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Confidential Filing

Genetic Manipulation Advisory Group (GMAG)

SOCIAL SERVICES

S 810

December 1980

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10 DOWNING STREET

From the Private Secretary

11 January 1984

Genetic Manipulation Advisory Group

The Prime Minister was grateful for your Secretary of State's further minute of 10 January about his proposals to abolish the Genetic Manipulation Advisory Group and replace it with a new Advisory Committee to the Health and Safety Commission.

In the light of this further explanation, the Prime Minister agrees that your Secretary of State should announce the changes set out in his minute of 13 December.

I am sending copies of this letter to the recipients of the earlier correspondence.

David Barclay

J.F. Bird, Esq.,
Department of Education and Science.

10 DOWNING STREET

From the Private Secretary

MR HATFIELD

Genetic Manipulation Advisory Group

The Prime Minister has now considered Sir Robert Armstrong's minute of 19 December about the Genetic Manipulation Advisory Group, in the light of the further minute of 10 January on this subject from the Secretary of State for Education and Science.

The Prime Minister has agreed that the Genetic Manipulation Advisory Group should be wound up, and that an Advisory Committee to the Health and Safety Commission should be established in its place. She also agrees that lead ministerial responsibility on genetic manipulation matters should be transferred from the Secretary of State for Education and Science to the Secretary of State for Employment, and that this transfer should be announced at the same time as the abolition of the GMAG.

David Barclay

11 January 1984

10 DOWNING STREET

Prime Minister

Sir Keith's earlier minute failed to explain why it was thought necessary to wind-up the Genetic Manipulation Advisory Group, and transfer its functions to an advisory Committee of the Health and Safety Commission.

Content, in the light of this further note, for the transfer to go ahead?

DNB
10/1

A0109PR1509

B

PRIME MINISTER

GENETIC MANIPULATION ADVISORY GROUP

Your Private Secretary wrote to mine on 20 December concerning my proposals to abolish the above Group and for the Health and Safety Commission to establish a new advisory committee in its place. I am sorry if my minute of 13 December did not make the case for the transfer clear.

The work of GMAG, which was originally almost wholly concerned with research and experimentation in genetic manipulation, has changed significantly since it was established in 1976. The questions it needs to address are now increasingly concerned with the industrial use of genetically manipulated organisms and with experimental work which is more directly industrially oriented than hitherto. The questions are, in short, questions related mainly to health and safety at work in laboratories, factories and industrial plants. It is inappropriate for Education and Science Ministers to remain (even indirectly) responsible for questions of this kind. They are matters which properly come within the province of the Health and Safety Commission. Indeed it is a fact that the main recipients of the bulk of the advice which has been given by GMAG in the past, and which will be needed in the future, are the HSC and the HSE, not myself.

The Health and Safety Executive's (HSE's) Medical Division and its Inspectors have worked very closely with GMAG for some considerable time now, and have steadily built up expertise in the area of the large-scale use of genetically manipulated organisms. What is needed now is an advisory committee which can work even more closely with HSE on these issues but which, at the same time, is accessible to other Ministers whose responsibilities touch upon aspects of genetic manipulation. For my part, my need for advice of this kind has been minimal and is now non-existent. Aside from the inappropriateness of an adhoc

committee which is wholly sponsored by this Department continuing to perform the functions described, GMAG as constituted simply would not be competent to offer advice on such things as the risks associated with industrial scale-up, a fact which GMAG itself readily acknowledges. It would not be in anyone's best interest, least of all the developing biotechnology industries, if we attempted to keep, as the locus for advice on health and safety in genetic manipulation work, a scientifically oriented advisory committee separate from the agency (HSE) responsible for enforcing Health and Safety at Work legislation.

There is unanimous agreement on the proposal among other interested Ministers and all the organisations which were consulted earlier this year, including the CBI and GMAG itself.

None of what is said above is intended to detract from the high reputation which GMAG has acquired during the 7 years it has been in existence, and to which your Private Secretary's letter alluded. There is absolutely no reason to suppose, however, that an advisory committee to the HSC, inheriting as it does the experience of GMAG plus a close relationship with the Health and Safety Executive, will not fulfil the new advisory role which we have outlined previously every bit as successfully as GMAG has fulfilled its allotted purpose. It is likely that the new Committee will include some of the existing GMAG members, though the balance of its membership overall will make it, appropriately enough, more industrially oriented than GMAG.

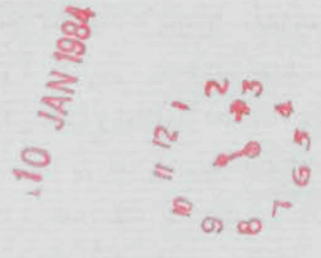
I hope that in the light of these further comments you can agree to the proposals in my minute of 13 December. I am copying this letter as before.

K.J.

10 January 1984

Social Services: GMAG

12/80



PRIME MINISTER

Genetic Manipulation Advisory Group

Sir Keith Joseph sought your agreement before Christmas to the winding up of the Genetic Manipulation Advisory Group, and the establishment in its place of an HSC Advisory Committee. You felt that his minute at Flag A failed to make out a convincing case for this change. Sir Keith has now written again (Flag B) to set out his thinking in more detail. His basic argument is that the work of GMAG has moved increasingly from the research field into the industrial sphere, where HSC are in a better position to offer advice. He thinks it likely that the new committee, if you agree that it should be established, will include some existing GMAG members, although the balance of its membership would be shifted in the direction of greater industrial expertise.

At Flag C is a note from Sir Robert Armstrong which supports Sir Keith's proposal, and seeks your agreement to an associated transfer of lead ministerial responsibility for genetic manipulation matters from the Secretary of State for Education and Science to the Secretary of State for Employment.

Agree:-

i) that Sir Keith Joseph should announce the winding up of the GMAG and the establishment of an HSC Advisory Committee in its place? Yes - although I hesitate because I do not feel well of the HSSC.

ii) that lead ministerial responsibility should be transferred from DES to D/Emp and that this change should be announced at the same time as (i)? Yes

DNB

10 January 1984

FILE

cc:- NIO
SO
WO
DHSS
DTI
MAFF
DOE
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R M

10 DOWNING STREET

From the Private Secretary

20 December, 1983

GENETIC MANIPULATION ADVISORY GROUP

The Prime Minister has considered your Secretary of State's minute of 13 December, in which he proposed the winding up of the Genetic Manipulation Advisory Group and the establishment in its place of an HSC Advisory Committee.

The Prime Minister considers that the case for this change has not been made out. She would have thought that the CMAG had a higher reputation than the Health and Safety Commission, and she does not see sufficient reason in your Secretary of State's minute for the transfer. I should be grateful for further advice.

I am sending a copy of this letter to the Private Secretaries to the recipients of your Secretary of State's minute.

(David Barclay)

Ms L. Olney,
Department of Education and Science

C CF: Please let me know when DES respond to my request for further advice

Dms 20/12

Ref. A083/3498

PRIME MINISTER

Genetic Manipulation Advisory Group:
Proposed Re-Constitution

In a minute dated December 13 the Secretary of State for Education and Science seeks your agreement to the replacement of the Genetic Manipulation Advisory Group (GMAG) by a new Advisory Committee on Genetic Manipulation, reporting to the Health and Safety Commission.

2. When GMAG was last re-constituted, at the end of 1980, you questioned the continuing justification for an advisory body on this subject. In the light of your previous interest, I have asked the Machinery of Government Division of the Cabinet Office to discuss the present proposal with officials concerned in DES and HSE. Their conclusion is that the proposal is sound: outside advice will clearly continue to be needed on changes in control procedures required to take account of developments in experimentation and use, and on the risks of, and precautions appropriate to, new techniques. A number of important issues currently claiming attention are mentioned in paragraph 6 of the Secretary of State for Education and Science's minute. The main arguments for a permanent, independent body (as opposed to reliance on ad hoc advice) are, first, the importance of consistency and, second, the capacity of an independent body to "hold the ring" in conflicts of interest between scientific/industrial interests on the one hand, and those whose health may be affected on the other. HSE point out that the tri-partite approach has materially assisted in the progressive dismantling of restrictions on genetic manipulation work achieved in recent years. Resource costs are small: the Committee will meet infrequently (certainly no more than once a quarter).

3. Though the submission does not make this clear, the Secretary of State for Education and Science has also agreed with the Secretary of State for Employment that, subject to your

approval, lead Ministerial responsibility on genetic manipulation matters should be transferred from him to the Secretary of State for Employment, simultaneously with the creation of the new body. GMAG was originally placed under the Secretary of State for Education and Science because genetic manipulation was then at the research stage. The emphasis has since shifted towards application, and HSC/E have built up expertise through their involvement in administering the Health and Safety (Genetic Manipulation) Regulations adopted in 1978. Against this background, the proposed transfer of lead responsibility to the HSE's sponsoring Minister seems reasonable. Ministers concerned with Health, Agriculture, Environment, Industry and Northern Ireland aspects of genetic manipulation would however continue to answer on these aspects. The change in lead Ministerial responsibility obviously needs to be made clear in the "inspired" PQ which DES propose.

RA

ROBERT ARMSTRONG

19 December 1983

CF: file please. DMB 19/12

PRIME MINISTER

Genetic Manipulation Advisory Group (GMAG)

Sir Keith Joseph wants to wind up the Genetic Manipulation Advisory Group and establish an Advisory Committee of the Health and Safety Commission to take over its functions. The main reason for doing so is the growing importance of industrial biotechnology.

GMAG has done a very good job in restoring public confidence in biotechnology (see Robin Nicholson's note at A). It is vital that its successor should maintain this record.

Agree that the Secretary of State should announce the winding up of GMAG, and the establishment of an HSC Advisory Group?

I see no reason for the change. I should have thought that the GMAG had a higher reputation than the HSC Commission. No do I see good reason in the paper - only certain assertions

mf

DMB

16 December 1983

W/0852 16 December 1983

MR DAVID BARCLAY, No 10

GENETIC MANIPULATION ADVISORY GROUP (GMAG)

I have followed the discussions which have been going on for the last few months on the winding up of GMAG and its replacement by an Advisory Committee for the HSC (ACGM). I am content both with the general approach to the new body and with the consultation process which has occurred prior to its being set up.

2. I think it is worth recording that GMAG has been an extraordinarily successful operation. It is hard to remember now that when it was set up there was widespread concern about genetic manipulation which was threatening both the conduct of scientific research and the exploitation of that research in this country. There is now widespread confidence that the risks are being properly assessed and contained, with the result that some of the leading research in the world in this area is carried out in this country and we have a growing biotechnology industry. That is the measure of GMAG's achievement and I hope that there will be some public recognition of this when GMAG is wound up. The UK's record in handling this whole area compares favourably with a number of other countries. We have neither over-reacted nor under-reacted.

3. Nevertheless, the need for continued success in this area is paramount and GMAG's success will be a measure of ACGM's task. I need hardly point out that a single "scare" or accident in this area of technology would have very

damaging consequences and there is a terrible example of the civil nuclear industry before us, which has moved from a clean bright futuristic image in the late 1950s to its present sorry state in only 25 years. It will be the responsibility of the ACGM together with the scientists and industrialists working in biotechnology to ensure that the technology maintains or improves its current image so that it can realise its full potential in the country's economic growth.

I am copying this minute to Sir Robert Armstrong.

RBN.

ROBIN B NICHOLSON
Chief Scientific Adviser

Social Services
SMAS

16 DEC 1983

B1212PR1508

A

PRIME MINISTER

GENETIC MANIPULATION ADVISORY GROUP (GMAG)

1. As you will be aware, this Department and the Health and Safety Executive conducted consultations earlier this year on the future of GMAG. In the light of the responses received, and with the support of colleagues in other interested Departments and of the Health and Safety Commission, I now wish to announce the winding-up of GMAG and the establishment in its place of an HSC advisory committee to be known as the Advisory Committee on Genetic Manipulation (ACGM).

2. The review of the role of GMAG begun by DES and HSE officials last year was timely for a number of reasons. There was an emerging consensus among experts that early fears about the risks inherent in genetic manipulation work - fears which had led the Secretary of State for Education and Science at the time to establish GMAG in 1976 - had proved largely unfounded. GMAG had thus found it possible to exclude much of the scientific and industrial work which was going on (but by no means all of it) from any requirements for prior scrutiny. At the same time, it was apparent that large scale industrial use of manipulated organisms was increasing and would continue to increase, making it desirable that GMAG should work even more closely with HSE - whose knowledge of the physical containment aspects of these processes had grown considerably - in the interests of reducing interference with industrial development to the necessary minimum.

3. The review took account of the known views of the CBI and the TUC, the views of the members of GMAG itself and the views of government departments with an interest, or potential interest, in GMAG's field of work. These departments included health,

agriculture, environment, industry and, of course, the Department of Employment and HSE. The consensus of opinion was that an advisory body on genetic manipulation would continue to be needed. It was needed primarily to advise HSE and HSC on the discharge of their responsibilities under the Health and Safety at Work Act and regulations made thereunder, but also to provide scientific and technical advice to interested Ministers on genetic manipulation questions arising within their respective fields.

4. Of the various options which were considered, the replacement of the existing GMAG by an advisory committee to the HSC appeared the most appropriate to current and future circumstances and needs, and the solution likely to commend the widest general support. The consultations conducted this year bear out that assessment. Almost all the bodies which responded (representing scientific, technological, industrial and professional interests) were in favour of the proposed ACGM and with the terms of reference, appointment and membership arrangements suggested for it, a copy of which I now attach. In so far as there was any comment on the proposals, it related mainly to the operation of the notification system for genetic manipulation work and the scope of the regulations governing this. These are matters which the new Committee can look at when it is established.

5. Subsequently, I informed colleagues of the results of the consultative exercise and I believe them to be content with what is suggested. The HSC, at its meeting on 8 November last, similarly, expressed itself content to proceed to establish the new advisory committee - as it is empowered to do.

6. The terms of office of the Chairman and the members of GMAG expire on 29 February 1984. It would be highly desirable, in my view, to have the ACGM established immediately thereafter. Though I understand that GMAG has it in mind to meet once more to deal with a back log of business which has accumulated while consultations on its future have been in progress, there are a

number of pressing new issues which a reconstituted committee will need to address, including for example the degree of containment appropriate to genetically manipulated oncogenes, a look at practice on "scale-up" and the industrial use of genetically manipulated organisms, and the degree of risk involved in spraying genetically manipulated organisms on crops. You may know that the latter question is causing much concern in the USA, and we must face it too.

7. With your leave, I propose to make a public announcement as soon as possible, probably by way of an inspired Parliamentary Question and Answer. That will leave the way clear for HSC to approach potential members and, in due course, to make appointments.

8. I am copying this minute, with attachments, to Jim Prior, George Younger, Nicholas Edwards, Patrick Jenkin, Norman Fowler, Norman Tebbit, Michael Jopling and Sir Robert Armstrong.

KJ.

13 December 1983

TERMS OF REFERENCE AND MEMBERSHIP OF THE NEW COMMITTEE

Terms of reference

a. TO ADVISE THE HEALTH AND SAFETY COMMISSION AND HEALTH AND SAFETY EXECUTIVE, IN CONNECTION WITH THEIR RESPONSIBILITIES UNDER THE HEALTH AND SAFETY AT WORK ETC ACT 1974, ON

i. the general standards of safe working to be observed by those undertaking activities relating to genetic manipulation;

ii. the categorisation of experiments;

iii. exemptions from the Health and Safety (Genetic Manipulation) Regulations 1978;

iv. the assessment of risks and precautions (and in particular of any new methods of physical or biological containment) and of any newly developed techniques for genetic manipulation;

v. at the request of HSE, the specific precautions necessary in individual cases of experimental work;

vi. at the request of HSE, the biological aspects of individual cases of the use of products of genetic manipulation;

vii. health monitoring and training of those undertaking genetic manipulation activities;

viii. the terms of any controls (regulations, codes of practice and guidance) to be applied generally to laboratories and other workplaces engaged in genetic manipulation or the use of products of genetic manipulation;

ix. such other matters as may be referred to the Committee by the HSC or HSE.

b. TO ADVISE THE HEALTH, AGRICULTURE, ENVIRONMENT, INDUSTRY AND NORTHERN IRELAND MINISTERS on such other matters relating to genetic manipulation as may be referred to the Committee by those Ministers and to offer comment on the technical or scientific aspects of any new developments in genetic manipulation which may have implications for their Departments.

Membership

The membership of the new committee would be as follows:

A chairman

5 employer representatives (3 nominated by the CBI, 1 by the Committee of Vice-Chancellors and Principals and 1 by the Research Councils).

5 employee representatives (nominated by the TUC)

8 scientific and medical specialists.

Appointments would be made by the HSC. There would be consultation with Government Departments prior to the appointments of the Chairman and specialist members.

Representatives of interested Government Departments would attend meetings as observers.

APPOINTMENTS IN CONFIDENCE FIRE 84

10 DOWNING STREET

From the Private Secretary

24 October, 1983

Genetic Manipulation Advisory Group (GMAG)

Thank you for your letter of 20 October to Tim Flesher about the chairmanship of the Genetic Manipulation Advisory Group.

The Prime Minister is content for Sir Robert Williams' term of office as Chairman of GMAG to be extended until 29 February, 1984.

I am sending a copy of this letter to Richard Hatfield (Cabinet Office).

DAVID BARCLAY

J. F. Bird, Esq.,
Department of Education and Science

S 5

(1)

Prime Minister

Agree to an exctension for Sir Robert Williams to 29 February 1984?

(Sir Robert Armstrong is content)

DEPARTMENT OF EDUCATION AND SCIENCE

ELIZABETH HOUSE, YORK ROAD, LONDON SE1 7PH

TELEPHONE 01-928 9222

FROM THE SECRETARY OF STATE

Tim Flesher Esq
lO Downing Street
LONDON SWl

20 October 1983

Dealt 21/10

Dear Tim

GENETIC MANIPULATION ADIVSORY GROUP (GMAG)

In March this year we sought the Prime Minister's approval to extend Sir Robert Williams' term of office as Chairman of GMAG until 31 October 1983. This was to allow sufficient time for consultations on the future of the Group to take place. At that time, it was hoped that these could be completed by the summer and that any agreed new arrangements could be in operation by the autumn.

Unfortunately, it has not been possible to keep to this timetable, mainly because of the very late arrival of comments from one or two important respondents. As a result we and the Health and Safety Executive are only now in a position to make the necessary approaches to Ministers and to the Health and Safety Commission.

Although no further meetings of the Group are planned, business arises from time to time requiring decisions from the Chairman and scientific work which must be notified to GMAG goes on. We therefore propose to extend Sir Robert's term of office to 29 February 1984. The other members of the Group are being consulted on whether they would also be willing to have their terms extended to the same date. Sir Robert has already indicated his willingness to continue to serve.

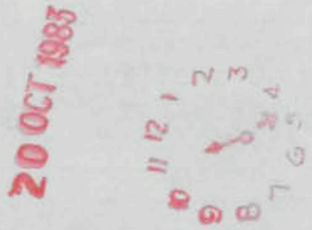
My Secretary of State will be making a full submission to the Prime Minister in due course, when the views of his colleagues and of the Health and Safety Commission on the outcome of the consultative round is known.

I am copying this letter to Richard Hatfield.

Yours sincerely

J F BIRD
Private Secretary

Social Services
Dec 80
GMAG



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14 March 1983

Genetic Manipulation Advisory Group (GMAG)

Thank you for your letter of 10 March to Tim Flesher. The Prime Minister is content for your Secretary of State to extend the appointment of Sir Robert Williams until 31 October of this year. She notes that your Secretary of State will be putting proposals to her in the summer on the future of the GMAG.

I am copying this to Richard Hatfield (Cabinet Office).

W F S RICKETT

Mrs. I. Wilde,
Department of Education and Science.

HL

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DEPARTMENT OF EDUCATION AND SCIENCE

ELIZABETH HOUSE, YORK ROAD, LONDON SE1 7PH

TELEPHONE 01-928 9222

FROM THE SECRETARY OF STATE

Prime minister

Content to extend Sir Robert Williams' appointment while consultations take place on proposals to replace the GMAG with an Advisory Committee to the Health and Safety ~~Executive~~ Commission? The extension would be until the end of October.

11/3

T Flesher Esq
Private Secretary
10 Downing Street
LONDON SW1

10 March 1983

Dear Tim,

GENETIC MANIPULATION ADVISORY GROUP (GMAG)

We propose to extend the period of office of the present Chairman of GMAG, Sir Robert Williams, until 31 October this year so as to allow time for public consultations on official proposals to replace the existing Group with an Advisory Committee to the Health and Safety Commission (HSC).

This proposed reconstitution of GMAG was foreshadowed in a minute from the then Secretary of State for Education and Science to the Prime Minister of 28 January 1981 when the appointment of Sir Robert Williams as Chairman was being proposed. Since then, officials of the DES and the Health and Safety Executive have reviewed the role and constitution of GMAG and have prepared a report to Ministers dealing with various options for the future, in consultation with other Departments which have an interest in the work of the Group. The favoured option of reconstitution as an HSC Advisory Committee has the support of all Departments, and the HSC itself has recently given its formal consent to the establishment of the new Advisory Committee subject to the outcome of consultations with outside organisations, including the TUC and the CBI, who also have an interest in the Group's work. With the agreement of Ministers at DHSS, DOE, DEmp, DOI, Scottish Office, Welsh Office and Northern Ireland Office we intend to initiate a 2 month period of consultation commencing on 1 April with a view to reaching a decision on firm proposals by the summer which the Secretary of State might put to the Prime Minister. It will be important to allow time thereafter for new arrangements to be put in place, hence the proposal to extend the present Chairman's term until 31 October.

Sir Robert Williams (whose 2 year term of office expired on 28 February) is willing to serve for a short additional period and it would clearly be desirable to offer him the extension

formally as soon as possible since, although no further meetings of the Group are at present planned, business continues to arise which requires decisions from the Chairman. The terms of office of other members of the Group were extended to 31 October at the end of last year.

I should be grateful if you would let me know as soon as possible if the Prime Minister has any objections to the proposed temporary extension of Sir Robert Williams' appointment. I am copying this letter to Richard Hatfield.

Yours ever,

Imogen Wilde

MRS I WILDE
Private Secretary

Social Services Dec 80

Genetic Manipulation

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Social Services

DEPARTMENT OF EDUCATION AND SCIENCE

ELIZABETH HOUSE, YORK ROAD, LONDON SE1 7PH

TELEPHONE 01-928 9222

FROM THE SECRETARY OF STATE

Prime Minister:
You may like to know of this report.

D J Wright Esq
Private Secretary to the Secretary of
the Cabinet
Cabinet Office
70 Whitehall
London
SW1A 2AS

28 July 1982

Dear David,

The first report of the Genetic Manipulation Advisory Group, which was set up in December 1976, was published as Cmnd 7215 in May 1978 and the second as Cmnd 7785 in December 1979. I now enclose the draft of the third report of the Group which my Secretary of State also wishes to publish as a Command Paper.

The Second Report indicated an increasing tendency on the part of the scientific community to regard some of the fears that had previously been expressed about the potential safety risks from genetic manipulation work as having been exaggerated. This tendency has continued during the period leading up to the present report, to the extent that it is now apparent that the hazards of engaging in genetic manipulation, if they exist at all, are far less than was conjectured when the Group was set up. This change in scientific opinion has enabled two important changes to be made during the period: (i) a new risk assessment scheme for the categorisation of genetic manipulation experiments has been introduced; this has resulted in most work now being carried out under the lower categories of physical containment; (ii) experiments judged by a local Biological Safety Committee to be appropriately conducted either with "good microbiological practice" or under Category 1 (the lowest category of containment) no longer have to be notified in advance to the Group and to the Health and Safety Executive on a case-by-case basis (they are instead notified in arrears, once every twelve months).

The draft report notes with gratification that there have been no recorded ill-effects associated with the practice of genetic manipulation in the 103 centres registered in the UK and the recategorisation of much work to lower levels of containment is in line with trends in the USA and elsewhere. Nevertheless the need for continued monitoring against possible longer-term effects is recognised.

Scientific interest in the subject remains high and much progress is being made in the application of recombinant DNA (deoxyribonucleic acid) technology to the production of health care products and other materials on an industrial scale - a matter of considerable economic importance.

The draft report itself is short and consists of 19 pages only but there are substantial appendices. There will be a foreword by my ... Secretary of State, a draft of which is attached also.

This will not be a politically controversial document and it seems reasonable therefore that it should be published during the summer recess. My Secretary of State would prefer not to wait till Parliament reassembles if that can be avoided.

I should be grateful if you will seek Sir Robert Armstrong's agreement to the publication of the report as a Command Paper during the summer recess.

I am copying this letter and enclosures to the Private Secretaries to the Prime Minister, the Leader of the House of Commons and the Paymaster General and to the Chief Press Secretary at No 10.

Yours ever,
Irene Wilde

MRS I WILDE
Private Secretary

DRAFT FOREWORD TO GMAG'S REPORT

Since the Second Report of the Genetic Manipulation Advisory Group (Cmnd 7785) was published in December 1979, much scientific information on the biological applications of recombinant DNA technology has accumulated. Because the original fears about this work have so far not been substantiated and because of the very responsible attitude of those who carry out the work, this Report explains that the Group were able, in early 1980, to introduce a risk-assessment scheme for the categorisation of experiments, and within a year to advise a further modification of the procedures governing the notification of individual experiments. The Report does however note that there will be a need for continued monitoring to verify that there are no long term health hazards associated with this work.

The Group have also revised their procedures for giving advice on the large scale use of genetically manipulated organisms. The Report records that the Group's advice on that area of work will in future be restricted to the biological properties of the organisms being used; the Health and Safety Executive will, as part of their responsibilities under the Health and Safety at Work Act 1974, continue to be concerned with the physical aspects of safety.

I am grateful to the Group for their most valuable work, in particular for ensuring that both research and the industrial applications of that research can continue under procedures and safeguards which, as far as can ever be the case, are acceptable to all concerned.

Covering letter with PM's 29/7

THIS DOCUMENT IS THE PROPERTY OF HER BRITANNIC MAJESTY'S GOVERNMENT
GENETIC MANIPULATION ADVISORY GROUP

Third Report of the Genetic Manipulation Advisory Group

Papers

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Supplement 2 (issued March 1980)

Supplement 3 (issued August 1980)

4. Note 11 The GMAG categorisation scheme

5. Note 12 Large scale use of genetically manipulated organisms (issued November 1979, revised February 1982)

6. Note 13 Genetic manipulation of plants and plant pests

7. Note 14 Revised guidelines for the categorisation of recombinant DNA experiments

Supplement 1 (issued January 1981)

8. Note 15 Code of practice for genetic manipulation containment facilities

Amendments to Note (issued June 1981)

IV Other current GMAG Notes

(a) Note 1 Local safety committees in genetic manipulation

(b) Note 2 Protective cabinets

(c) Note 3 Nucleic acid purity and characterisation in relation to the categorisation of genetic manipulation work

(d) Note 4 (revised)

(i) Transfer of recombinant material between laboratories

(ii) Reduction of categorisation for handling recombinant DNA

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VI Guidelines for Microbiological Safety

VII Paper submitted to GMAG in March 1982 by Dr S Brenner and M I Wigby, MRC Laboratory of Molecular Biology

VIII Paper submitted to GMAG by Dr H R Smith and Dr B Rowe

MEMBERSHIP OF THE GENETIC MANIPULATION ADVISORY GROUP

Membership at 28 February 1982.

Chairman:

Sir Robert Williams, MD, FRCP, FRCPath, FFCM	Formerly Director of the Public Health Laboratory Service, London

Appointed as scientific experts:

B. Atkinson Esq, PhD, FIChem, FEng	Director, Brewing Research Foundation Research Establishment, Redhill, Surrey
E. Hoggarth, Esq, PhD, FRSC	Formerly Deputy Chairman, ICI Pharmaceuticals Division
J. Ingle, Esq, PhD	Scientific Adviser to the Secretary to the Agricultural Research Council
B.W. Langley, Esq. PhD	ICI Corporate Laboratory, Runcorn
R.F. Sellers, Esq, PhD, ScD, MRCVS	Director, Animal Virus Research Institute, Pirbright, Surrey
Professor P.M.B. Walker, CBE, PhD, FRSE	Department of Zoology, University of Edinburgh

Appointed to represent the public interest:

Mrs. Jocelyn Chamberlain, MB, BS, FFCM	Department of Epidemiology, Institute of Cancer Research, Royal Marsden Hospital
Professor M. Kogan, MA	Professor of Government and Social Administration, Brunel University
Mrs. C. Margaret Puxon, MD, FRCOG	Barrister

Appointed to represent the interests of employees:

Professor D.C. Ellwood, PhD, FRSC	Centre for Applied Microbiological Research, Porton Down, Salisbury (ASTMS)
Ms. Donna Haber	Association of Scientific, Technical and Managerial Staffs, London (ASTMS)
R. Owen, Esq, MB, ChB, FFOM, DMJ, DIH, LRSC	Trades Union Congress

Professor R. Williamson, PhD	Department of Biochemistry, St. Mary's Hospital Medical School, London (ASTMS)

Appointed to represent the interests of management:

J.A. Gilby, Esq, BSc, C.Chem, FRSC	Technical Director, Beecham Pharmaceuticals Division (UK), London
Professor M.H. Richmond, PhD, ScD, FRCPath	Vice Chancellor, University of Manchester

Assessors:

R.P. Norton, Esq	Department of Education and Science
T.J.B. Geffen, Esq, MD, FRCP	Department of Health and Social Security
D.O. Haines, Esq, MB, BS, DCP, FRCPath	Health and Safety Executive
W.E.O. Jones, Esq	
E.J. Morris, Esq (alternate)	
C. Wray, Esq, BVMS, PhD, MRCVS	Ministry of Agriculture, Fisheries and Food
A. Bishop, Esq	Scottish Office

Secretariat:

K.I. Gibson, Esq, PhD I.B. Flinn, Esq	At the Medical Research Council 20 Park Crescent, London W1N 4AL

Former members who retired between 1 August 1979 and 28 February 1982:

Sir William Henderson, DSc, FRCVS, FRSE, FRS

J.B. Brooksby, Esq, CBE, DSc, MRCVS, FRS

Sir Frederick Dainton, MA, DSc, FRS

J. Maddox, Esq, MA

Professor J.H. Subak-Sharpe, PhD, FRSE

Professor P. Wildy, MA, MB, BChir, FRSE, FRCPath

The membership of the Group's Technical Subcommittee is given in Appendix II.

TERMS OF REFERENCE

The Genetic Manipulation Advisory Group was set up in December 1976 by the then Secretary of State for Education and Science, in consultation with her colleagues, with the following terms of reference.

1. To advise:

   (a) those undertaking activities in genetic manipulation, including activities related to animals and plants, and

   (b) others concerned

2. To undertake a continuing assessment of risks and precautions (and in particular of any new methods of physical or biological containment) and of any newly developed techniques for genetic manipulation and to advise on appropriate action.

3. To maintain appropriate contacts with relevant government departments, the Health and Safety Executive and the Dangerous Pathogens Advisory Group.*

4. To maintain records of containment facilities and of the qualifications of Biological Safety Officers.

5. To make available advice on general matters connected with the safety of genetic manipulation, including health monitoring and the training of staff.

* Now replaced by the Advisory Committee on Dangerous Pathogens.

DEFINITION

The group have adopted for the purposes of defining their remit the following definition of genetic manipulation; and the same definition serves to define the scope of the Health and Safety (Genetic Manipulation) Regulations introduced in August 1978:

> 'The formation of new combinations of heritable material by the insertion of nucleic acid molecules, produced by whatever means outside the cell, into any virus, bacterial plasmid, or other vector system so as to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation'.

1. Introduction:

Since the Second Report was issued in 1979 (CMND 7785), it has become apparent that the hazards specifically attributable to genetic manipulation of micro-organisms are, if they exist at all, far less than were conjectured when the Group was set up and can be contained by appropriate biological and physical containment. It is also apparent that the pace of fundamental research and industrial application using recombinant DNA technology is much more rapid than was predicted; there are now 103 centres in the U.K. using the technology. We therefore considered it useful to prepare a Third Report, and to indicate how GMAG has revised its procedures in response to the changes in scientific opinion.

Two important changes have been introduced in this period. The first was the introduction of a new risk assessment scheme (GMAG Note 8) to replace the earlier categorization scheme which had been based on that in the 'Williams' Report (Cmnd 6600). The second was the issue of GMAG Note 14, which stipulated that experiments judged by the local Biological Safety Committee to be appropriately conducted simply with 'good microbiological practice' (GMP) or under Category I containment need no longer be notified on a case-by-case basis. These relaxations have been made possible by the responsible way in which local biological safety committees have developed, demonstrating competence to operate the new risk assessment scheme. We continue to place reliance on local safety committees, not only to categorize work but also to maintain surveillance of proper work practices. Our recategorization of much of the work to lower levels of containment is consistent with trends in the United States and other countries.

The present time also seemed appropriate for the production of a Third Report since many of the original objectives set for GMAG by the Secretary of State have been achieved, and in particular satisfactory safety standards for microbiological work for genetic manipulation have been implemented - an important achievement in an area where many of the investigators had not had previous training in microbiological practices. GMAG has also encouraged the development of a wide range of disabled host/vector systems that should enable almost all work to be carried out in a safe manner without very elaborate containtment procedures.

Moreover, some of the anticipated benefits of the recombinant DNA technology and its application for the production of industrial or medical materials, are well on the way to being realised.

It has been very reassuring that no ill-effects associated with the practice of genetic manipulation have been recorded in the 103 centres now registered in the United Kingdom. So far as we are aware, experience has been the same in other industrial countries. Nevertheless continued monitoring is of course needed to verify that there are no longer-term effects.

Developments in this field have raised important questions of what role and responsibilities GMAG should have in connection with the 'use' as opposed to the 'construction' of genetically manipulated micro-organisms. After discussion there was a consensus view that the Group should continue to keep under surveillance the large scale use of genetically manipulated organisms and continue to advise on the biological aspects of scale-up work.

2. Membership

The list on page .... gives the present membership. Since the last report the Secretary of State appointed Sir Robert Williams to succeed Sir William Henderson as Chairman. Dr E Hoggarth was also appointed as a scientific member with experience in industrial scale fermentation techniques to replace Dr R J C Harris; Dr R F Sellers replaced Dr J B Brooksby as a scientific member. Mr J Maddox resigned from the Group when he re-joined the staff of Nature to avoid any 'conflict of interests' - he has not yet been replaced. Professor P Wildy, Professor J H Subak-Sharpe and Sir Frederick Dainton have resigned their membership of the Group. Professor M H Richmond has replaced Sir Frederick Dainton as the nominee of the Committee of Vice-Chancellors and Principals.

In September 1981 Professor B Atkinson, who has special expertise in pilot plant and large scale fermentation, was appointed to the Group as a Scientific member.

We record our great appreciation to Sir William Henderson who guided the Group through a very active period when the risk assessment scheme was implemented and subsequently revised as a result of the rapidly increasing volume of data which became available on disabled host/vector systems. His special knowledge and expertise in the large scale fermentation of micro-organisms proved invaluable when the first industrial applications of genetically manipulated organisms were reviewed by us.

We also acknowledge the important scientific contribution which Professor Wildy, Professor Subak-Sharpe and Sir Frederick Dainton made to our work.

We were saddened by the death of Dr Harris who, following his appointment to the staff of the Health and Safety Executive (HSE), continued to attend some of our meetings as an observer for the Executive.

3. Calendar of Business

The Department of Education and Science continues to sponsor GMAG within central government and the Medical Research Council provides the Secretariat. We usually hold our regular meetings at the Natural Environment Research Council's London Office and we are most grateful to them for providing the necessary facilities and domestic arrangements.

Following our introduction of a risk assessment scheme for the categorisation of experiments in January 1980 together with the announcement in September 1980 that from that date experiments which fall into Category I or GMP do not have to be submitted for case- by-case consideration, the routine business of the Group has dropped sharply. In 1980 the Group met seven times and in 1981 five times. Advice to centres in which genetic manipulation has commenced, and any particular experiments on which local safety committees have asked for specific advice, along with the applications relating to the relatively few Category II or III experiments are now dealt with on a postal basis to avoid delay. No new Category IV containment facilities have been set-up since our last report and only two new category III facilities have been visited since the last report and they have not been put into

operation. A revised code of practice for laboratories was introduced in 1981. The Group has added to the list of exempted organisms, which are set out in the two supplements to Note 8 (included in appendix III). The Subcommittee on Validation of Safe Vectors was disbanded in 1979 and a Technical Subcommittee set-up in its place under the Chairmanship of Professor P M B Walker with a core membership (see Appendix II) and powers to co-opt additional members when considered necessary. The Technical Subcommittee's terms of reference are wide and in addition to advising on disabled host/vector systems it is asked to consider any scientific/technical matter on which specialist advice may be needed.

4. Risk Assessment Scheme for Categorisation of Experiments

The new risk assessment scheme for the categorisation of laboratory experiments involving genetic manipulation was introduced in January 1980 and a further radical revision of our procedures for reviewing work was introduced in July 1980 (GMAG Note 14). The information and data that were accumulating on the expression of eukaryotic genes in prokaryotic organisms and also the information on the behaviour of disabled host/vector systems in the human gut justified us to advise further reduction on the constraints which had been applied to that time.

The initial concern about the possible colonisation of the human gastrointestinal (GI) tract with an organism capable of producing a substance that may have adverse physiological effects, stimulated much work on the survival of E. coli in the human and animal GI tract and it was found that the disabled E. coli strain used in genetic manipulation work did not generally survive in the GI tract for more than a few days.

It was also demonstrated that E. coli K12 is so enfeebled that it was incapable of being converted to a transmissable pathogen by DNA inserts. Dr Brenner developed an E. coli host/vector system the details of which are given in Appendix VII and VIII that could not survive in the GI tract for more than a few days (usually 3-4 days) and could also be readily monitored because of its special properties. When used in conjunction with a non-transmissable plasmid - that is a plasmid which is not readily transferred from one bacterial strain to another - it represented a suitable laboratory system for genetic manipulation work and as such was designated as having an Access factor of 10^{-9} (compared to E. coli K12 which was designated 10^{-3}). A considerable amount of information on the behaviour of DNA inserts in plasmids and the expression in bacterial systems has become available since the technique of genetic manipulation commenced in 1972. The combined information on the behaviour of E. coli in the GI tract, the behaviour of DNA inserted into plasmids and the expression of products from these inserts enabled us to estimate the likely risk factors in a range of disabled systems. Depending on the degree of disablement of the bacterial system, the product (if any) being made and the possible resulting damage in a 'worst case' situation, it was possible to give some guidance on the likely overall risk of an experiment and thus the level of containment required for a particular piece of work. This system also encouraged the use of disabled host/vector systems because the more disabled the system, and the more accurate the information available on the DNA insert and on its expression of the product, the less constraints were required for the work.

The conclusion of the National Institute of Allergy and Infectious Diseases (NIAID) Workshop on Recombinant DNA Risk Assessment held in April 1980 in Pasadena confirmed our views concerning the revision of the risk factors for our categorisation scheme. The NIAID Workshop analysed the 'worst' possible case situation which may occur as a result of genetic manipulation work using E. coli with regard to the possible adverse effects of hormone producing strains of E. coli. It also discussed the possible occurrence of autoantibodies or autoreactive cells due to the production of eukaryotic polypeptides and concluded that the public health risk would appear to be extraordinarily low.

In the USA the National Institutes of Health (NIH) made substantial changes to their guidelines at about the same time as we revised our categorisation procedures. Most other countries follow the NIH guidelines but it was significant that, based on the published scientific data and information accumulating at that time, quite independent national advisory groups were able to reach similar conclusions and recommend an almost universal lowering of constraints on genetic manipulation work as consistent with proper regard to the safety of workers using this technique. The Recombinant DNA Advisory Committee (RAC) of the NIH is presently considering proposals to modify their guidelines radically which if accepted by the Director of NIH will allow a further reduction in the constraints on genetic manipulation work in the USA.

5. Safety Committees

As part of our general policy to place greater responsibility on local safety committees for the surveillance of this work it was agreed with the HSE that all work under Category I containment or work designated good microbiological practice could go ahead without the necessity for case- by- case review by us. Centres were asked to submit a list of the experiments done in Category I or carried out under conditions of good microbiological practice to us and the HSE at the end of every 12 months. This not only removed many of the administrative burdens on the centres and GMAG but also allowed us to discharge our public duty to maintain a watching brief over genetic manipulation work being undertaken in the UK.

We have placed considerable confidence in the local safety committees and we have been impressed by the responsible way in which they have carried out their duties and operated the risk assessment scheme. It is for this reason we place much emphasis on the structure of the local safety committee when a new centre is established. We consider it important to include a broad representation as well as members with the appropriate expertise to advise on the categorisation of experiments. Whenever there is any local difficulty in reaching a decision or where it is felt that a second opinion should be sought then we are always prepared to give advice. However, our experience during the last year indicates that local safety committees are competent to operate the scheme and only on relatively few occasions has our advice been sought on specific proposals. In all we have been asked to give advice on or confirm the local safety committee's categorisation in six cases involving Category I or GMP work in the past year (1 March 1981 to 28 February 1982).

An important area of uncertainty that remains is in some aspects of work involving viruses infecting eukaryotic organisms; we still wish to keep under case by case review experiments involving non-defective virus vectors (GMAG Note 14 supplement 1).

6. Scale-up work - involving the 'use' of a genetically manipulated organism

Although work involving the 'use' of a genetically manipulated organism is not covered by the genetic manipulation regulations we consider our present terms of reference sufficiently wide to include this activity in our overall surveillance of the field and that the public still requires reassurance about the safety standards required for large scale work involving the use of genetically manipulated organisms. We have therefore reviewed all such work to ensure that due consideration has been given to carrying out the work safely. GMAG's contribution in this connection clearly relates to the possible biological hazards; the safety of the plant used is more appropriately considered by the HSE Inspectorate. We recently met the Confederation of British Industry (CBI) genetic engineering working party to discuss and review procedures for advising on large scale work, and have recognised that it is possible to give some further guidance to industry and also to simplify the procedures so far adopted for receiving requests for advice. The details have been agreed by us, and by the HSE, and a revised GMAG Note 12 has now been published which explains that the Group no longer require a site visit before it gives its advice on scale- up proposals and work with exempted organisms or those made under conditions of good microbiological practice can proceed after notification to GMAG and the HSE. For work involving organisms constructed under Category I

containment or above then applicants would have to await for GMAG and HSE to give their advice before proceeding. The GMAG Note 12 (revised) is reproduced in full in Appendix III.

7. Commercial Proposals

The Health and Safety (Genetic Manipulation) Regulations do not distinguish where the genetic manipulation work is being done; industrial centres are required - like academic institutions - to notify GMAG and HSE of genetic manipulation activities. The Group recognises the potential importance of the industrial use of genetically manipulated organisms and has maintained its policy of giving every encouragement to the progression of laboratory developments to industrial application where this is consistent with good manufacturing practice. It is particularly gratifying to note that the first ever industrial large scale use of genetically manipulated organisms took place in the UK. The necessary confidentiality scheme instituted some time ago (see our First Report, 1978, Cmnd 7215) is still being operated.

8. International Relations

We have continued to maintain as close a liaison as possible with relevant governmental and non-governmental organisations abroad.

The Chairman and Secretary represented the Group at the European Science Foundation (ESF) Liaison Committee for Recombinant DNA Research. The Liaison Committee met for the last time in January 1981 following a decision by the ESF Council to disband it; since most countries had

accepted the guidelines promulgated by the National Institutes of Health (NIH - USA) there was little value in continuing the Liaison Committee. The ESF also accepted the Liaison Committee's recommendation that 'large scale' work involving the 'use' of a genetically manipulated organism did not involve any novel or unknown hazard. The ESF secretariat will however, continue to circulate information published by the national advisory groups to the member organisations.

As mentioned in Section 4 the results of the NIH risk assessment programme and their workshop to discuss risk assessment of work involving E. coli were particularly helpful to us in finalising our July 1980 risk assessment procedures (GMAG Note 14).

The Commission of the European Communities have revised their earlier proposal for a 'Directive' to control genetic manipulation activities and instead have submitted a 'Recommendation' to the European Parliament for their consideration. However,the Economic and Social Committee (ECOSOC) which held a colloquy in May 1981 to discuss the safety aspects of recombinant DNA work have reiterated their view that a 'Directive' should be promulgated; the exact scope of such a Directive however, remains unclear. The European Science Foundation agreed that a 'Recommendation' was an adequate legal instrument. The European Parliament approved the 'Recommendation' proposed by the Commission on 22 February 1982. The Council of the European Community have now to consider the 'Recommendation'.

The Council of Europe have also discussed the possible impact of recombinent DNA technology in relation to man and his environment. A draft Council of Europe Recommendation 'Genetic Engineering' has

recently been submitted to the Parliamentary Assembly for their consideration.

9. Difference Between the NIH and GMAG Procedures

During the short history of recombinant DNA technology two main sets of guidelines have emerged; those developed by the GMAG (UK), and those by the NIH (USA). The social and statutory pressures have been quite different in the two countries and these have had a major influence on the development of the guidelines, but although their respective evolutionary courses have been quite different the final outcome has been very similar.

One of the important similarities between the UK and the USA is the shift in emphasis from central advisory bodies to local biological safety committees for advice on individual experiments. The requirements for physical and biological containment are now very similar indeed in the UK and the USA. However, there are some important differences in procedures between the countries -

a) The UK has, unlike the USA, specific legislation which places a statutory requirement on all centres to notify to the HSE and GMAG their intention to do work involving genetic manipulation. However it should be emphasised that the notification procedure is relatively simple and once initial notification has been given the details required for experiments in Category I or GMP are minimal and retrospective.

b) The UK, GMAG has agreed that it would wish to be notified of all large scale work and in certain cases to continue to advise on individual proposals.

Both of the above procedures have been retained to ensure that we properly discharge our responsibilities to keep the whole field under review. We consider that it is an important aspect of our duty to the public to maintain a general awareness of development in work involving genetic manipulation and its location.

10. Medical Monitoring

We reviewed our Health Monitoring note and issued, on the advice of our Medical Monitoring Subcommittee (Chairman: Professor P Wildy), a revised note (GMAG Note 6) in January 1980. Although the categorisation of experiments was being reviewed at that time (GMAG Note 11) and some work designated 'good microbiological practice' thus removing the necessity of a physical containment facility - it was agreed that medical surveillance should be extended to cover all concerned with genetic manipulation. The extent of the health review was left very much to the discretion of the local Supervisory Medical Officer (SMO). What was considered important was that all those involved in genetic manipulation should have easy access to the local SMO and that there should be adequate health records kept of every worker and of the experiments undertaken. No accidents or reports of any untoward effects on health as a result of this work have been notified to us.

We have recently reconsidered our advice on the need for epidemiological monitoring of workers involved in genetic manipulation. The diversity of genetic manipulation work does not suggest that any particular health risks would be common to all workers using this technique. It was therefore agreed that there was no immediate case for setting up a prospective epidemiological study. But it was noted that the HSE continued to maintain a national Register of all those named on notifications submitted, which could be used as a basis for retrospectively determining the incidence of specific diseases if indicated. We feel it is very important that a proper record of all workers involved in genetic manipulation is maintained and made available should there be a need to mount a study at an appropriate time in the future. The HSE have already acknowledged the importance of the need to maintain adequate records of workers and we advise that the matter should be kept under review to determine whether there is a case for implementing an epidemiological study in the future.

11. Technical Subcommittee

The Technical Subcommittee under the Chairmanship of Professor P M B Walker has had four meetings. Its major task to date has been the revision of the risk assessment scheme for the categorisation of experiments. The Subcommittee has had considerable help from many scientists who were coopted for their expertise in various aspects of genetic manipulation work. We are most grateful to all regular members and coopted members of our Technical Committee for their willingness and time they have given and without whom much important progress would not have been made. The Committee have also revised the Code of Practice (GMAG Note 15 and its supplement), which had remained unchanged since first published in the 1979 Williams Report.

12. Good Microbiological Practice (GMP)

Following the introduction of the GMAG risk assessment scheme and the inclusion in the scheme of experiments designated 'good microbiological practice' the Joint Co-ordinating Committee for the Implementation of Safe Practices in Microbiology issued broad Guidelines for Microbiological Safety which we accepted as appropriate for work designated 'good microbiological practice'. The guidelines are reproduced in full in Appendix VI. The joint Co-ordinating Committee and GMAG are at present co-operating on the production of fuller guidelines for the benefit of those working in the field.

13. Genetic Manipulation in Plants

Since the second GMAG report we have issued a Guidance Note on Genetic Manipulation of Plants and Plant Pests - GMAG Note 13 issued in January 1980 and reprinted in the appendix. The Note was prepared by a Subcommittee which was initially chaired by Professor K Mather and following his retirement, from 1.1.1979, by Dr J Ingle. Work which involves plant pests requires a licence from the Ministry of Agriculture Fisheries and Food (MAFF) or Department of Agriculture and Fisheries for Scotland (DAFS) or Forestry Commission Secretariat (FCS) following advice from GMAG. Plant experiments which do not involve plant pests may, where appropriate, be started once GMAG and HSE have been notified.

14. Environmental Implications

Many of the potentially exciting applications of genetic manipulation, particularly in relation to agriculture, will ultimately necessitate the

deliberate release of the genetically manipulated organism or plant into the environment. In anticipation of requests for advice concerning the deliberate release of such organisms the Group has had preliminary discussions with representatives of MAFF and the Natural Environment Research Council (NERC) to decide whether it is possible or advisable to issue guidance notes on such matters. While it has been decided, in view of the complexity of the issues, not to offer specific guidance the Group would wish to be kept informed at the earliest possible stage in the development of any work in which the objective is to deliberately release the genetically manipulated organism or plant into the environment. It is strongly recommended that during the developmental stages special care is taken to keep full and accurate records of laboratory experiments and field trials using, initially, non-manipulated organisms. The records can then be used as background information when the local safety committees or GMAG are asked to advise on the use of the genetically manipulated organism. For the present each case will be examined on a case-by-case basis.

Some consideration has also been given to the possibility of any environmental impact that may result from the accidental release of a genetically manipulated organism. The risk assessment procedure require that some preliminary consideration be given to the likely damage (if any) that may be caused by a particular organism should it 'escape' from the laboratory environment. Until more information is available on the behaviour of a particular genetically manipulated organism in the environment and in competition with other natural organisms it is difficult to give any general advice. However, the Group consider that it is important to keep close liaison with NERC and MAFF to ensure that such matters are kept under close surveillance.

15. Future

The Group has considered its future work. The majority view was that the Group should, at least for the foreseable future, continue to keep the field of genetic manipulation under review and continue to be available for advice to local biological safety committeess and others concerned.

cc MOD
DHSS
SO
WO
MAFF
CSD

MLPS
Social Services

10 DOWNING STREET

From the Private Secretary

2 February 1981

Dear Mary

The Prime Minister has considered your Secretary of State's further minute of 28 January about the Genetic Manipulation Advisory Group.

She has agreed that the Group should continue in existence for a further two years, and that Sir Robert Williams should take over the chairmanship.

I am sending copies of this letter to David Omand (Ministry of Defence), Mike Tully (Department of Health and Social Security), Geoffrey Robson (Scottish Office), John Craig (Welsh Office), Kate Timms (Ministry of Agriculture, Fisheries and Food) and Geoffrey Green (Civil Service Department).

Yours ever

Mike Pattison

Mrs. Mary Bowden
Department of Education and Science.

YLS

Prime Minister

You queried the continued need for GMAG. Mr Carlisle argues that its work is in an area of growing public concern, and that it therefore has a valuable role for at least a couple of years. In this case, there are strong arguments in favour.

Agree to continue for 2 years and to appoint Sir Robert Williams. MH 29/1

FOI 2 years only. not

PRIME MINISTER

GENETIC MANIPULATION ADVISORY GROUP

I have seen the letter of 9 January from your Private Secretary to mine conveying your doubts about the need for GMAG's continued existence.

The Group operates under terms of reference which are at Annex A. You will see from these that the Group's remit includes animals and plants in addition to humans. This alone really rules out a full incorporation of GMAG into the Medical Research Council (MRC). (But, in the interests of economy, the MRC do provide the GMAG's secretariat.)

There is a more powerful argument in favour of keeping GMAG. In the next two years or so progress with the development of genetic manipulation techniques and with their industrial application will continue at a fast pace. So we should expect there to be conflicts between, on the one hand, scientists and industry who tend to chafe at what they see as unnecessary controls, and on the other the general public, Parliament and the trades unions who perceive possible dangers to health. There is a need, therefore, for an impartial, yet expert, central body to offer balanced advice and take balanced decisions. GMAG, with its membership representatives of scientists, employers, employees and the public interest, is acknowledged as expert and seen to be impartial.

There is also an international dimension. We must not get too far out of step with other countries in our controls on genetic manipulation work, or our industry may be put at a disadvantage. An EC draft Recommendation on the Registration of DNA work is going through the Brussels machinery; GMAG's advice will be essential in helping to determine the UK's position on this.

Your Private Secretary's letter mentioned the settled nature of the guidelines. I agree that the statutory framework (the Health and Safety (Genetic Manipulation) Regulations 1978) is unlikely to be much altered. But within that framework there is much scope for changing detailed control procedures by administrative action, and it is over changes of this nature - and there have been several since the 1978 Regulations came into effect - that the Health and Safety Executive (HSE) will continue to require expert advice from GMAG.

All this persuades other interested colleagues and me of the need for the continuation of GMAG. I would not wish to suggest that GMAG will carry on in its present form indefinitely: eventually HSE may have built up sufficient internal expertise to be able to take a rather differently constituted GMAG under its wing. But it is needed, at least for the next couple of years, in its present form.

I should be grateful for your approval to the continuation of GMAG and to my appointing Sir Robert Williams as the next Chairman, in accordance with my Private Secretary's letter to yours of 31 December.

I am copying this to the Ministers in charge of the Departments to which your Private Secretary's letter went.

M.C.

MARK CARLISLE
28 January 1981

ANNEX A

TERMS OF REFERENCE OF GMAG

1. To advise:

   (a) those undertaking activities in genetic manipulation, including activities related to animals and plants, and

   (b) others concerned.

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3. To maintain appropriate contacts with relevant government departments, the Health and Safety Executive and the Dangerous Pathogens Advisory Group.

4. To maintain records of containment facilities and of the qualifications of Biological Safety Officers.

5. To make available advice on general matters connected with the safety of genetic manipulation, including health monitoring and the training of staff.

6. To submit a report at intervals of not more than a year.

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cc MOD
DHSS
SO
WO
MAFF
CSD

HS

Sec Services

10 DOWNING STREET

From the Private Secretary

12 January 1981

do not chase

Genetic Manipulation Advisory Group

The Prime Minister has seen your letter of 31 December about the future of GMAG. (Despite its date, the letter only arrived here on 9 January).

The Prime Minister would like more information about the work of the Group, and the justification for its continued existence. She had understood that the guidelines had already been laid down, and she has asked whether the Medical Research Council could not continue any further work which might be necessary.

I am sending copies of this letter to David Omand (Ministry of Defence), Mike Tully (Department of Health and Social Security), Godfrey Robson (Scottish Office), John Craig (Welsh Office), David Jones (Ministry of Agriculture, Fisheries and Food) and Geoffrey Green (Civil Service Department).

M. A. PATTISON

Mrs. Mary Bowden,
Department of Education and Science.

FROM THE SECRETARY OF STATE

ELIZABETH HOUSE,
YORK ROAD,
LONDON SE1 7PH
01-928 9222

Prime Minister

Mr Carlisle wants a new Chairman for GMAG, to carry on his work. Agree appointment of Sir Robert Williams

31.12.80.

M A Pattison Esq
10 Downing Street
London SW1

Why do we need to conduct it. Have the guidelines not already been laid down. Dear Mike Can the MRC not conduct the work - if any is necessary? R. 9/1/81.

GENETIC MANIPULATION ADVISORY GROUP (GMAG)

The present chairman of the Genetic Manipulation Advisory Group (GMAG), Sir William Henderson, is due to finish his two year term of office at the end of this year. He has expressed a wish not to be reappointed. In seeking a replacement, my Secretary of State has been conscious of the need to secure the services of a senior and experienced person in the medical or allied fields, who is capable of representing the UK at international conferences, is of sufficient stature to maintain public and scientific confidence in the Group, and is known to be a firm Chairman.

My Secretary of State considers it possible that the Prime Minister may have become aware of recent ill-founded speculation in the scientific press about the future of GMAG. While it is true that the Group now needs to meet less frequently than hitherto, there is still an unfinished advisory task for the Group to do. My Secretary of State understands that, at a meeting of GMAG on 19 December, there was overwhelming support among the membership for the Group's continued existence, on both scientific and public interest grounds. He endorses the Group's own view about the need for its continued existence, and feels that it is right that he should now appoint a new chairman.

My Secretary of State proposes, subject to the Prime Minister's approval, to appoint Sir Robert Williams as GMAG's next chairman, for about a two-year period. Sir Robert is by profession a pathologist and, while he has not himself been concerned with genetic manipulation, he was Chairman of the Working Party whose deliberations led to the establishment of GMAG in 1976. He will retiring from his present post as Director of the Public Health Laboratory Service, and from the publish service, in mid-summer 1981. He is a fit and vigorous 64.

Consultation has been carried out, by officials, with all interested Departments, and there is general support for the proposal. The appointment is proposed to be from 1 March 1981 (Sir William Henderson has agreed to serve on beyond the end of 1980 to ensure continuity).

It would be helpful if you could be good enough to secure the Prime Minister's approval to this appointment.

I am copying this letter to the Private Secretaries to the Secretaries of State for Defence, Social Services, Scotland and Wales, Minister of Agriculture,Fisheries and Food and Minister of State, Civil Service Department.

Yours ever

Mary Bowden

MRS M E BOWDEN
Private Secretary

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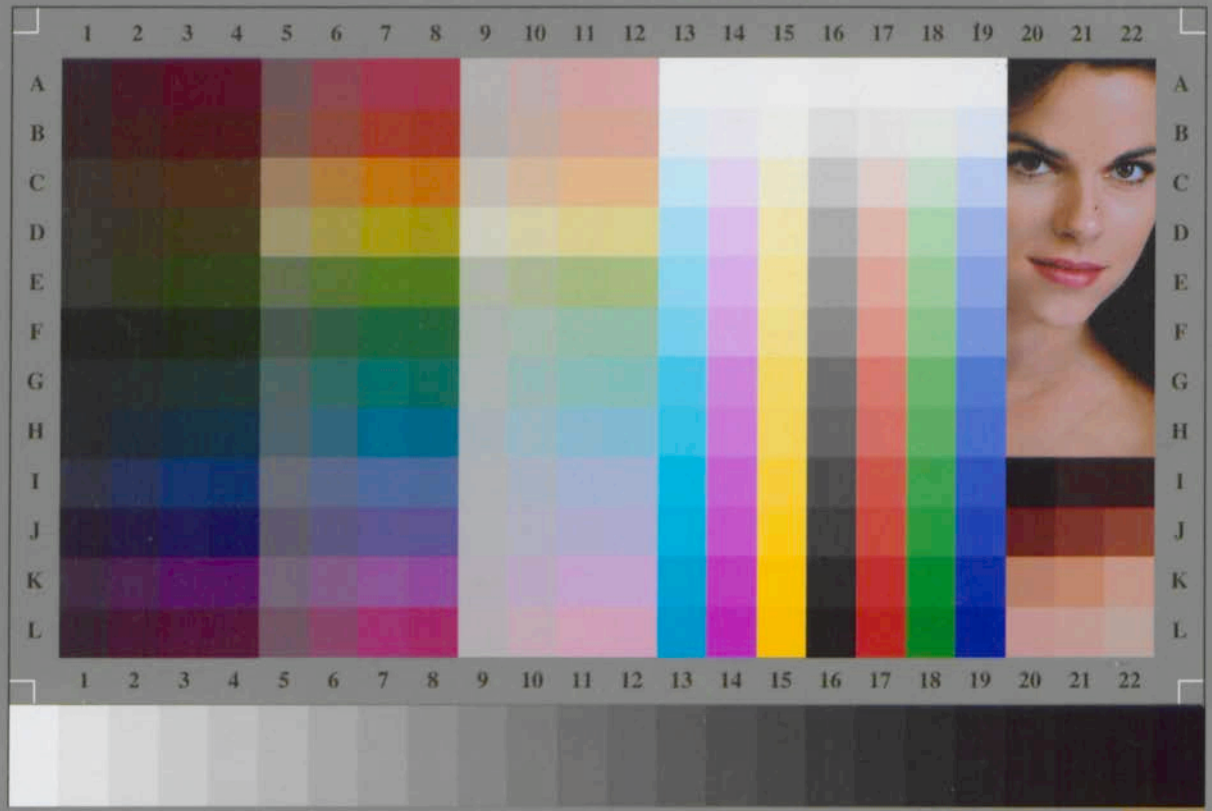

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