

MEMORANDUM OF UNDERSTANDING ON THE CONTROL AND REGULATION OF CONTAINED USE AND DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS (GMOs)

Introduction

1. The parties to this memorandum, of understanding are the Department of Environment (DOE), the Health and Safety Executive (HSE) , the Ministry of Agriculture Fisheries and Food (MAFF) , the Scottish Office (SO) and the Welsh Office (WO).¹
- 2 . The purpose of the memorandum is to ensure efficient, effective and economic co-ordination of the control and regulation of contained uses and deliberate releases of genetically modified organisms (GMOs) in relation to the statutory responsibilities set out in Annex I.²
3. All the parties are committed to close co-operation in order both to protect the environment and human health and safety and to ensure that users of GMOs are not faced with conflicting demands which may unnecessarily inhibit research or industry.

Framework for liaison

4. Annex II shows the main interfaces between the parties and the related working arrangements in relation to the statutory responsibilities set out in Annex I.
5. HSE and DOE are joint competent authorities for the purposes of EC Directives 90/219/EEC (contained use) and 90/220/EEC (deliberate release) . Subject to paragraph 6 and in consultation and co-operation with the other parties, HSE leads on contained use and DOE on deliberate release issues.
6. DOE, jointly with SO, WO and MAFF, retains lead responsibility for policy, setting standards and guidance in relation to all environmental issues, whether in relation to contained use or deliberate release. HSE similarly retains lead responsibility for all human health and safety issues affecting both contained use and deliberate release.
7. HSE or DOE, as appropriate, is responsible for ensuring that copies of individual notifications, consent applications and Summary Notification Information Formats (SNIFs) are circulated expeditiously to the other parties with a relevant interest and that a reasonable period of time is allowed for comment. The distribution of information under these arrangements will be in confidence and subject to any statutory limits on disclosure.
- 8 . HSE and DOE will consult the other interested parties, as appropriate, on liaison with the European Commission and other member states, on briefing and debriefing for competent authority meetings and, where it is desirable for other parties to speak to a brief, on the arrangements for appropriate representation at such meetings.
9. Each interested party will nominate a contact point who will be responsible for the receipt, circulation and processing, within statutory or other agreed timescales, of papers relating to notifications, consent applications and SNIFs. The nominated contact point will

¹ *References to these parties include, where appropriate references to their agencies.*

² *The operation of other legislation which may also have a bearing on work with GMOs (such as the medicines Acts 1968 and 1971, the Food and Environment Protection Act 1985, the Plant Health Act 1967, and the Animals (Scientific Procedures) Act 1986) is not covered by this memorandum.*

also be responsible for co-ordinating contributions to briefing, etc for competent authority meetings.

10. HSE will provide the secretariat for the Advisory Committee on Genetic Modification (ACGM) and DOE the secretariat for the Advisory Committee on Releases to the Environment (ACRE). Both secretariats will work in close collaboration and consultation with each other and with other interested parties. In particular, they will ensure that appropriate working arrangements are developed (eg for the clearance of papers and briefs and the appointment of assessors) to take account of other parties' interests in relation to the regulatory matters covered by this memorandum.

11. Each party will consult the other relevant party or parties where statutory responsibilities overlap, but without prejudice to the exercise of individual statutory responsibilities.

12. Where two or more parties disagree on any matter covered in this memorandum which cannot be resolved at working level, the matter will be referred to the Joint Review Group described in paragraphs 23 and 24.

Enforcement

Contained use of Genetically modified micro-organisms

13. HSE are responsible for the enforcement of the human health and safety aspects of contained uses of genetically modified micro-organisms. They are also responsible for the enforcement of environmental aspects of such uses, subject to the following undertakings, which apply only to the protection of the environment:

- a. to assist in the preparation and development of and to follow the Secretary of State's³ guidelines and advice on inspection policy and standards, and to make use of the guidelines when undertaking inspection and assessment of:
 - i. the adequacy of risk assessments required under Regulation 7 of the Genetically Modified organisms (Contained Use) Regulations 1992 for operations subject to Regulation 9(2), and therefore not already submitted to HSE as part of a notification;
 - ii. the veracity of any information notified to the Executive for the purposes of Regulations 8, 9 and 10; and
 - iii. compliance with any conditions attached to consents issued by the Executive and the Secretary of State for the purposes of Regulations 8(3) and 9(5);
- b. to report annually to the Secretary of State on enforcement action taken in respect of environmental protection, giving details in particular of the number of inspection visits paid, legal proceedings instituted and problems encountered which might require action in the future; and

³ "The Secretary of State" here and elsewhere in the memorandum means the Secretary of State for the Environment and the Minister of Agriculture, Fisheries and Food, acting jointly, as respects England, the Secretary of State for Wales, as respects Wales, and the Secretary of State for Scotland, as respects Scotland.

c . to seek the Secretary of State's expert advice, as necessary, on the investigation and policy implications of any serious incidents or dangerous occurrences where damage, or potential damage, to the environment is a possible issue and inform him of the results of such investigations and any enforcement action taken.

Contained use of Genetically modified organisms which are larger than micro-organisms

14. HSE are responsible for enforcement in relation to the human health and safety aspects of contained uses of genetically modified organisms which are larger than micro-organisms (eg plants and animals). They also have delegated responsibility from the Health and Safety Commission, which is the agent of the Secretary of State, for enforcement in relation to environmental aspects of such uses, under section 108(1)(a) of the 1990 Act and the Genetically Modified Organisms Contained Use Regulations 1993, subject to the terms and conditions of the agency agreement at Annex III.

Deliberate release of all GMOs

15. HSE have delegated responsibility from the Health and Safety Commission, which is the agent of the Secretary of State, for enforcement in relation to all aspects of the deliberate release of all GMOs (whether micro- or larger organisms) , subject to the terms and conditions of the agency agreement at Annex III.

General undertakings on enforcement of both contained uses and deliberate releases

16. A point of contact for operational issues relating enforcement will be nominated by HSE and notified to the other parties. Any issue that cannot be resolved at this or more senior levels will be referred to the Joint Review Group.

17. HSE will inform the other interested parties before they begin prosecutions (eg HSE will liaise with SO on enforcement matters in Scotland).

18. The Secretary of State's staff may, with the agreement of the inspectorate, accompany inspectors or make independent visits in relation to matters covered by this memorandum of understanding.. They will not give advice on technical matters and if they observe infringements during an independent visit will report the matter to the inspectorate as soon as is practicable.

Incidents/accidents

19. HSE are responsible for co-ordinating action in relation to accidents involving GMOs which present an immediate or delayed hazard to human health or to the environment. Whenever one party learns of an incident/accident in which one or more parties may have an interest, the information should be passed on as soon as practicable to HSE and to any other affected party or parties.

20. Where incidents/accidents affect the interests of more than one party, the parties will agree appropriate arrangements for the presentation of information to the public, press, Parliament, etc. SO or WO, as appropriate, will normally be responsible for handling the presentation of information about the environmental consequences of incidents/accidents occurring in Scotland or Wales. These arrangements do not preclude HSE inspectors on

the spot from giving appropriate information, relating to the conduct of their duties, to the public, etc.

Co-ordination of Policy and technical standards, etc

21. In their role as lead co-ordinating bodies, HSE and DOE will ensure that other interested parties are consulted, as appropriate, on any proposals to amend regulations or update technical standards, etc.

22. It is the responsibility of the signatories to this memorandum of understanding to ensure that it is brought to the attention of all relevant staff.

Joint Review Group

23. A Joint Review Group, chaired at Grade 5 level, will meet whenever the need arises, and at least once every 12 months, to review the working of this memorandum of understanding. The chair will be taken alternately by DOE and HSE and there will be a joint secretariat. The terms of reference for the committee are:

To keep under review the working of the memorandum of understanding and in particular:

- i. Resolve any problems referred to the Group, and identify, consider and, if possible, resolve any problems of a general nature arising from the practical application of the statutory provisions.
- ii. Make recommendations for changes to the memorandum as necessary.
- iii. Consider operational implications of policy decisions.
- iv. Discuss other matters of common interest.

24. Group membership will comprise at least one official from each party, together with a Chairman and Secretary. In the event of the Group's inability to resolve particular issues which may bear on policy matters, the matter will be referred to senior management.

Signed
N J KING
for DOE

A W BROWN
for HSE

P W MURPHY
for MAFF
I M WHITELAW
for SO

A H H JONES
for WO

Annex I

STATUTORY AND OTHER RESPONSIBILITIES UNDERLYING THE MEMORANDUM

Relevant legislation, etc

1. DOE, HSE (Employment), MAFF, SO and WO Ministers are designated for the purposes of Section 2(2) of the European Communities Act 1972 in relation to the control and regulation of genetically modified organisms.

2. The Genetically Modified organisms (Contained Use) Regulations 1992, in conjunction with the Health and Safety at Work, etc Act 1974 and the 1972 Act, give effect to Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms, which lays down common environmental and human health and safety measures for such operations.

1. The regulations cited in paragraph 2 also cover the human health and safety aspects of contained uses of larger GMOs (eg plants and animals), which are not addressed in the Directive 90/219/EEC. The environmental aspects of such uses are controlled under provisions in Part VI of the Environmental Protection Act 1990 and The Genetically Modified Organisms (Contained Use) Regulations 1993.

4. The Genetically Modified Organisms (Deliberate Release) Regulations 1992, in conjunction with Part VI of the Environmental Protection Act 1990 and the 1972 Act, give effect to Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms. The Directive lays down common environmental and human health safety measures in relation to the R&D release and marketing of such organisms as or in products.

5. The administration of the release of public information to the public about genetically modified organisms also takes account of Directive 90/313/EEC on the freedom of access to information on the environment. The Directive sets out the terms and conditions on which such information held by public authorities may be disseminated to the public and is implemented by The Environmental Information Regulations 1992.

Responsibilities

6. The Health and Safety Executive has responsibility in Great Britain for direct effects on human health from all work activities involving GMOs.

7. The Department of Environment has responsibility in England for all issues concerned with genetically modified organisms which affect the environment or living organisms supported by the environment, including indirect effects on human health that may result from environmental pathways.

8. Under Section 126 of the 1990 Act, the Secretary of State and the Minister for Agriculture, Fisheries and Food may act jointly in relation to matters in which both Ministers are concerned. Examples of matters for which the Minister of Agriculture, Fisheries and Food has responsibility in respect of the environment include farmed animals (including fish and shellfish), agricultural and horticultural crops (including ornamentals), plant varieties and seeds, evaluation of agricultural and garden pesticides, veterinary medicines, fertilisers, animal feeding stuffs, food and forestry, as well as the marine environment.

9. The Scottish Office Environment Department has the same responsibilities for the environment in Scotland as the Department of Environment has in England. The Scottish Office Agriculture and Fisheries Department also has similar responsibilities to those of the Ministry of Agriculture, Fisheries and Food in respect of the agricultural and marine environment in Scotland.

10. The Welsh Office has the same responsibilities for the environment in Wales as the Department of Environment has in England. The Welsh Office Agriculture Department has similar responsibilities to those of the Ministry of Agriculture, Fisheries and Food in respect of the agricultural and marine environment in Wales.

Annex II INTERFACES AND RESPONSIBILITIES

A. CONTAINED USE

Interface

[Unless otherwise stated, references are to the Genetically Modified Organisms (Contained Use) Regulations 1992].

Notification of and consent for activities involving genetic modification

1. Risk assessments for the purposes of Reg 7 and, in respect of "larger" GMOs, for the purposes of S.108(1)(a) of the EPA 90 and the GMO (Contained Use) Regulations 1993.
2. Notifications and consents under Regs 8 and 9.
3. Approval of shorter notification periods for purposes of Regs 8 and 9.
4. Requests under Reg 10(1) for further information for the purposes of evaluating notifications or determining consents.
5. Conditions attached to or revocations or variations of consents under Reg 10(2).

Responsibilities

1. HSE will discuss with DOE and other interested parties, as appropriate, the adequacy of non-consent risk assessments, insofar as they relate to protection of the environment.
2. HSE is post-box for all notifications and consent applications made in Great Britain. HSE will copy all notifications and consent applications to DOE and to other interested parties, as appropriate. Those relating to premises in Scotland will be copied to SO and those to premises in Wales to WO, including multi-site proposals which affect premises in either Scotland or Wales. Papers will be circulated within 3 working days of their receipt by HSE. HSE will co-ordinate scrutiny of notifications and consent applications.
3. HSE will consult other interested parties, as appropriate, before approving shorter notification periods.
4. HSE will copy such request to other relevant interested parties and inform them of the outcome. They will also ask the notifier for additional information requested by other parties.
5. HSE will consult other interested parties, as appropriate, on the form and content of consents issued insofar as they relate to the protection of the environment, taking account of any conditions which have been agreed on the recommendation of those parties. They will consult similarly before taking action to

revoke or vary consents issues. HSE will not issue a consent without the agreement of DOE, SO or WO, as appropriate, as it relates to environmental matters.

6. Any further information notified under Reg 10(4) or modifications to or termination of activities made under Reg 10(5).

6. HSE will copy such information to other interested parties and will, as appropriate, consult other interested parties before making any modification or termination, insofar as it relates to protection of the environment.

7. Approval of form of notifications (Reg 10(6)).

7. HSE will consult other interested parties, as appropriate, on proposed amendments to forms design.

Conduct of activities involving genetic modification

8. Approval of method for determination of containment measures for Group II Type A operations (Reg 12(3)).

8. HSE will consult other interested parties, as appropriate, on the method proposed for approval.

9. Notification of accidents under Reg 14.

9. See paragraphs 19 and 20 of main text.

Disclosure of information notified and publicity

10. Disclosure of information notified and register of information (Regs 15 and 16).

10. HSE will inform and, where appropriate, discuss with other relevant interested parties proposed decisions on disclosure and entries placed on the register, and ensure that other parties are made aware of which information is confidential. Other parties will direct to HSE all requests for information about contained use notifications and consents.

Additional duties, etc

11. Information to be sent to the Secretary of State (Reg 18).

11. HSE will co-operate with other interested parties, as appropriate, in the exchange of relevant information for the purposes of the Regulations.

12. Reports to the European Commission (Reg 19).

12. HSE will discuss with other interested parties, as appropriate, periodic reports to the European Commission on notifications made.

13. Exemption certifications (Reg 20).

13. HSE will consult other relevant interested parties on proposals for exemptions.

B. DELIBERATE RELEASE

Interface

[References are to the Genetically Modified Organisms (Deliberate Release Regulations [1992] or to the Environmental Protection Act 1990 (EPA)]

Consents to release or market

1. Applications for consents to release or market (Regs 6 and 11).

2. Further information requested in connection with consent applications (S.111(6) EPA).

3. Decisions on consent applications and limitations and conditions attached to and revocation or variation of consents issued (S.111(8), (10) and S.112 EPA).

4. Information notified to the Secretary of State as a result of specific or general S.112 conditions or Reg 9.

Duties placed on Secretary of State

5. Submission of UK Summary Information Formats (SNIFs) to Commission and comments from other member states on UK SNIFs (Reg 14 and 15).

Responsibilities

1. DOE is post-box for all consent applications made in Great Britain. DOE will copy consent applications to HSE, MAFF, SO and WO, as appropriate, within 3 working days of their receipt. DOE will co-ordinate scrutiny of consent applications.

2. DOE will copy such requests to those who received copies of the original application and inform them of the outcome. They will also ask the applicant for additional information requested by other parties.

DOE will consult other relevant interested parties, as appropriate, on the issue of individual consents and the limitations and conditions attached to them and ensure that such consents refer to the appropriate statutory authority. They will consult similarly on proposals to revoke or vary consents. No consent shall be issued, revoked or varied as it relates to the protection of human health and safety without the agreement of HSE. Similarly, no consent which affects the interests of any other interested party or parties shall be issued, revoked or varied without their agreement.

4. DOE will inform other relevant interested parties, as appropriate, of such information.

5. DOE will ensure that SNIFs and, in relation to marketing, product dossiers are sent to the Commission for comment by other member states and consult other interested parties, as appropriate, on the resolution of any substantial objections, in

particular any which are referred to Article 21 (90/220/EEC) proceedings.

Public register of information and exclusions from register

6. Decisions on confidentiality issues (S.123 EPA) and register of information (S.122 and Regs 17 and 18).

6. (a) DOE will inform and, where appropriate, discuss with other interested parties proposed decisions on confidentiality and entries placed on the register, and ensure that other parties are made aware of which information is confidential. Other parties will direct to DOE all requests for information about deliberate releases.

(b) The following arrangements will apply to the keeping of the register:

i. DOE will maintain a copy of all register entries at its HQ and will ensure that copies of register entries relating to consents to market GMOs in the UK are circulated to every other office responsible for the keeping of registers.

ii. Register entries relating to R&D releases in England and Wales will be kept at the relevant HMIP divisional office.

iii. Register entries relating to R&D releases in Scotland will be kept and maintained at the relevant HSE office.

Advisory Committee on Releases to the Environment (ACRE)

7. Appointments under S.124 of EPA 90.

7. DOE will be responsible for arrangements for agreeing and making appointments in consultation with other interested parties. Appointment letters will be signed by the appropriate DOE Minister.

Other obligations arising from 90/220/EEC

8. Summary notification Information Formats (SNIFs) from other member states.

8. DOE will ensure that SNIFs from other member states and, in relation to marketing, product dossiers are circulated to other interested parties, as appropriate, for comment and will co-ordinate responses to the Commission, taking account of other interested parties comments.

9. Proposals to provisionally restrict or impede the use and/or sale of products agreed under 90/220/EEC (Article 16).

10. Report on the control of the use of all products placed on the market under the Directive.

9. DOE will co-ordinate action on the environmental and human health aspects of such proposals in consultation, as appropriate, with other interested parties.

10. DOE will consult other parties on the preparation of reports to the Commission.

Annex III

**AGREEMENT BETWEEN THE SECRETARY OF STATE AND THE HEALTH AND
SAFETY COMMISSION ON THE RELEASE AND MARKETING OF GENETICALLY
MODIFIED ORGANISMS (GMOs) AND ENVIRONMENTAL ASPECTS OF CONTAINED
USES OF "LARGER" GMOs: ENFORCEMENT**

[Copy of original agreement attached]

AGREEMENT BETWEEN THE SECRETARY OF STATE AND THE HEALTH AND SAFETY COMMISSION ON THE RELEASE AND MARKETING OF GENETICALLY MODIFIED ORGANISMS (GMOs), AND ENVIRONMENTAL ASPECTS OF CONTAINED USES OF "LARGER" GMOs: ENFORCEMENT

1. The Secretary of State hereby invites the Health and Safety Commission ("the Commission"), subject to paragraph 3, to perform the functions referred to in paragraph 2 ("the relevant functions"), being functions which in the opinion of the Secretary of State for Employment can appropriately be performed by the Commission in connection with its functions.
2. The relevant functions are the functions specified in paragraph 1 of Annex A, being the Secretary of State's enforcement functions under Part VI of the Environmental Protection Act 1990 ("the 1990 Act") as amended by the Environmental Protection Act (Modification of Section 112) Regulations 1992.
3. The functions are to be exercised in relation to the release and marketing of genetically modified organisms under the 1990 Act and the Genetically Modified Organisms (Deliberate Release) Regulations 1992 and the import and acquisition of genetically modified organisms under the 1990 Act and the Genetically Modified Organisms (Contained Use) Regulations 1993.
4. Subject to the terms and conditions set out in Annex A and the initial programme of work set out in Annex B, acceptance of this invitation shall:
 - (a) constitute an agreement between the Secretary of State and the Commission under section 125(1) of the 1990 Act and section 13(1)(b) of the Health and Safety at Work, etc Act 1974 ("the 1974 Act"); and
 - (b) activate for the purposes and duration of the agreement the delegation by Secretary of State to the Commission of the relevant functions.

Signed:

Michael Howard
One of Her Majesty's Principal Secretaries of State

Department of the Environment

Date:.....27 January 1993

The agreement comprised in the terms of the above invitation is hereby accepted:

Signed by authority of the Health and Safety Commission:

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Date: 2.2.93

Annex A

TERMS AND CONDITIONS

Functions

1. The relevant functions are those specified in section 125(2) of the 1990 Act:
 - (i) the service and withdrawal of prohibition notices (section 110);
 - (ii) the appointment of inspectors (section 114(1));
 - (iii) the authorisation of inspectors to prosecute before a magistrates' court (section 114(4));
 - (iv) the service of notices requiring persons to furnish information (section 116);
 - (v) the institution of proceedings (section 118(10));
 - (vi) the power to arrange for the remedying of harm (section 121).
2. The Commission shall direct the Health and Safety Executive ("the Executive") under section 11(4)(a) of the 1974 Act to exercise the relevant functions on behalf of the Commission in accordance with the following undertakings.

Appointment of inspectors

3. The Executive shall:
 - (a) consult the Secretary of State on the relevant qualifications, experience, training, instruction, tasks and instruments of appointment of inspectors under section 114 of the 1990 Act for the purposes of the agreement;
 - (b) appoint under section 114 of the 1990 Act such numbers of inspectors as appear sufficient for the purpose of carrying the agreement into effect and inform the Secretary of State of the arrangements for their deployment; and
 - (c) inform the Secretary of State of any proposed changes to the deployment of the inspectors appointed for the purposes of the agreement.
4. Inspectors appointed under these arrangements shall have the powers set out in sections 115 and 117 of the 1990 Act.

Programme of work

5. The Executive shall perform the relevant functions in accordance with a costed programme of work and the Secretary of State's requirements for environmental protection. The agreed programme of work for the period from the commencement of the agreement until March 1993 and from April 1993 to March 1994 is at Annex B. The programme shall be updated and revised to cover subsequent annual periods in accordance with the arrangements set out in paragraph 6.
6. Starting from October 1993, the Executive shall submit to the Secretary of State for his approval at the beginning of October each year a costed programme of work for the financial year beginning in the following April. The proposed programme will take account of the Secretary of State's current requirements for environmental protection, which the

Secretary of State shall communicate to the Executive by June of each year, starting in June 1993. The programme will also, as appropriate, include details or take account of:

- (a) the expected number of planned inspection visits and the procedure to be used for prioritising them as well as the capacity of inspectors to respond to urgent needs;
- (b) the staff, management and training arrangements for the inspection team, including the grade of each member of it, and the proportion of his or her time allocated to the relevant functions;
- (c) the development of inspection procedures and instructions, including the procedures and warrants necessary for the exercise of rights of entry to and inspection of premises and the taking of samples under section 115 of the 1990 Act;
- (d) proposed arrangements for liaison with and support from other bodies and inspectorates, including the Executive's Research and Laboratory Services Division and the Agricultural Inspectorate;
- (e) proposed arrangements for liaison with the Secretary of State's officials and for attendance at meetings of the Advisory Committee on Releases to the Environment;
- (f) proposed arrangements for dialogue, nationally and internationally, with scientists, technologists and professional societies and other organisations on matters relating to environmental aspects of inspection and enforcement in connection with the relevant functions ; and
- (g) proposals for support and advice to the Secretary of State on the development of standards, technical guidance and publications in connection with environmental aspects of the relevant functions.

Reports to the Secretary of State

7. The Executive shall submit to the Secretary of State at the end of April 1993, and annually thereafter, a report on the work carried out in fulfilment of the agreement during the preceding financial year. It will give an account of the work done under the costed programme of work for that year, and will include in particular the number of inspection visits paid, information on prosecution and other enforcement action taken, and a description of any problems identified which might require action in the future.

8. The Executive shall seek the Secretary of State's expert advice, as necessary, and report to him, as soon as practicable after their occurrence, on the investigation of any serious incidents or 'dangerous occurrences which have policy or prosecution implications or which might be widely publicised.

Exchange of information

9. The Secretary of State shall provide to the Commission and Executive such information as either of them may at any time reasonably require for the purpose of performing the functions specified in the agreement, and the Commission and Executive shall provide to the Secretary of State such information as he may at any time reasonably require in connection with the performance of those functions.

Financial arrangements

10. The Secretary of State shall pay the Executive the full amount of the costs incurred in performing the relevant functions, in so far as they are included in the approved programme of work.

11. The Secretary of State shall be responsible for additional liabilities only where he has consented to that additional expenditure in writing before it was incurred. The Executive shall notify the Secretary of State as soon as possible if the agreed sum for any year in relation to the costed programme of work is likely to be inadequate.

12. From the commencement of the agreement until 31 March 1994, the Executive's costs shall be determined in accordance with the costed programme of work specified in Annex B. The Secretary of State's total liability in this period shall be £20,000 from the commencement of the agreement until 31 March 1993 and £120, 0,00 from 1 April 1993 until 31 March 1994.

13. The Secretary of State's total liability in the period of 12 months commencing on 1 April 1994, and in any subsequent period, shall be limited to the amount, if any, agreed by him in writing in accordance with the arrangements set out in paragraphs 6, 10 and 11 and with the other terms and conditions of the agreement.

14. The Executive shall produce such accounts, documents, records or explanation as the Secretary of State may reasonably request relating to expenditure in connection with the agreement.

15. The Secretary of State shall make payments to the Executive against quarterly returns in respect of the agreed programme of work submitted to The Biotechnology Unit, Department of Environment, Room A323, Romney House, 43 Marsham Street, London SW1P 3PY. They will be within the limits of the agreed budget or for such higher sums as have been given prior approval.

16. The Secretary of State will make payments quarterly in arrears on receipt of a detailed expenditure account/invoice for each of the first three quarters; and made an advance payment for the final quarter on receipt of an invoice for the estimated cost of that quarter. This invoice should be submitted by mid-February for payment within the financial year, any adjustment necessary will be made to the next invoice.

17. Payment will be made through the Paymaster General by means of receivable orders.

General

18. The Executive shall not disclose to a third party information, reports or results relating to work carried out under the agreement, except for the purposes of enforcement action or in compliance with a court order, without the agreement of the Secretary of State.

Period of agreement

19. The agreement shall come into effect on 2 February 1993 and shall terminate on the expiry of twelve months' written notice given at any time by either party to this agreement to the other.

ANNEX B

PROGRAMME OF WORK for 1992-3 and 1993-4 TO BE CONDUCTED UNDER THE AGENCY AGREEMENT

1. This document sets out the programme of work agreed between the Secretary of State and the Health and Safety Executive for the periods from 1 February 1993 to 31 March 1993 and from 1 April 1993 to 31 March 1994.
2. The plan of work is intended to cover that part of the work of THSD's Biotechnology Group concerned with:
 - (a) The Genetically Modified organisms (Deliberate Release) Regulations, 1992, and
 - (b) Environmental aspects of the contained use of genetically modified organisms covered by the Environment Protection Act 1990, and in particular Section 108 (1) (a), as applied by the Genetically Modified Organisms (Contained Use) Regulations, 1993.
3. Most activity for the period 1 February 1993 to 31 March 1993 related to the setting up of appropriate liaison, management and working procedures for the purposes of the Agreement, within HSE's Technical and Health Sciences Division and between THSD and the Biotechnology Unit of Dept. of the Environment. Estimated costs during this period are therefore weighted towards input to this activity.
4. A major activity for the period 1 April 1993 to 31 March 1994 is the inspection of release sites in connection with consents granted by the Secretary of State. In this first year of operation the sites of all releases will be visited at least once. We estimate there will be ten consents. As a very rough average, we anticipate that 4 working days will be needed to cover all the activities associated with a single visit.
5. Inspection visits will also be made to sites notified under the Genetic Manipulation Regulations, 1989 for environmental reasons. This will include 10 visits to sites where releases are still being conducted and at least 30 sites where post-release monitoring is continuing.
6. Planned inspections of sites where contained uses of GMOs which are larger than micro-organisms (plants and animals) are based on the assumption that approximately 75 sites will be subject to section 108 (1) (a) of the Environment Protection Act and the Genetically Modified organisms (Contained Use) Regulations, 1993 during the period covered by this programme. A very preliminary estimate is that the target number of inspections of these sites will be 20 (27 per cent of all sites). The work on environmental aspects of these visits will be of very variable duration requiring between 0.5 and 5 working days, dependant on the nature of the work and the location). We have assumed 1 day per visit will be the average value.
7. The details of the programmes and the costings are given in Appendices 1 (for 1992-3) and 2 (for 1993-4). The key to the headings is given in Appendix 3.
8. The staff qualified to undertake inspection, etc. and the contact points for the different aspects of the work are given in appendix 4. Their qualifications and experience are given in Appendix 5.

9. As these programmes are being drawn up prior to implementation of the Regulations, they must be regarded as approximate forecasts. If significant deviations occur, the plans will be revised appropriately.

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APPENDIX 1: PROGRAMME OF WORK FOR THE PERIOD 1 FEBRUARY 1993 TO 31 MARCH 1993.

<u>Activity</u> (see Appendix 3 for key)	Time (person days)		Cost per activity	
	Gd 6	PSI/SI	AO	(£ Dec 1992)
<u>A Statutory functions</u>				
1. Planned enforcement related activities				
b. Contained use		5	2	1 332.57
2. Contingent enforcement related activities		3		671.25
<u>B Non-statutory functions</u>				
1. Set up procedures	10	3		945.31
<u>C Overheads</u>				
1. Training		10	2	2 451.32
2. Line management functions	4	4		1 991.24
3. Travel and subsistence				
b. Other				1 760.00
<u>4 Totals</u>	15	55	17	19 994.62

The grade mix for PSI/SI has been assumed as 1:1 for this period.

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APPENDIX 2 PROGRAMME OF WORK FOR THE PERIOD 1 APRIL 1993 TO
31 MARCH 1994

<u>Activity</u> (see Appendix 3 for key)	<u>Time (person days)</u>		<u>Cost per activity</u>	
	<u>Gd 6</u>	<u>PSI/SI</u>	<u>AO</u>	<u>(£ Dec 1992)</u>
<u>A Statutory functions.</u>				
1. Planned enforcement related activities				
(a) Deliberate releases	2	40	10	10 567.22
(b) Contained uses	2	20	10	6 092.22
2. Contingent enforcement related activities				
	5	20	5	8 379.85
<u>B Non-statutory functions.</u>				
2. Input to ACRE				
		65	15	16 147.40
3. Residual Inspection responsibilities				
	1	160	40	40 350.46
4. Standards, technical guidance, publications				
		10	5	2 772.05
5. Conferences				
		10		2 237.50
<u>C Overheads.</u>				
1. Training				
		30	15	8 316.15
2. Line management functions				
	20	15		8 837.45
<u>D Travel and subsistence</u>				
(a) for Ala				
				4 500.00
(b) Other				
				9 500.00
<u>E Training courses (fees)</u>				
				2 000.00
<u>Totals</u>	30	370	100	119 700.30

Assumes grade mix of 1:1 PSI:SI for 1993-4.

* The sum included here is for Laboratory/testing costs for all enforcement activities.

APPENDIX 3: ACTIVITY KEY FOR THE PURPOSES OF APPENDICES 1 AND 2

Activity

A1 Activities arising from scheduled inspections of release or contained use sites or in connection with GMO products, including tests, inspections, information gathering and taking and examination of samples under S.115 or 116 of the EPA 1990, etc. for the purposes of:

- a monitoring and advising on compliance with the conditions attached to consents to release or marketing GMOs granted in accordance with S.111 and 112 of EPA 90;
- b. determining the adequacy of environmental risk assessments and associated records made in connection with contained use (i.e.) importation or acquisition) of GMOs under S.108 of the EPA 90.

A2 Activities arising from scheduled inspections under A 1 or unscheduled inspections of release or contained use sites or in connection with approved GMO products for the purposes of investigating or dealing with unforeseen incidents or occurrences, and including:

- a the service and withdrawal of prohibition notices under S 110 in connection with proposals for import, acquisition, release or Marketing of GMOs;
- b dealing with any cause of imminent danger of damage to the environment in accordance with S.117;
- c instituting and pursuing proceedings for offences committed under S.118;
- d remedying harm in accordance with S.121 in connection with offences committed under S.118;
- e any tests, inspections, information gathering and taking and examining of samples required to support activities a to d;
- f investigating public complaints to determine if any offence has occurred.

B1 Activities arising from the establishment of procedures, line Management structures and liaison arrangements necessary to bring the Agency Agreement into effect, including:

- a the development of inspection procedures and instructions, including procedures and warrants necessary for the exercise of rights of entry to and inspection of premises and the taking of samples under S.115 of the EPA 1990;
- b the development of procedures for prioritising planned inspection visits for the purposes of activity A 1;
- c arrangements for liaison with and support from other bodies and inspectorates, including the Executive's Research and Laboratory Services Division and Agricultural Inspectors;
- d arrangements for liaison with the Secretary of State's officials and for access to information held by the Secretary of State;
- e staff training

B2 Activities relating to the assessment of applications for release or marketing of GMOs considered by the Advisory Committee for Releases to the Environment (ACRE) and its working groups.

B3 Activities relating to the Inspection of sites notified under the Genetic Manipulation Regulations, 1989 in relation to environmental matters, but not covered by A1.

B4 Activities relating to support and advice on standards, and criteria for inspection and enforcement, including the development of related guidance.

B5 Activities related to conferences, seminars, etc. which are relevant to the exercise of environmental aspects of activities A1 and A2.

C1 Staff costs of training activity to enable Inspectors to perform their activities under this Agreement.

C2 Line management of staff, including supervision of agreed duties and personnel functions.

C3 Activity C3a covers travel and subsistence spent on performing statutory functions under Ala, which are recoverable by the Secretary of State via fees and charges to consent applicants or holders. Activity C3b covers travel and subsistence for all other activities.

Notes

Costs per activity are based on full economic day rates for staff of the relevant grade mix based on staff in post and grade at Dec 1992.

Procedures for prioritisation Of visits will be forwarded in due course.

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**APPENDIX 4 STAFF UNDERTAKING DUTIES UNDER THE AGENCY AGREEMENT
AND CONTACT POINTS**

Head of Group Biotechnology/Environment:
Dr H P A Illing (Gd 6)

Heads of Sections:
Biotechnology (Environmental and Agricultural Applications)
Dr D A Bosworth (T/Prin. Spec. Insp.)

Biotechnology (Industrial and Laboratory Applications)
Dr A N Cottam (Prin. Spec. Insp.)

Specialist Inspectors:

Dr P Logan
Dr M Iosson
Dr S Warne

Any changes to this list will be notified to the Dept of Environment via Dr I Gillespie as required by the Agency Agreement.

It is anticipated that all these staff will be warranted under the Environment Protection Act 1990 in order to allow flexibility in their day-to-day deployment.

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APPENDIX 5 - QUALIFICATIONS AND TRAINING

All professional staff are required to have a good degree in a relevant discipline. Relevant disciplines include most fields of biology, such as microbiology, biochemistry, ecology or agriculture, and chemical engineering. Currently, all Inspectors also possess a relevant higher degree. They undergo a one-year 'in house' training programme prior to joining the Group. Each Inspector is required to undertake appropriate further training and professional development through a structured programme set out in the Biotechnology section of the manual for Specialist Inspector Training and Development. This programme includes both internal and external courses and meetings. Appropriate training records are maintained.

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