

**ADVISORY COMMITTEE ON  
GENETIC MODIFICATION**

**FIRST ANNUAL REPORT  
(MARCH 2000)**

## **ADVISORY COMMITTEE ON GENETIC MODIFICATION**

### **FIRST ANNUAL REPORT - TO MARCH 2000**

#### **CHAIRMAN'S FOREWORD**

The science of genetic modification is a late twentieth century one. Compared to the more traditional scientific fields of endeavour, it is in its infancy. It was initially recognised that the technology may need careful monitoring and this worked well. However, the full impact of genetic modification on society has only become apparent in the last decade. It is recognised that these developments need careful attention and an appropriate level of control to ensure they reach full potential with safety and integrity. Its implications for mankind are vast and probably, as yet, only partly imagined.

The safety of discoveries and advances made by experimentation with genetically modified organisms (GMOs) in containment come under the watchful remit of the Advisory Committee on Genetic Modification (ACGM). It is ACGM's role to develop safety principles for such experimentation in genetic modification. In order to achieve this, it is necessary to have an objective and clear sighted view of the technology of genetic modification to ensure that it is managed safely by all those involved. Since its inception, ACGM has worked consistently to oversee the development of a framework of controls to provide a high level of protection to human health and the environment while still allowing society to reap the many benefits.

Britain is not alone in its concern to protect humankind and the environment while at the same time enabling scientific advancement. Indeed, it is the recent amendment to the European Union Directive 90/219/EEC which has occupied centre stage in ACGM's work this year. Other member States of the European Union are working towards the same goal - to enable the science of genetic modification to move forward while at the same time ensuring safe practices and so protecting human health and the environment.

**Professor Kay E. Davies**

**Chairman, ACGM**

## **ACGM's ROLE**

- **Brief historical background to ACGM**

In the 1970s, the Government set up a working party to consider the technology of genetic modification (GM). It recommended that because of the potentially great benefits, GM work should continue but with strict safeguards because of the degree of uncertainty involved. The Genetic Manipulation Advisory Group (GMAG) was set up to examine proposals for work involving the construction of genetically modified organisms (GMOs) and regulations were introduced in 1978 under the Health and Safety at Work etc. Act 1974 to require notification to GMAG. It was in 1984 that GMAG became the Health and Safety Commission's Advisory Committee on Genetic Modification (ACGM). In 1989, the regulations were extended to cover the use (as opposed to just construction) of GMOs and the release of GMOs to the environment, though the purpose of the legislation was restricted to the protection of human health and did not extend to the environmental protection.

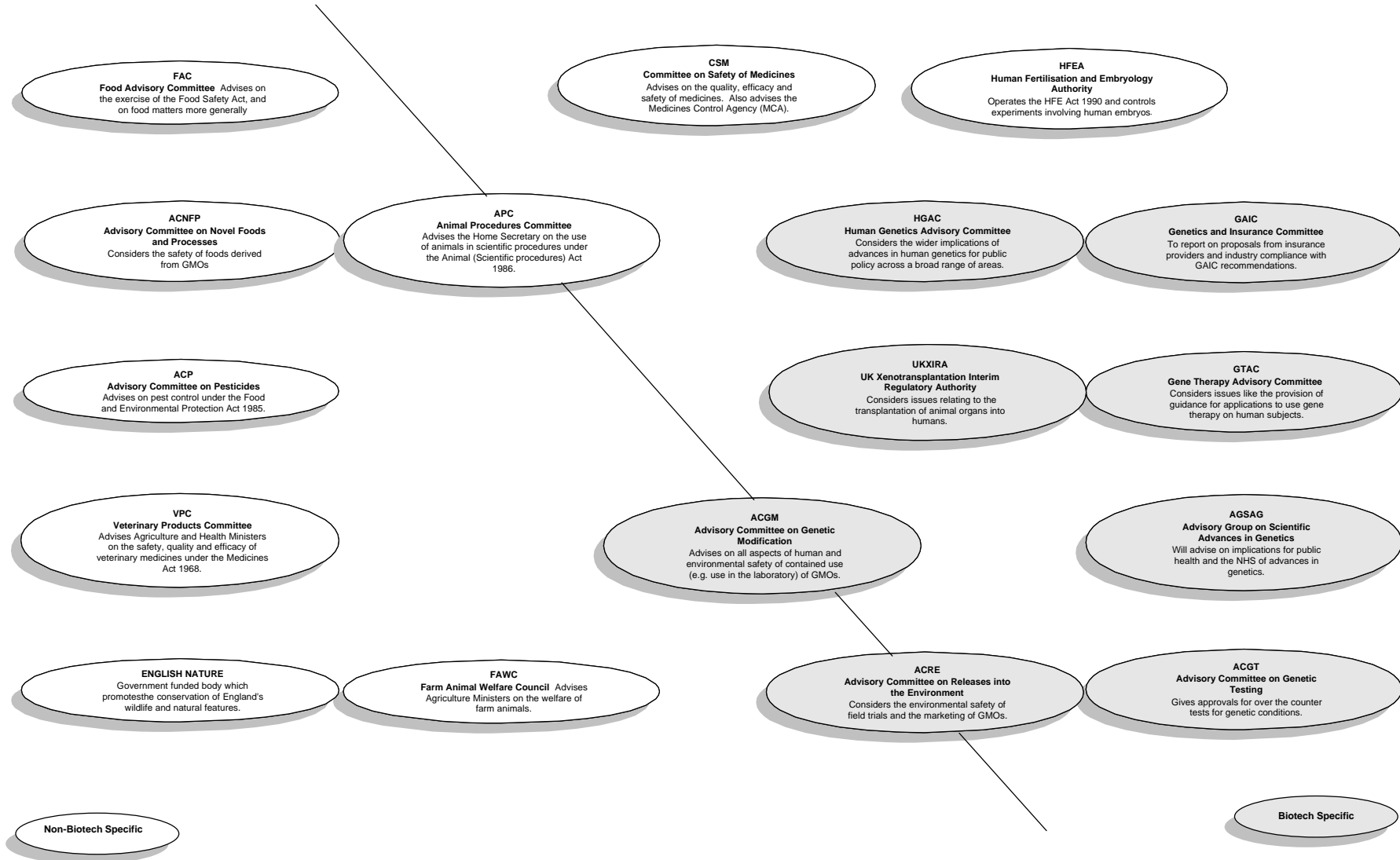
As the deliberate release of GMOs into the environment became a significant issue in the late 1980s a new committee, the Advisory Committee on Releases to the Environment (ACRE), was formed independently of ACGM. Initially ACRE had a joint secretariat between the Health and Safety Executive (HSE) and the Department of the Environment (DOE). However, in 1992 it became a statutory committee under the Environmental Protection Act 1990 (EPA) with the Secretariat being wholly provided by DOE (which later became Department of Environment, Transport and the Regions (DETR)). ACGM continues in its specific remit, namely to oversee the safety of genetic modification activities in containment. With the implementation into national legislation of the European Directive on the contained use of genetically modified micro-organisms (GMMs) (Directive 90/219/EEC) the scope of the regulations, for the first time, covered both human health and environmental protection.

ACGM is one of many committees whose work impinges on genetic modification. The array of different committees can be seen in Diagram 1, 'Biotechnology/Genetics Regulatory/Technical Bodies' (taken from 'The Advisory

# DIAGRAM 1 BIOTECHNOLOGY/GENETICS REGULATORY/TECHNICAL BODIES

## FOOD & AGRICULTURE

## MEDICAL/THERAPEUTIC



and Regulatory Framework for Biotechnology: Report from the Government's Review'). Active co-ordination between all of these bodies is an important aspect of their work.

- **The wider perspective**

During the 1980s, the European Commission had turned its attention to genetic modification mainly to ensure adequate protection across the Community for human health and the environment; and also because it recognised the need to harmonise standards and avoid barriers to trade. The outcome was two EC Directives which led in 1992 to the two sets of regulations, developments of which are currently taking place. These regulations deal separately with contained use and deliberate release<sup>1</sup>, and both cover the protection of human health and the environment.

After several years experience of the 1990 contained use Directive, the need for change had become apparent and resulted in the 1998 EC amending Directive on the contained use of GMMs. The drafting of new Regulations to replace the Genetically Modified Organisms (Contained Use) Regulations 1992 (as amended in 1996 and 1998), has been in direct response to the amending Directive and this has been the main focus of this year's<sup>2</sup> work by the ACGM.

## **THE ADVISORY AND REGULATORY FRAMEWORK FOR BIOTECHNOLOGY: REPORT FROM THE GOVERNMENT'S REVIEW- MAY 1999**

- **Implications for ACGM**

In the Foreword to the above-mentioned Advisory and Regulatory Framework for Biotechnology Report, the Government made clear its overriding responsibility to protect the health of the public and the environment, and its reliance on advice from the ACGM and other similar advisory committees on modern biotechnology in fulfilling this responsibility. Following the review of the whole advisory system, and an assessment of its findings, the Government has determined to strengthen the advisory system by introducing some changes. The main thrust of these changes is fuelled by the

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<sup>1</sup> This report only deals with contained use as deliberate release is outside ACGM's remit

<sup>2</sup> April 1999 to March 2000. However, as this is the first ACGM annual report we have extended it back a little.

determination that the system should be as open and transparent as possible - ensuring that the public can engage with the work of the advisory committees. In a bid to achieve this aim, the Report from the Government's Review sets out nine 'best practice principles on transparency, timeliness and exchange of information between committees'.

ACGM has, in fact, been implementing most of these principles within its current working practices. These include publishing on the Internet meeting agendas and placing summaries of the discussion under each agenda item on the Internet within 2 weeks of the meeting. All papers and minutes are also available from HSE's Information Centres following the meetings. Although confidential information is removed, every effort is made to keep this to a minimum. Notwithstanding these existing actions, there are some changes still needed to implement the 'best practice principles' fully. The main changes involve establishing a register of members' interests; the publication of annual reports; publishing details of ACGM's work plan; and possibly the organisation of public meetings and of joint meetings with other committees. In immediate response to this call for change, ACGM has:

- w established a register of members' interests which can be found at Annex 1;
- w published its first annual report - this document bears witness to that;
- w planned to publish its work programmes after the Committee has been reconstituted in Spring 2000 and after its new work programme has been approved by the Health and Safety Commission. The new work programme will then be included in an ACGM Newsletter and so placed on the Internet;
- w considered the possibility of public meetings as an embryonic idea - since careful thought needs to be given as to how this could be organised and if indeed it would be the best format in ACGM's case for public exchange of information;
- w been working towards establishing a basis for exchange of information with other biotechnology committees - secretariats already regularly

include updates of other committees' activities in their reports. In addition, ACGM would be open to appropriate joint meetings although, in reality, its work seldom overlaps to any extent with that of other committees. ACGM would also support periodic meetings of Chairs to discuss common strategic themes when necessary. Deciding mechanisms for co-ordination with the Food Standards Agency (FSA) and Agriculture and Environment Biotechnology Commission (AEBC) and Human Genetics Commission (HGC) will be a priority over the next few months. (AEBC and HGC are the two new strategic advisory biotechnology-specific bodies created, as a result of the Advisory and Regulatory Framework for Biotechnology: Report from the Government's Review'. See below.)

## **TERMS OF REFERENCE, CONSTITUTION AND PROCEDURE**

Reconstitution of ACGM was due in June 1999. This would, however, have disrupted the Committee during consultation on implementation of the revised Directive on the contained use of genetically modified micro-organisms (GMMs). To avoid such disruption, the Health and Safety Commission extended the current terms of appointment until 1 April 2000. At the meeting of ACGM on 8 October 1999 the Committee endorsed a recommendation for revised terms of reference, constitution and procedure, to be put forward to the Health and Safety Commission (HSC). These were accepted by HSC at their meeting on 7 December. An abridged version of these revisions is given below .

- **Terms of Reference**

*Previous Terms of Reference (to 3 August 1999)*

To advise the Health and Safety Commission and Executive and the Secretary of State on all aspects of human and environmental safety of the contained use of genetically modified organisms.

*Current Terms of Reference (modified to take account of the new Strategic Advisory Bodies)*

To advise the Health and Safety Commission and Executive and the Secretary of State 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, the Human Genetics Commission and, in particular, the Agricultural and Environmental Biotechnology Commission.

*Proposed amended Terms of Reference (from April 2000)*

To advise the Health and Safety Commission and Executive, the Secretary of State, the MAFF Minister, the First Secretary of the National Assembly for Wales and the 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, the Human Genetics Commission and, in particular, the Agriculture and Environment Biotechnology Commission.

The current terms of reference take account of the Government Review (described above) which, in addition to the introduction of the 'best practice principles' also announced the need for a comprehensive strategic advisory structure for biotechnology. This is set to take the form of two new Non Departmental Public Bodies (NDPBs) - two new biotechnology specific commissions namely, the Human Genetics Commission (HGC), and the Agriculture and Environment Biotechnology Commission (AEBC). The idea behind this is that the new commissions, in conjunction with the Food Standards Agency (FSA), will stay in touch with the work of the regulatory/advisory bodies, like the ACGM, consulting them as necessary but not controlling or overseeing the work of the regulatory/ advisory bodies. The new Commissions' function is to detect cross-boundary issues and look at the bigger picture from a strategic viewpoint. A major plank of their remit will be public consultation.

The Proposed Amended Terms of Reference for ACGM extend the current Terms of Reference in order to take full account of the recent devolution of power to Scotland and to Wales. Provision is being made for the devolved administrations to have access to the existing committee (should they wish it). It is envisaged that if the devolved administrations use ACGM as a source of advice, rather than setting up their own alternative, then they would have a say in appointments. (See 'Membership' below.)

- **Remuneration**

Members of ACGM and its Technical Sub Committee (see below) receive no payment. They give their time freely and show a high level of commitment to the work of the committee.

- **Membership**

This year's membership: at present there are 13 members including the chairman:

<b>Member</b>	<b>Name</b>	<b>Nominated by / independent</b>	<b>Employed by</b>
<b>Chairman</b>	Professor Kay E Davies	Independent	Oxford University
<b>Employer nominees</b>	Dr Kenneth Edwards	Committee of Vice Chancellors and Principles (CVCP)	University of Leicester
	Dr Robin Fears	Confederation of British Industries (CBI)	SmithKlineBeecham Pharmaceuticals
	Dr Mike Gale	Research Councils	John Innes Centre
	Professor Stephen Hughes	Confederation of British Industries (CBI)	Exeter University
<b>Employee nominees</b>	Mrs Dot Carey	Trades Union Congress (TUC)	NERC - Institute of Virology and Environmental Microbiology
	Dr Julian Kinderlerer		University of Sheffield
	Dr Ron Owen		Consultant
	Dr Roger Spillar		Management Scientific and Finance (MSF)
<b>Independent members</b>	Professor John Beringer	Independent	University of Bristol
	Professor Michael Roberts		Institute of Terrestrial Ecology
	Professor Joyce Tait		University of Edinburgh
	Mr Stephen Vbranch		Jacobs Engineering

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- **Proposed amended Membership:**

The proposed amended membership will comprise a maximum of 17 members (including the chairman) as follows:

	Nominating body (if applicable)	
Chairman		
Employer nominees	CBI	2 members
	CVCP	1 member
	Research Councils	1 member
Employee nominees	TUC	4 members
Competent authority nominee (environmental issues)		1 member
National Assembly for Wales nominee (if they wish)		1 member
Scottish Executive nominee (if they wish)		1 member
Independent members		3 members
Lay members		2 members

To date, membership of ACGM has been by employer nomination (Confederation of British Industry (CBI), Research Councils, and Committee of Vice Chancellors and Principals (CVCP)), and employee nomination (Trades Union Congress (TUC)). In addition, independent members have been selected by the secretariat on the basis of their expertise and field of knowledge.

This partially *ad hoc* process of member selection was recognised as not fully fitting in with the Open Government and 'Nolan' principles (of the First Report on Standards in Public Life - May 1995). In view of this and in recognition of the broad principles

outlined in the Advisory and Regulatory Framework for Biotechnology Report, changes to the membership structure were put forward to HSC. The changes were specifically in answer to the Report's call for 'the best available advice ..... both scientific and non-scientific ...' to ensure openness and transparency. Therefore, while membership is intended to reflect the science and technology of GM, which is where the Committee's needs for specific expertise principally lie, and still recognising that ACGM is an HSC Committee and so must remain a tripartite body, the following changes have been proposed and accepted:-

- w In recognition of the growing importance of risk perception and communication in the GM field, relevant membership will also be sought in these areas. Therefore, in addition to the employer and employee nominees, it is proposed to add two new lay members to represent 'public interest' (though no implication is intended that ACGM at present does not have the public interest at heart). Consideration has been given to whether the new members should be 'lay' in the sense of having no specialist knowledge of biotechnology or involvement with it. An alternative would be to appoint members involved in GM but with a perspective outside that of the current member sources - representatives of, say, consumer protection or environmental groups. At this point in time it seems advisable to maintain broad criteria for selection of the two lay members and define those criteria largely by exception such that the new members should have no formal connection with existing nominating bodies or scientific institutions engaged in GM work, and as far as possible should consider the issues before the Committee from the standpoint of the general public.
- w Devolution of power to the Scottish Executive and to the National Assembly for Wales has meant that responsibility for the environmental aspects of GM within ACGM's scope now lies with those bodies in Scotland and Wales respectively. Provision is made for this by enabling Scotland and Wales to nominate a member onto the committee, should they wish to do so.

- w Members will be appointed so that the committee collectively has specialist expertise in the following disciplines:
- virology - human (research or clinical), animal, plant;
  - bacteriology - general (ecology/physiology);
  - large scale/industrial production;
  - Biological Safety Officer/safety management;
  - ecology - plant, animal, microbial;
  - animal experience -(not necessarily veterinary), possibly experience in transgenics;
  - risk communication / public perception.
- w An appointments panel will be set up to consider all nominations and will then make recommendations to HSC . From April 2000<sup>3</sup> Members will be appointed for terms varying between one and three years in order to achieve a rolling appointments programme and maintain continuity.

## **TECHNICAL SUB COMMITTEE**

In June 1996 ACGM was restructured and divided into two components: a main committee, smaller than before, to take the broader view; and a Technical Sub Committee (TSC) reporting to it to consider the detailed science. TSC also has a role to advise HSE and other members of the competent authority directly on notifications made under the Genetically Modified Organisms (Contained Use) Regulations.

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<sup>3</sup> The timetable for appointing new Members is very likely to slip a little.

The membership of the TSC is selected to reflect current developments in the biotechnology field. It has a Chairman, one employee representative nominated by the TUC, and one employer representative nominated by the CBI. There are 10 other independent experts. The TSC acts in a less formal manner than the main ACGM committee, with the aim of discussing detailed scientific issues relating to the safety of GM activities, providing sound advice to the main committee, and hence HSE and HSC.

The membership of the TSC over the past year has included:

Member	Name	Nominated by / independent	Employed by
Chairman	Mr Steve Vbranch	Independent	Jacobs Engineering
Employer nominee	Mr John Thorley	CBI	Consultant
Employee nominee	Dr Julian Kinderlerer	TUC	University of Sheffield
Independent members	Dr Phil Minor	Independent	National Institute for Biological Standards and Control
	Professor Don Jeffries		St Bartholomew's Hospital
	Dr Joanna Marshall		Oxford University
	Professor Tony Minson		Cambridge University
	Dr Mike Mackett		CRC Patterson Institute
	Professor David Onions		Glasgow University
	Dr Rick Randall		University of St. Andrews
	Dr Penny Hirsch		Rothamstead Experimental Station
	Professor Douglas Young		St. Mary's Hospital, London
	Mr Steve Eley		CBD, Porton
Dr Ian Cooper	Institute for Virology and Environmental Microbiology		

During the course of the year both Professor David Onions and Professor Don Jeffries resigned due to workload commitments. Both had been involved with ACGM for many years, and have provided an invaluable contribution to its work. Suitable replacement will be sought.

The TSC met twice during 1999. The focus of much of the activity, as for the main committee, has been the development of the new legislation and technical guidance to accompany it. The updating and completion of the ACGM Compendium of guidance provided a huge challenge. The finalised Compendium now covers all aspects of contained use activities with GMOs. New sections include guidance on work with prions, plant viruses and transgenic plants, as well as updated sections on animal and plant containment. The document will be available in April / May 2000, both as paper copies and, through the Internet, to a wider audience in Europe and beyond.

As the technology continues to develop and evolve, the TSC will play an important role in advising ACGM on the safety aspects of new developments.

## **IMPLEMENTATION PLAN**

- **Implementation Deadline - Contained Use Directive**

ACGM has met three times during the last year and a bit - on January 8 1999, October 8 1999 and January 17 2000. A large part of each of these meetings was concerned with working towards the implementation of the amendment to Directive 90/219/EEC on the contained use of genetically modified micro-organisms (GMMs). The amending Directive was adopted on 26 October 1998 and the time given to implement it was 18 months - the implementation date being 5 June 2000. To ensure that this deadline can be met it was hoped to bring the new regulations into force 3 months before the deadline, so giving users the chance to make the necessary adjustments and complete the transitional provisions by June, or shortly thereafter. Things have, however, slipped a little.

- **Brief background to this year's work**

The amendment to Directive 90/219/EEC meant that the Genetically Modified Organisms (Contained Use) Regulations 1992 (as amended in 1996 and 1998) had to be replaced. Alongside this was the consequent need to revise the Guide to the Regulations and update the ACGM Compendium of Guidance (See separate section below).

There are a number of differences between the 1992 Regulations and the Regulations 2000. Essentially the most significant change is a greater emphasis on risk assessment and the linking of notification procedures to a classification of activities based on that risk assessment and linked to containment levels. The amended Directive's requirement to assess risk to human health and the environment presents a more structured approach to risk assessment involving a move away from the earlier system of classifying activities into Group I or Group II and Type A or Type B. Instead, the risk assessment for GMMs will lead directly to the classification of the activity into one of four classes corresponding to the four levels of containment. (Class 1 being activities of no or negligible risk up to Class 4 which are activities of high risk.) The new simplified classification system will drive the notification system.

The Regulations 2000 will continue to also cover human health aspects of GM animals and plants. (Environmental protection aspects for these are covered under the Environmental Protection Act 1990 and associated Regulations.)

- **The Consultation Process**

Under the Health and Safety at Work etc. Act 1974 the Health and Safety Commission is required to consult the public on all proposals for new legislation to be made under the Act. ACGM, together with various stakeholder groups, had been closely involved in developing the UK line during renegotiation of the Directive. The first major step towards formal public consultation was taken at the ACGM meeting on 8 January 1999 when the draft Consultative Document "Proposals for revised Genetically Modified Organisms (Contained Use) Regulations" was presented to members for their consideration, advice and endorsement. Members were invited to review the entire draft of the Regulations and associated Guide and draw attention to any errors or

inconsistencies as well as commenting on the substance. This was a mammoth task involving close scrutiny of nearly 250 pages. After suggesting certain amendments, ACGM endorsed the draft Consultative Document for presentation to HSC.

HSC, taking into account ACGM's advice, approved the Consultative Document on 23 March and it was published on 7 May 1999. The consultation period which followed closed on 7 August of that year. Sixty four responses were received from a range of notified contained use centres, organisations representing industry, academic and employee interests, local authorities, environmental and public interest groups and other stakeholders. GM centres were by far the largest group of respondents.

An analysis of the comments was then carried out. The overall reaction to the proposals was broadly positive with the removal of the current micro-organism classification and activity categorisation criteria, the streamlining of notification procedures and the introduction of a structured risk assessment framework being especially welcomed. A very large proportion of the comments were suggestions or requests for clarification rather than material changes to provisions. The two most contentious issues to emerge were the disposal of GMMs and provisions for disclosure of notified data. Several GM centres also raised concerns about the proposed fees, especially the introduction of fees for notification of significant new information and additions to connected programmes.

At the ACGM meeting on 8 October 1999, and in the light of the comments received, members were invited to:

- w consider the analysis of responses to the consultative document;
- w reconsider the draft Regulations now revised to take account of comments from consultees and the draft Guide;
- w to advise on whether the revisions were acceptable and whether there were any further aspects which needed work;
- w if satisfied, to endorse the revised draft Regulations and Guide for subsequent submission to the HSC.

ACGM was generally content with the proposed modifications and, making various observations and suggesting further areas for improvement. The committee endorsed the revised draft Regulations and Guide for submission to the Commission for approval on 21 December 1999 and subsequent transmission to Ministers.

- **Transitional Provisions**

The transitional provisions in the new Regulations will affect all contained use activities which had commenced before the new Contained Use Regulations come into force (hopefully May 2000) and will continue on 5 June 2000. All premises which wish to remain notified from 5 June will therefore have to take action.

ACGM recognised the need for the GM community to have early warning of the actions needed to fulfil the transitional provisions. Two ACGM Newsletters have dealt almost exclusively with this matter and have offered detailed guidance to the GM centres.

- **Notification Forms and Information Disclosure**

The new Regulations have quite extensive information requirements associated with notifications. An important aspect considered by ACGM has been how to help users comply with the information requirements. Although it is important to maintain the flexibility for people to notify the required information in any format they wish, the production of non-mandatory forms can help. ACGM have been involved in advising on the style and content of these forms. There were three main aims:

- w to ensure the forms are easy to complete;
- w to clearly identify confidential and personal information, so that it may be protected; and,
- w to aid the disclosure of information to the public (except confidential or personal information).

The forms will be the basis of the greatly improved public register of notifications. The register will be maintained at HSE offices, initially in paper form. However, ACGM strongly favours moving to an electronic register on the Internet and positively encourages HSE to develop this possibility.

## **COMPENDIUM OF GUIDANCE**

- **Background**

The Compendium of Guidance for practitioners of genetic modification under conditions of contained use was originally a collection of free-standing guidance notes issued by HSE and ACGM over the years. In 1997, ACGM's principle work had been to advise on the first tranche of a revised ACGM Compendium, the aim being to bring those earlier guidance notes up to date in a single document. Technical advances had taken place and needed to be reflected in this revised guidance.

Technical advances have not, however, been the only driving force behind a further revision of the Compendium. Just as a revision of the Genetically Modified Organisms (Contained Use) Regulations has necessitated a revision of the Guide to the Regulations, so , in part, has it led to a need to revise the Compendium so that it is consistent with the new legislation. (The Compendium of Guidance, of course, is not to be confused with the Guide to the Regulations since the latter is concerned purely with interpretation and clarification of the legal requirements of GM work and does so by addressing and explaining each Regulation. The Compendium, on the other hand, is a technical guide aimed at promoting good working practices in the GM field.)

In addition to the two forces of technical advancement and regulatory change driving the revision of the Compendium, a third factor contributing to the need to revise the Compendium is that information/advisory 'gaps' existed in the 1997 version of the Compendium, mainly in relation to work with GM animals and plants. A revision presented ACGM with the opportunity to fill those gaps.

- **Present Position**

ACGM's revised Compendium of Guidance is a fully integrated document with material organised under three main sections namely:

- w application of other legislation;
- w risk assessment;
- w containment and control measures.

The full list of topics covered in the revised Compendium, which has just been published to coincide with the new Contained Use Regulations 2000, is:

- w Application of other legislation to work involving genetic modification.
- w Risk assessment of genetically modified organisms - general introduction.
- w Risk assessment of genetically modified micro-organisms other than eukaryotic viruses.
- w Risk assessment of genetically modified human and animals viruses and viral vectors.
- w Risk assessment of work with genetically modified plant viruses.
- w Risk assessment of work with genetically modified plants.
- w Risk assessment of work with genetically modified animals.
- w Regulatory requirements for determining GMO containment and control measures and general guidance.
- w Selection of containment and control measures for laboratory and large scale activities involving GMMs.
- w Selection and containment and control measures for work with genetically modified plants.
- w Selection of containment and control measures for plants infected with GMMs.

- w Selection of containment and control measures for genetically modified animals.
- w Selection of containment and control measures for animals infected with GMMs.

### **LIKELY FUTURE WORK PROGRAMME . APRIL 2000 - 2003.**

Following the implementation of the amended contained use of genetically modified micro-organisms Directive, it is foreseen that some of the committee's time will be devoted to advising on questions of interpretation. In addition, ACGM will continue to consider how it can inform / engage the public about biotechnological risks. A provisional outline plan of work, including these and other tasks, for the years 2000-2003 is set out below:

- w **Continuing to give advice on issues arising from notifications made under the Regulations.**

ACGM's TSC will continue to scrutinise individual notifications where additional technical expertise is needed.

- w **Monitoring the introduction of the new Contained Use Regulations.**

This will include:

advising on interpretation;

advising on issues that should be considered by the European Commission;

advising on completion of the EC exemption criteria and guidance on 'safe' GMMs. Later, ACGM may be involved in the assessment of

dossiers put forward to the European Commission for consideration under this exemption;

advising on the completion of the EC guidance on risk assessment.

**w    Updating and revising the ACGM Compendium of Guidance.**

This will include:

providing advice on any further updating the Compendium might need to ensure that it is in line with the revised Directive, especially in terms of risk assessment procedures and containment requirements;

ensuring that the guidance in the Compendium continues to reflect the latest scientific developments. The TSC will provide detailed technical advice to the ACGM as part of this work.

**w    Advising on likely scientific and technical developments and their implications for planning and policy making.**

These considerations may also highlight areas of research.

**w    Advising on UK strategy in wider international discussions and initiatives.**

**w    Considering whether and how ACGM can inform public perception of biotechnological risk.**

This is part of a much wider debate within all biotechnology Advisory Committees which advise Government. Transparency of decision making and other openness issues will be key. ACGM will be required to have an input into the many relevant initiatives which are already underway across Whitehall.

## **CONTACTS FOR FURTHER INFORMATION**

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## **GLOSSARY**

<b>ACGM</b>	Advisory Committee on Genetic Modification
<b>ACRE</b>	Advisory Committee on Releases to the Environment
<b>AEBC</b>	Agricultural and Environmental Biotechnology Commission
<b>CBI</b>	Confederation of British Industries
<b>COSHH</b>	Control of Substances Hazardous to Health Regulations 1999
<b>CVCP</b>	Committee of Vice Chancellors and Principals
<b>DETR</b>	Department of the Environment, Transport and the Regions
<b>ECA</b>	European Communities Act 1972
<b>EPA</b>	Environmental Protection Act 1990
<b>FSA</b>	Food Standards Agency
<b>GMAG</b>	Genetic Manipulation Advisory Group
<b>GM</b>	Genetic Modification
<b>GMM</b>	Genetically Modified Micro-organism
<b>GMO</b>	Genetically Modified Organism
<b>HGC</b>	Human Genetics Commission

<b>HSC</b>	Health and Safety Commission
<b>HSE</b>	Health and Safety Executive
<b>HSWA</b>	Health and Safety at Work etc. Act 1974
<b>MAFF</b>	Ministry of Agriculture, Fisheries and Food
<b>NDPB</b>	Non Departmental Public Body
<b>NGO</b>	Non Governmental Organisation
<b>TD</b>	Technology Division (of HSE)
<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 ACGM.

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

<b>Members' Name</b>	<b>Interest</b>
<b>Chairman</b>	
Prof. Kay Davies	<p><b>Employer:</b></p> <ul style="list-style-type: none"> <li>♦ Oxford University</li> </ul> <p><b>Commercial Interests:</b></p> <ul style="list-style-type: none"> <li>♦ Member of the Scientific Advisory Board of SmithKline Beecham.</li> </ul> <p><b>Non-commercial interests:</b></p> <ul style="list-style-type: none"> <li>♦ Member of the Advisory Committee on Genetic Testing from 1997 - 1999.</li> </ul>
<b>Employer Nominees</b>	
Prof. Stephen Hughes	<p><b>Employer:</b></p> <ul style="list-style-type: none"> <li>♦ Exeter University</li> </ul> <p><b>Commercial Interests:</b></p> <ul style="list-style-type: none"> <li>♦ Non-retained consultancies managed by Biotechnology South</li> </ul>

	<p>West Ltd.</p> <p><b>Non-commercial interests:</b></p> <ul style="list-style-type: none"> <li>♦ Unilever Professorial Research Fellowship.</li> <li>♦ Member of Nuffield Council on Bioethics working group on GM Crops.</li> <li>♦ Trusteeships: Annals of Botany Company; Centre for the Application of Molecular Biology in International Agriculture; and Biotech South West.</li> </ul>
Dr. Kenneth Edwards	<p><b>Employer:</b></p> <ul style="list-style-type: none"> <li>♦ University of Leicester</li> </ul> <p><b>Commercial Interests:</b> None.</p> <p><b>Non-commercial interests:</b> None.</p>
Dr. Mike Gale	<p><b>Employer:</b></p> <ul style="list-style-type: none"> <li>♦ John Innes Centre</li> </ul> <p><b>Commercial Interests:</b></p> <ul style="list-style-type: none"> <li>♦ Director, Plant Bioscience Ltd.</li> <li>♦ Director, Norwich Research Ltd.</li> <li>♦ Director, Norwich Biosciences Ltd.</li> <li>♦ Director, John Innes Enterprises Ltd.</li> <li>♦ Director, Norwich Research Park Devel. Partners.</li> <li>♦ Lectured to Zeneca, Berkely, Calif. (1998).</li> </ul> <p><b>Non-commercial interests:</b></p> <ul style="list-style-type: none"> <li>♦ Fellow of Royal Society.</li> <li>♦ Foreign Member of Chinese Academy of Engineering.</li> <li>♦ Past support from, Zeneca, Ciba-Geigy, Advanced Technologies Cambridge Limited, Plant Breeding International (Unilever), Nickersons Biochem (Lima Grain).</li> <li>♦ Member of Board of Trustees of the International Rice Research Inst., Los Banos, Philippines.</li> <li>♦ Consultant, Rockefeller Foundation New York.</li> </ul>
Dr. Robin Fears	<p><b>Employer:</b></p> <ul style="list-style-type: none"> <li>♦ SmithKlineBeecham Pharmaceuticals</li> </ul> <p><b>Commercial Interests:</b></p> <ul style="list-style-type: none"> <li>♦ Share holding in</li> </ul>

	<p>SmithKlineBeecham.</p> <ul style="list-style-type: none"> <li>♦ Member of Policy and Operations Committee of EuropaBio.</li> </ul> <p><b>Non-commercial interests:</b> None.</p>
<b>Employee Nominees</b>	
Mrs Dot Carey	<p><b>Employer:</b></p> <ul style="list-style-type: none"> <li>♦ NERC at Institute of Virology and Environmental Microbiology</li> </ul> <p><b>Commercial Interests:</b> None.</p> <p><b>Non-commercial interests:</b> None.</p>
Dr. Julian Kinderlerler	<p><b>Employer:</b></p> <ul style="list-style-type: none"> <li>♦ University of Sheffield</li> </ul> <p><b>Commercial Interests:</b></p> <ul style="list-style-type: none"> <li>♦ Occasional consultancy to UNEP and UNIDO re GMOs.</li> </ul> <p><b>Non-commercial interests:</b></p> <ul style="list-style-type: none"> <li>♦ Adviser to UNEP, UNIDO and Various governments including Namibia and South Korea on safe use of GMOs.</li> <li>♦ Member of ACRE until June 1999.</li> </ul>
Dr. Ron Owen	<p><b>Consultant to:</b></p> <ul style="list-style-type: none"> <li>♦ TUC</li> </ul> <p><b>Commercial Interests:</b> None.</p> <p><b>Non-commercial interests:</b></p> <ul style="list-style-type: none"> <li>♦ Medical Adviser - Trades Union Congress.</li> </ul>
Dr. Roger Spillar	<p><b>Employer:</b></p> <ul style="list-style-type: none"> <li>♦ MSF (Manufacturing, Science, Finance)</li> </ul> <p><b>Commercial Interests:</b> None.</p> <p><b>Non-commercial interests:</b> None.</p>
<b>Independent Members</b>	
Prof. Michael Roberts	<p><b>Employer:</b></p> <ul style="list-style-type: none"> <li>♦ Institute of Terrestrial Ecology.</li> </ul>

	<p><b>Commercial Interests:</b> None.</p> <p><b>Non-commercial interests:</b> None.</p>
Prof. John Beringer	<p><b>Employer:</b></p> <ul style="list-style-type: none"> <li>♦ University of Bristol.</li> </ul> <p><b>Commercial Interests:</b> None, other than single unexpected payment from Monsanto following meeting when Monsanto put forward ideas re safer GM transgenic crops.</p> <p><b>Non-commercial interests:</b> Member of NERC.</p>
Mr. Stephen Vbranch	<p><b>Employer:</b></p> <ul style="list-style-type: none"> <li>♦ Jacobs Engineering UK Ltd.</li> </ul> <p><b>Commercial Interests:</b></p> <ul style="list-style-type: none"> <li>♦ Shares in CelltechChiro.</li> <li>♦ Pensions (on retirement) from: GlaxoWellcome, G D Searle and CelltechChiro.</li> </ul> <p><b>Non-commercial interests:</b> None.</p>
Prof. Joyce Tait	<p><b>Employer:</b></p> <ul style="list-style-type: none"> <li>♦ University of Edinburgh.</li> </ul> <p><b>Commercial Interests:</b> None.</p> <p><b>Non-commercial interests:</b> None.</p>