interests:</b></p> <p><input checked="" type="checkbox"/> None</p>
Dr Penny Hirsch	<p><b>Employer:</b></p> <p><input checked="" type="checkbox"/> Rothamsted Research</p> <p><b>Commercial Interests:</b></p> <p><input checked="" type="checkbox"/> None</p> <p><b>Non-commercial Interests:</b></p> <p><input checked="" type="checkbox"/> BBSRC - CASE studentship.</p> <p><input checked="" type="checkbox"/> Industrial sponsor Syngenta, to start 2001 (Syngenta give some support to the student, none to Rothamsted or Dr Hirsch).</p>
Professor Bert Rima	<p><b>Employer:</b></p> <p><input checked="" type="checkbox"/> Queen's University Belfast</p> <p><b>Commercial Interests:</b></p> <p><input checked="" type="checkbox"/> Consultant to Lovells (65 Holborn Viaduct, London</p> <p><b>Non-commercial Interests:</b></p> <p><input checked="" type="checkbox"/> Assistant Director in Research in the Northern Ireland Health and Social Services Research and Development Office. (Seconded from the University 50% of his time).</p> <p><input checked="" type="checkbox"/> Director of Ulidia Housing Association Limited in Northern Ireland.</p>
Mr Spyros Elia	<p><b>Employer:</b></p> <p>Thomas Tallis School</p> <p><b>Commercial Interests:</b></p> <p><input checked="" type="checkbox"/> None</p> <p><b>Non-commercial Interests:</b></p> <p><input checked="" type="checkbox"/> None</p>
Professor David Wynford -Thomas	<p><b>Employer:</b></p> <p><input checked="" type="checkbox"/> University of Wales College of Medicine</p> <p><b>Commercial Interests:</b></p> <p><input checked="" type="checkbox"/> None</p> <p><b>Non- commercial Interests:</b></p> <p>None</p>

