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TYPE: ACTION DOCUMENT NUMBER: 9203127
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS C

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FROM: STEWART, W.D.P.: OFFICE OF SCIENCE AND TECHNOLOGY, GREAT BRITAIN

TO: DR. D.A. BROMLEY

DATE OF CORRESPONDENCE: 09/25/92

SUBJECT: HE IS FORWARDING A COPY OF THEIR PROPOSALS FOR NEW REGULATIONS ON GENETICALLY MODIFIED ORGANISMS, WITH A VIEW TO WORKING TOWARDS A CLOSER HARMINOZATION BETWEEN U.S. AND U.K. NATIONAL REGULATIONS.

****

DIRECTORATE ASSIGNED: INTERNATIONAL/POLICY

STAFF ASSIGNED: JEFF SCHWEITZER

ACTION REQUIRED: FOR DAB'S SIGNATURE

STAFF ACTION: for DAB'S SIGNATURE

****

SENDER'S DUE DATE:

OSTP DUE DATE: 11/04/92 STAFF DUE DATE

DATE COMPLETED: DATE COMPLETED/DEPT: 10/27/92

****

COPIES TO: D. Allan Bromley
LIFE SCIENCES

****

WHITE HOUSE TRACKING #: CONTACT PERSON:

PHONE: EXT:

REMARKS: Response was prepared by Clif Gabriel, signed by Dr. Bromley, and mailed.(dic)



OSTP RECEIVED: 10/19/92 DEPT RECEIVED: 10/20/92

FILE: P-INTERNATIONAL

CENTRAL FILES:

TYPE: ACTION
ORIGINATOR: 02
STATUS I
DOCUMENT NUMBER: 9203127
DIRECTORATE STATUS

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DIRECTORATE ASSIGNED: INTERNATIONAL/POLICY

STAFF ASSIGNED: JS

ACTION REQUIRED: FOR DAB'S SIGNATURE

STAFF ACTION: FOR DAB's signature

****

OSTP DUE DATE:
SENDER'S DUE DATE:
DATE COMPLETED: 11/04/92

STAFF DUE DATE 11/4/92
DATE COMPLETED/DEPT:

****

COPIES TO: D. Allan Bromley
LIFE SCIENCES

****

WHITE HOUSE TRACKING #:

CONTACT PERSON:
PHONE:
EXT:

REMARKS: Life Sciences will draft.

OSTP RECEIVED: 10/19/92
FILE: P-INTERNATIONAL

DEPT RECEIVED:

CENTRAL FILES:

THE WHITE HOUSE

WASHINGTON

October 27, 1992

Bill

Dear Professor Stewart:

Thank you for the opportunity to comment on the draft UK regulations on both the contained and field use of genetically modified organisms (GMOs). It is obvious this draft represents a great deal of effort on the part of all involved in its creation. I believe your decision to separate the regulations on the basis of activity rather than on the basis of human health and environmental risks makes sense. However, I must admit the continued reliance on the process of genetic modification rather than level of risk to trigger oversight is difficult to justify scientifically.

Fortunately, U.S. biotechnology regulatory oversight mechanisms are gradually evolving to the regulatory philosophy established by Office of Science and Technology Policy scope document (copy enclosed). The basic tenets of this document are: (1) regulations should not be based on how an organism is produced but rather on risk; and (2) the level of oversight should reflect the level of risk. Due to existing statutes and regulations, the complete adoption of this philosophy by U.S. regulatory agencies has been difficult. However, progress is being made as demonstrated by the U.S. Food and Drug Administration's proposed policy on biotechnology produced foods.

I would appreciate a copy of your GMO regulations once they are final. To the extent possible, it is important that we continue to work toward international harmonization of biotechnology regulations.

Sincerely yours,

Allan

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Enclosure

Professor William D. P. Stewart
Chief Scientific Adviser
Cabinet Office
Office of Public Service and Science
70 Whitehall
London SW1A 2AS

3127

CABINET OFFICE
Office of Public Service and Science
OFFICE OF SCIENCE AND TECHNOLOGY
70 Whitehall, London SW1A 2AS
Telephone: 071-270 0259 Facsimile:071-270 0616

From the Chief Scientific Adviser and Head of Office
Professor William D. P. Stewart, FRS, FRSE

W0571

Dr D Allan Bromley
Director
Office of Science and Technology Policy
Executive Office of the President
The White House
Washington
DC 20500

25 September 1992

Dear Dr Bromley

RELEASE OF GENETICALLY MODIFIED ORGANISMS

1. It was a pleasure to meet you at Leeds Castle in May, and to enjoy, as always, stimulating and useful discussions.

2. As mentioned in your last memo, we agreed to exchange copies of relevant documents relating to regulations in biotechnology and the release of genetically modified organisms, with a view to working towards closer harmonisation between national regulations.

3. I enclose the UK's revised proposals for regulations relating to GMOs that have recently been published, together with a covering consultation paper. Five UK Departments have been involved in the preparation of these papers following a period of consultation with interested UK parties. A major change has been the separation of regulations on the actual activity - contained use or deliberate release - rather than between human health and safety and environmental protection as in an earlier draft. If you have any immediate thoughts on the proposals, I should be pleased to receive them.

4. In writing, I am pleased to let you know that William Waldegrave, who has Cabinet responsibility for science, has agreed to attend future meetings of the Carnegie Group on behalf of the UK. While I shall miss our regular discussions I have been proud to be associated with the group during its formative stages.

5. I wish you and friends at the Carnegie Commission on Science, Technology and Government every success for the future. I shall of course continue to see you all at various international meetings, and will be pleased to do what I can to assist the work of the group.

Yours sincerely,

Lynn Drummond
(PRIVATE SECRETARY)

pp PROFESSOR W D P STEWART
Chief Scientific Adviser

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Direct Line 071 - 276 8353
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14 August 1992

Proposed New Genetically Modified Organisms Regulations
Second Consultation

This letter is addressed to those who responded to, and to other organisations with an interest in, the consultation paper issued in October 1991 by the Department of the Environment and the Health and Safety Commission, together with the Ministry for Agriculture, Fisheries and Food, the Scottish Office and Welsh Office. We are grateful for all the comments to that document which contained proposed new regulations to implement the two EC directives on genetically modified organisms. The consultation period ended on 22 January, 1992.

We received about 200 responses to the consultation. These criticised both the structure and complexity of the proposed regulations, and questioned points of detail. Officials at DOE and HSE have since engaged in discussions with interested parties, the Advisory Committees on genetic modification (ACGM and ACRE), Competent Authorities of EC member states and the European Commission to resolve these questions and concerns.

As a result, we have prepared the attached new draft regulatory package. The consultation paper outlines the main changes, the most significant of which has been the separation between regulations on the basis of *activities* (ie contained use or deliberate release) rather than separation on the basis of human health and safety and environmental protection as in the previous draft.

In addition to the two new sets of draft regulations, the consultation package also includes draft guidance to the two sets of regulations and a proposed scheme of fees and charges. Comments are invited specifically on the regulations, and the scheme of fees, but views on the draft guidance would also be welcome.

We invite you to send your response to Mr M Sargeant at the above addresss before 28 September 1992.

We look forward to hearing from you.

Yours sincerely,

N. J. King

Dr N J King

14 August 1992

GENETICALLY MODIFIED ORGANISMS: PROPOSED NEW REGULATIONS

A consultation paper issued jointly on behalf of the Secretary of State for the Environment, the Health and Safety Commission, the Minister of Agriculture, Fisheries and Food, the Secretary of State for Scotland and the Secretary of State for Wales.

Enclosed with the paper are revised draft proposals for regulations and accompanying draft guidance to implement two European directives on genetically modified organisms, following consultation on earlier drafts issued in October 1991.

Introduction

1. Activities involving genetic modification (GM) are by now a well-established feature of modern biotechnology and the safety record associated with such work has been extremely good. This has in part been due to a well established system of regulation of GM activities, which has ensured that safety goes hand in hand with technical progress and innovation.

2. Regulations to control the safety of GM in the UK have been in place since 1978. The current operative regulations are the Genetic Manipulation Regulations 1989, made under the Health and Safety at Work, etc Act 1974 (HSW Act). These regulations require notification to the Health and Safety Executive (HSE) of genetic modification activities, including proposals to introduce genetically modified organisms (GMOs) into the environment.

3. However, these regulations do not provide explicitly for the same degree of protection of the environment, being primarily concerned with the protection of human health. Consequently, separate powers allowing for the protection of the environment were taken in Part VI of the Environmental Protection Act 1990 (EP Act). At the same time as this new national legislation was being developed, the EC introduced directives 90/219/EEC and 90/220/EEC.

4. Directive 90/219/EEC deals with contained uses of genetically modified microorganisms and directive 90/220/EEC with deliberate release into the environment and marketing of GMOs. These directives established common human health and environmental safety standards for all GM work. They were due to be implemented in national legislation by 23 October 1991.

5. In October 1991, the Department of the Environment (DOE) and the Health and Safety Executive (HSE), together with the Ministry of Agriculture, Fisheries and Food (MAFF),the Scottish Office (SO) and the Welsh office (WO) published a consultation paper containing two sets of closely associated draft regulations for this purpose; these were to be made under Part VI of the EP Act and the HSW Act. The consultation period ended on 22 January 1992

and approximately 200 responses were received. Responses addressed two main areas: the complex structure and lack of transparency of the requirements, and points of detail, often involving ambiguity.

6. The regulations and accompanying guidance have now been substantially redrafted to take account of these comments. These new regulatory proposals do not detract from the need to observe other statutory requirements, such as those concerning plant and animal health requirements, health requirements, and occupational health and safety generally.

Structure and effect of the regulations

7. Two separate sets of regulations are now proposed as a consequence of radical restructuring:

- The Contained Use of Genetically Modified Organisms Regulations 199-, to be made under the HSW Act, and the European Communities Act 1972 (EC Act). The regulations provide for both the human health and environmental protection aspects of the *contained use* of all GMOs.

- The Genetically Modified Organisms (Deliberate Release) Regulations [199-], to be made under the EP and EC Acts. The regulations will introduce controls on the *release and marketing* of all GMOs to provide for both environmental protection and human health.

8. The major change in the new approach has been in separating *contained use* and *release* into two separate sets of regulations, which now reflect the structure of the two directives.

9. The Contained Use Regulations now follow closely the wording of directive 90/219/EEC. The use of the HSW and EC Acts as parent legislation has enabled the regulations to be drafted *without* recourse to the EP Act. This arrangement means that certain definitions in the EP Act, which caused considerable difficulty when applied to contained use are *no longer* used.

10. Directive 90/219/EEC only covers the contained use of genetically modified microorganisms. It does not cover genetically modified **non-microorganisms**, such as whole plants and animals. In relation to human health and safety, such non-microorganisms are currently covered by the Genetic Manipulation Regulations 1989 and will continue to be covered by the proposed new regulations. In relation to environmental protection, it is proposed that section 108 (1)(a) of the EP Act will be brought into force. This will ensure that anyone intending to make, or acquire from another person, a genetically modified non-microorganism which is not an approved product will need to carry out a risk assessment and should keep it available for inspection. Further details will be included in the guidance to the regulations.

11. The Deliberate Release Regulations are changed little compared with the earlier version.

Changes in detail made as a result of consultation

12. A number of further changes have been made in the new draft regulations. Annex 1 summarises those of significance. The main effect is to remove ambiguity in the earlier versions which led to considerable uncertainty of interpretation. In most cases the clarifications set out have been agreed at European level.

Administrative arrangements and information to the public

13. HSE will lead on implementation of the Contained Use Regulations, with the DOE retaining responsibility for environmental policy, together with the SO, WO and MAFF as appropriate. A single post box will operate, whereby all communication concerning contained use activities will be with HSE, although notifications of contained uses will be scrutinised by both HSE and DOE and other departments as appropriate.

14. DOE, together with SO, WO and MAFF as appropriate, will lead in implementing the deliberate release regulations, though policy on human health and safety aspects will continue to lie with HSE. All applications for consents to release and market will be scrutinised by DOE and HSE. The single post box in these cases will be with DOE.

15. The two existing Advisory Committees will continue to advise on activities involving the use of GMOs. The Advisory Committee on Genetic Modification (ACGM) will advise on all aspects of contained uses: i.e. both human health and safety and environmental protection. The secretariat will continue to be provided by HSE who will work in close collaboration with DOE, SO and WO. The Advisory Committee on Releases to the Environment (ACRE) will advise on all aspects of releases and marketing. The secretariat will be provided by DOE who will work in close collaboration with HSE and MAFF, SO and WO as appropriate. These committees will advise the Secretary of State for the Environment, the Health and Safety Commission and Executive, the Secretaries of State for Scotland and Wales, and the Minister for Agriculture, Fisheries and Food, as appropriate.

16. As provided for in the previous draft regulations, the new drafts include provisions for making certain information available to the public as is allowed under directives 90/219/EEC and 90/220/EEC, and required by a further directive on the freedom of access to environmental information (90/313/EEC).

17. HSE will maintain a public register of all notifications requiring consent. Registers will be maintained at the Head Offices of HSE and at the HSE Area Office in whose area the notifying body is situated. The register will contain the information which, under the terms of the Contained Use Directive, cannot be kept confidential. Similar information in

relation to notifications not requiring consent will, if requested, be made available by HSE.

18. In England and Wales, DOE will be responsible for registers of information on release and marketing of GMOs. These registers will contain the details as set out in the draft regulations and will contain contact names and addresses. The new draft regulations will enable confidentiality issues to be decided before any entry is placed on the register. Applicants will be encouraged to submit applications about 45 days before ACRE meetings, the dates of which will be published. This should allow sufficient time for comments or representations to be made. In England and Wales the registers will be held at DOE Headquarters and local offices of HMIP, the Pollution Inspectorate. In Scotland, HSE will be responsible for these registers.

Fees and charges

19. It is Government policy to charge for consents and authorisations, and proposed charges for these were therefore included in the October 1991 consultation paper. These have now been revised to reflect the new structure of proposed regulations. Annex 2 sets out proposals for fees for notifications and consents for contained uses, and a proposed scheme for five bands of fees and their associated charges for release and marketing consents. The underlying costs are explained, as requested by many consultees. The scheme will be subject to Treasury approval.

Enforcement

20. Contained Use Regulations: HSE will carry out inspection and enforcement of all contained use activities (as set out in Regulation 21), although the policy on standards for environmental protection will lie with and be agreed by environment departments. The responsible body for these activities will be the HSE Specialist Inspectorate in Bootle, Merseyside.

21. Deliberate Release Regulations: The Secretary of State has powers under Part VI of the EP Act to delegate enforcement of the deliberate release regulations to individuals or to any public authority. Arrangements for enforcement need to take into account that the regulations cover risks to both humans and the environment.

22. In the first instance, arrangements will be made for the Health and Safety Executive to enforce all aspects of the regulations. This arrangement will be kept under review as circumstances develop, one of which will be the formation of the Environment Agency, in two to three years' time.

Consultation arrangements and timing

23. Comments are invited on all aspects of these proposals, including the draft guidance though this will, in any case, be refined during the consultation period. Comments should be sent to the following address to arrive no later than 28 September 1992:

Mr Martin Sargeant
Biotechnology Unit
Room A347
Department of the Environment
43 Marsham Street
London SW1P 3PY
Telephone: 071 276 8353

24. As with the earlier consultation exercise, comments will be copied, where appropriate, to other interested Government Departments. Comments from any organisations in Scotland should be copied to The Scottish Office Agriculture and Fisheries Department, Room 326, Pentland House, Robb's Loan, Edinburgh, EH14 1TY. Comments from any organisations in Wales should be copied to the Welsh Office, Environment Division 3, Crown Building, Cathays Park, Cardiff, CF1 3NQ.

25. Responses will be deposited in Departmental libraries and may be published, unless a particular request is made to treat the response as confidential. The comments made to such responses will nevertheless be included in any summary of comments received and views expressed.

26. As already noted, the EC directives were to have been implemented in national legislation by 23 October 1991. Subject to any changes indicated as a result of consultations, Ministers therefore intend to lay these revised proposed regulations before Parliament with the minimum of delay with the intention of the regulations being in force by the end of November 1992.

Annex 1
Changes proposed in new draft regulations

1. One of the main substantive issues which arose out of the earlier consultation exercise related to problems with definitions. In a number of cases, DoE and HSE have taken these points up with experts from the relevant sectors and the advisory committees (ACGM and ACRE), and with the EC Competent Authorities and the European Commission. Any agreed interpretations with other Member States are not, however, definitive, as these are questions for the national courts and the European Court of Justice. The main changes and clarifications are summarised below.

1.1. "Acquire" and "keep": These terms are no longer used.

1.2. "Traditional plant breeding": As in the EC directives, the draft regulations do *not* seek to control protoplast fusion of plant cells where the same result can be produced by "traditional" methods. Consequently, the interpretation of "traditional breeding methods" is extremely important. The following interpretation, which is set out in the guidance to the new draft regulations, has been agreed between all the Competent Authorities of the Member States.

> "Traditional breeding means practices which use one or more of a number of methods (eg physical and/or chemical means, control of physiological processes) which can lead to successful crosses between plants of the same botanical family."

1.3. "Placing on the market": The interpretation of this term agreed between Competent Authorities of the EC Member States is set out in the guidance to the regulations. In particular, the supply of cultures to centres notified under the Contained Use Regulations from culture collections will *not* be regarded as requiring a consent to market, even if a small administrative charge is made for such supply.

1.4 "Microorganisms": Comments received after consultation indicated that the previous proposals were not clear about the status of animal and plant cell cultures. Again, this matter has been discussed with our European colleagues and agreement reached that such cultures *will* be regarded as "microorganisms". This is explicitly stated in the contained use regulations.

1.5. "Harm" and "Damage to the environment": These are terms defined in the Environmental Protection Act 1990. The Act does, however, permit "harm" and "damage to the environment" to be disregarded in specifically defined circumstances. The regulations do so, to a limited extent, for GMOs like bio-pesticides and medicinal products where this is stated in the consents applicable to them. Following suggestions made by many respondents to the first consultation exercise, clarification and examples are now given in guidance.

1.6. Naked DNA and recombinant plasmids: Concern was expressed in the consultation that it was unclear whether the regulations covered these two categories. The EC Competent Authorities agreed that these molecules are *not* intended to be covered by the directives. Clarification is given in guidance.

1.7. Self-Cloning: The definition of this term has been the subject of much discussion both nationally and in Europe. The interpretation agreed by Member States has been used in the Contained Use Regulations.

2. Most other substantive points raised during and after the consultation exercise concerned questions of operational procedure such as:

2.1. Waste streams: The general comment arising from the previous consultation was that the draft left unclear whether waste streams from large scale Group I contained facilities would require a consent to release. The new regulations and guidance clarify the position: the EP Act defines genetically modified organisms as being under control if there is a system of "physical, chemical or biological barriers". A consent is required under the Deliberate Release regulations if GMOs are not under control. Since *Group I* organisms, by definition, have limited survivability and/or replicability and are thus without adverse consequences for the environment, the effluent from Group I Type B contained operations will *not* require a consent under the Deliberate Release Regulations. However, it will be essential that the information notified to HSE under the Contained Use regulations includes details of waste procedures, including details on the levels of viable organisms in the waste.

2.2. Period of a consent to release: In the previous draft regulations, consents were to be limited to a period of three months. This caused much comment, in particular from plant breeders. In the light of these, and subsequent, comments and discussions, this proposal was recognized to be impracticable. The new proposals therefore make reference to a "limited period" of a consent. This will allow the Secretary of State to decide the period of a consent on a case-by-case basis, as appropriate. The period could extend to several years.

2.3. Notification of programmes of work: A number of responses highlighted the need to be able to notify entire programmes of work, either in contained use or as deliberate releases. This has been addressed by removing the fixed period of a consent for deliberate releases, and by stating in the guidance that programmes of work, as in strain development or plant breeding programmes, may be notified provided that a single risk assessment covers each programme. Details are given in the guidance to the Deliberate Release Regulations about the way in which a single consent might cover a plant breeding programme from early R & D trials, through Distinctiveness, Uniformity and Stability (DUS) and Value for Cultivation and Use (VCU) trials, up to (but not including) applying for a final consent to market an approved variety.

2.4. Risk assessment: Many respondents commented upon the lack of a method of environmental risk assessment. This has been addressed in the draft guidance to the Release Regulations by setting out an approach to risk assessment and indicating the particular points of information supplied under the Schedules that should be taken into account.

2.5. "BATNEEC": Several respondents commented on the difficulty of knowing how to implement BATNEEC. Preliminary guidance is included as part of the guidance to the regulations. This will be expanded in advance of the coming into force of the Release Regulations.

Annex 2

I. Proposals for fees and charges for consents under the Deliberate Release Regulations

1. This Annex sets out proposals for fees and charges for consents to release or market GMOs. The figures outlined in this proposal are provisional and subject to refinement in the light of further information, any relevant pay settlements and approval by Treasury.

Introduction and statutory background

2. The EP Act introduces provisions on the environmental safety of GMOs. Under the Genetically Modified Organisms (Deliberate Release) Regulations 1992 anyone wishing to release or market GMOs needs to obtain a consent from the Secretary of State.

3. Applications to release or market GMOs will be reviewed by the DOE and HSE in the context of environmental protection and human health and safety prior to consents being issued. In addition, s.124 EP Act provides for the Secretary of State to appoint a committee to advise on consents to release or market GMOs and on the conditions which may be attached to such consents. All consent holders must comply with the specific conditions of the consent and are subject to the certain general duties which are a condition of all consents. The Secretary of State may appoint inspectors to enforce the new regulatory controls. The main function of the inspectors will be to ensure that the conditions attached to consents are complied with.

4. Under s.113 EP Act the Secretary of State may, with Treasury approval, draw up a scheme of fees and charges for consents issued. Government policy on fees and charges for services offered to external bodies or individuals is to set these at levels which, as far as is practicable, secure full recovery of costs incurred.

Costs to be recovered.

5. There are three main areas of expenditure with respect to consents:

- staff costs for processing applications and servicing the Advisory Committee on Releases to the Environment (ACRE);

- work done by ACRE on advising on applications; and

- the costs of inspection to monitor that the conditions attached to consents are complied with once they have been issued.

6. Expenditure within the areas of staff, committee and inspection will vary according to the kind of consent which is sought. There are five main types:-

(i) New applications to release for R&D purposes;

(ii) R&D applications considered under streamlined procedures, for which committee discussions are not necessary because they concern the repeat of or slight modification to proposals to release organisms for which experience has already been gained;

(iii) Applications to put GMO products developed in the UK on the market (those which have been reviewed in the UK at the R&D stage);

(iv) Applications for GMO products developed outside the UK;

(v) Applications to vary consents which have already been issued.

7. Variations will consist of minor changes to an existing proposal, such as a change in the planting/harvesting schedule, a change in the disposal arrangements from burning to burial or addition or withdrawal of a site for release owing to availability of the GMO.

8. Variations may result from a request made by the applicant to the Secretary of State or may be the result of an inspection, for example to satisfy a new standard for release, thereby ensuring compliance with BATNEEC.

Structure of the proposed scheme

9. The scheme of fees and charges comprises two main elements:

(i) **a fee** to cover the costs of issuing or varying consents to release or market GMOs; and

(ii) an **annual subsistence charge** to cover the costs of inspecting release sites.

10. The period covered by the annual charge will run from the date of issue of the consent and will be payable annually for the period of the consent. Payment of the charge will constitute one of the conditions of the consent issued.

11. On the basis of actual costs the following scheme is proposed:

	FEE	ANNUAL SUBSISTENCE
R&D release:	£1,800	£270
Marketing: (non-UK)	£2,900	*
Marketing: (UK)	£1,700	*
Streamlined/repeat	£450	£270
Variation	£150	N/A

* There would only be a charge made for annual subsistence if specific conditions placed on the consent warranted it.

12. The fees and charges reflect, for each application type, the administrative costs of processing applications, issuing consents and maintaining public registers in addition to inspection. The fee will cover the incurred costs as set out below:

New R&D proposals

- in house technical review
- review by and advice from ACRE (in committee)

Streamlined/repeat R&D proposals

- in house technical review
- review and advice from ACRE (by post)

Marketing of products developed outside the UK

These cases will receive:

- in house technical review
- review by and advice from ACRE (in committee)

Marketing of UK developed products

Products which have been developed in the UK and have been reviewed in the UK during R&D stages will have received preliminary reviews both in house and by the committee. For this reason the costs associated with the review of a marketing application will be lower than for products developed outside the UK. Costs arise from:

- in house technical review at a level necessary to take account of the information over and above that seen from R&D stages (whether new or streamlined release applications);
- review and advice from ACRE (in committee);

Variations to consents issued

- in house technical review

13. Submission of application fee

(i) R&D consents

An initial fee of £450 should be submitted with the application. If an additional fee is required because the application constitutes a new R&D release, the applicant will be notified within 14 days and be required to submit payment of the additional sum within 14 days. If appropriate an annual subsistence charge will included as one of the consent conditions.

(ii) Marketing consents

The appropriate fee will be payable on submission of the application to the Department. If the application is unsuccessful the fee will not be refunded. If circumstances warranted the attaching of conditions to the consent, an annual subsistence charge will be required, payment of which will constitute one of the consent conditions.

Review of the charging scheme

14. The scheme and the level of charges will be reviewed after 1 year of operation and periodically thereafter.

Guidance

15. Guidance will be prepared on the broad criteria which will determine into which consent category applications will fall.

Comments are invited on these proposals and should be sent to the contact name and address on page 5.

II. Proposals for fees and charges for consent applications under the Contained Use Regulations

16. For contained uses, it is proposed that HSE's full costs should be recovered in relation to all consents. Consideration is also being given to whether charges should be made for scrutiny of advance notifications not requiring consent. Such notifications are, in effect, subject to a form of "negative approval" because HSE is able to stop the work proceeding by objecting in writing. Regulation 22 of the draft Contained Use Regulations accordingly gives the Executive powers to make charges for all notifications.

17. It is not proposed however that there should be any charge made for retrospective notifications of Type A operations involving Group I organisms and activities involving organisms other than micro-organisms which satisfy the criteria of Schedule 2 Part III of the regulations.

18. Estimated charges in relation to four categories of contained activities are set out below. They are based on the administrative costs of processing notifications and in-house scientific scrutiny by HSE staff.

Category	Estimated Charge
Consent for first use of premises for activities involving Group II micro-organisms	£130
Consent for individual activities involving Group II micro-organisms in Type B operations	£270
Notification of first use of premises for activities involving Group I micro-organisms and organisms other than micro-organisms	£100
Notification of individual activities involving Group II micro-organisms in Type A operations, Group I micro-organisms in Type B operations, and organisms other than micro-organisms which do not satisfy the criteria of Schedule 2 Part III of the regulations	£180

HSC
Health & Safety
Commission

GENETICALLY MODIFIED ORGANISMS (GMOs)
REVISED PROPOSALS FOR NEW REGULATIONS

Department of Environment

Health and Safety Commission

Ministry of Agriculture, Fisheries and Food

Scottish Office

Welsh Office

c Crown copyright

August 1992

The Health and Safety Commission is acting in compliance with its duty to consult, under section 50(3) of the Health and Safety at Work etc. Act 1974, bodies which appear to it to be appropriate, before submitting proposals for the making of Regulations.

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HEALTH AND SAFETY

The Contained Use of Genetically Modified Organisms Regulations 199-

A R R A N G E M E N T O F R E G U L A T I O N S

PART I

INTERPRETATION AND GENERAL

1. Citation and commencement.

2. Interpretation.

3. Application.

4. Meaning of "work" and "at work".

5. Modification of section 3(2) of the Health and Safety at Work etc. Act 1974.

PART II

NOTIFICATION OF AND CONSENT FOR ACTIVITIES INVOLVING GENETIC MODIFICATION

6. Prohibition of certain work with genetically modified organisms outside containment.

7. Risk assessment.

8. Notification of the intention to use premises for activities involving genetic modification for the first time.

9. Notification of individual activities involving genetic modification.

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Draft proposals for Regulations to be made by the Secretary of State, being the Minister designated[1] for the purposes of section 2 of the European Communities Act 1972 in relation to measures relating to the control and regulation of genetically modified organisms under the said section 2 and sections 15(1) and (2), (3)(b), (4)(a), (5)(b) and (9), [43(2), (4), (5), (6) and (9)], 52(2) and (3) and 82(3)(a) of, and paragraphs 1(1)(b) and (c) and (5), 4(1), 6(1), 15(1), 16 and 20 of Schedule 3 to, the Health and Safety at Work etc. Act 1974.

PART I

INTERPRETATION AND GENERAL

Citation and commencement

1. These Regulations may be cited as the Contained Use of Genetically Modified Organisms Regulations 199- and shall come into force on 199-.

Interpretation

2. -(1) In these Regulations, unless the context otherwise requires -

"the 1989 Regulations" means the Genetic Manipulation Regulations 1989[2];

"accident" means any incident involving a significant and unintended release of genetically modified organisms in the course of an

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([1]) 1991/-.

([2]) S.I. 1989/1810.

activity involving genetic modification which presents an immediate or delayed hazard to human health or to the environment;

"approved" means approved in writing for the time being by the Executive;

"activity involving genetic modification" means any operation involving the contained use of a genetically modified organism;

"contained use" means any operation in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers or a combination of physical barriers with chemical or biological barriers or both, are used to limit their contact with the general population and the environment;

"the contained use Directive" means Council Directive No. 90/219/EEC[3] on the contained use of genetically modified micro-organisms;

"the Executive" means the Health and Safety Executive;

"genetic modification" in relation to an organism means the altering of the genetic material in that organism by a way that does not occur naturally by mating or natural recombination or both and within the terms of this definition -

(a) genetic modification occurs at least through the use of the techniques listed in Part I of Schedule 1; and

(b) the techniques listed in Part II of that Schedule do not give rise to genetic modification,

and "genetically modified" shall be construed accordingly;

"genetic modification safety committee" means the committee established in accordance with regulation 11;

([3]) OJ No. L 117, 8.5.90, p.1.

"micro-organism" means a microbiological entity, cellular or non-cellular capable of replication or of transferring genetic material including animal or plant cell cultures;

"organism" means a biological entity capable of replication or of transferring genetic material and includes a micro-organism;

"self-cloning" means the removal of nucleic acid from a cell or organism, followed by the re-insertion of all or part of that nucleic acid - with or without further enzymic, chemical or mechanical steps - into the same cell type (or cell-line) or into phylogenetically closely related species which can naturally exchange genetic material with the donor species;

"Type A operation" means any activity involving genetically modified micro-organisms for the purposes of teaching, research or development, or for non-industrial or non-commercial purposes on a scale at which the practices and conditions of the operations relative to the culture volume and numbers of organisms involved are such that -

(a) the system used to keep the organisms under containment reflects good microbiological practice and good occupational safety and hygiene; and

(b) it is possible easily to render the organisms inactive by standard laboratory decontamination techniques;

"Type B operation" means any activity involving the genetic modification of micro-organisms other than a Type A operation.

(2) Genetically modified organisms shall be classified -

(a) in the case of micro-organisms, as Group I micro-organisms if they comply with such of the criteria set out in Part I of Schedule 2 as are applicable to the particular case, in accordance with the guidelines set out in Part II of that Schedule which gives effect to Commission Decision

91/448/EEC[4], or as Group II micro-organisms if they do not comply with the said criteria; or

(b) in the case of genetically modified organisms other than micro-organisms, in accordance with the criteria set out in Part III of Schedule 2.

(3) In these Regulations, unless the context otherwise requires -

(a) a reference to a numbered Part, regulation or Schedule is a reference to the Part, regulation or Schedule in these Regulations so numbered; and

(b) a reference to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule in which that reference occurs.

Application

3. -(1) These Regulations shall have effect with a view to protecting persons against risks to their health, whether immediate or delayed arising from activities involving genetically modified organisms and for the protection of the environment.

(2) Regulations 8 to 12 shall not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(3) These Regulations shall not apply to the genetic modification of organisms solely by any of the techniques referred to in Part III of Schedule 1 or to any organisms so modified.

(4) Nothing in these Regulations shall prejudice any requirement imposed by or under any enactment which relates to public health or the protection of the environment.

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(4) OJ No. L 239, 18.8.91. p.23.

(5) These Regulations shall not extend to Northern Ireland.

Meaning of "work" or "at work"

4. For the purpose of these Regulations and Part I of the Health and Safety at Work etc. Act 1974 [5] the meaning of work shall be extended to include any activity involving genetic modification and the meaning of "at work" shall be extended accordingly.

Modification of section 3(2) of the Health and Safety at Work etc. Act 1974

5. Section 3(2) of the Health and Safety at Work etc. Act 1974 shall be modified in relation to an activity involving genetic modification so as to have effect as if the reference to a self-employed person was a reference to any person who is not an employer or an employee and the reference to his undertaking included a reference to such an activity.

PART II

NOTIFICATION OF AND CONSENT FOR ACTIVITIES INVOLVING GENETIC MODIFICATION

Prohibition of certain work with genetically modified organisms outside containment

6. -(1) Subject to paragraph (2), any operation in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of is prohibited unless it is undertaken in conditions of contained use in accordance with these Regulations.

([5]) 1974 c.37.

(2) Paragraph (1) shall not apply to an operation in which -

(a) genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of, where such organisms are or are contained in an "approved product within the meaning of regulation 2(1) of the Genetically Modified Organisms (Deliberate Release) Regulations 199-[6] and the operation is conducted in accordance with any conditions and limitations attached to that approval; or

(b) genetically modified organisms are released in circumstances in which the consent of the Secretary of State is required under Part VI of the Environmental Protection Act 1990[7].

Risk assessment

7. -(1) A person shall not -

(a) use any premises for activities involving genetic modification for the first time; or

(b) undertake any activity involving genetic modification,

unless he has ensured that, before commencing that use or activity as the case may be, an adequate assessment of the risks created thereby to human health and the environment has been made.

(2) Without prejudice to the generality of paragraph (1), the purposes of the assessment undertaken under that paragraph shall include -

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([6]) S.I. 199-/

([7]) 1990 c.43.

(a) classifying any genetically modified organisms involved in the activity in accordance with the provisions of Schedule 2; and

(b) where appropriate, making decisions about the levels of containment required for the activity concerned.

(3) In making the assessment required by paragraph (1) the person making that assessment shall, in particular, take due account of the parameters set out in Schedule 3 in as far as they are relevant.

(4) The assessment shall be reviewed forthwith if -

(a) there is reason to suspect that the assessment is no longer valid; or

(b) there has been a significant change in the activity to which the assessment relates.

(5) The person making the assessment shall make a record of it and of any subsequent review and shall keep that record for at least 10 years from the date on which use of the premises or the activity, as the case may be, to which the assessment related, ceased.

Notification of the intention to use premises for activities involving genetic modification for the first time

8. -(1) Subject to the following paragraphs of this regulation and regulation 10, no person shall undertake any activity involving genetic modification at any premises for the first time, unless he has notified the Executive of his intention to do so at least 90 days in advance or before such shorter time as the Executive may approve and with that notification has furnished the particulars specified in Schedule 4.

(2) In the case of activities involving the genetic modification of micro-organisms, separate notifications shall be made of an

intention to use the premises for activities involving the genetically modified micro-organisms of Group I or Group II.

(3) In the case of activities involving genetically modified micro-organisms of Group II, the premises shall only be used for those activities after the Executive has given its consent.

(4) In any other case, the use of the premises for the activity may be commenced at or after the end of the period of 90 days or such shorter period as the Executive may have approved in pursuance of paragraph (1) unless the Executive objects in writing before the end of the relevant period.

(5) In any case in which a consent is required under paragraph (3), the Executive shall communicate its decision on the application in writing within 90 days after the application was received.

(6) Nothing in this regulation shall prevent a person from notifying under regulation 9 an individual activity which he intends to undertake in the premises at the same time as making a notification under this regulation; in such a case he shall not commence the activity except in accordance with the time periods specified in this regulation.

Notification of individual activities involving genetic modification

9. -(1) Subject to the following paragraphs of this regulation and regulation 10, no person shall undertake any activity involving genetic modification unless he has notified the Executive of his intention to do so at least 60 days in advance or before such shorter time as the Executive may approve and has furnished the particulars specified in the following paragraphs of this regulation and, except in the case of an activity to which paragraph (5) applies, the activity may be commenced after the expiry of the relevant period if by then the Executive has not objected in writing.

(2) In the case of an activity which is -

(a) a Type A operation involving only micro-organisms classified as Group I; or

(b) an activity involving genetically modified organisms other than micro-organisms and which satisfy the criteria set out in Part III of Schedule 2,

it shall be a sufficient compliance with paragraph (1) if the person undertaking the activity keeps a record of such activities and at the end of each calendar year notifies the Executive as soon as reasonably practicable thereafter -

(i) of the total number of risk assessments under regulation 7 undertaken during that year;

(ii) where appropriate, that he is intending to continue to undertake such activities; and

(iii) that the information notified to the Executive in accordance with regulation 8 remains correct.

(3) In the case of an activity which is a Type B operation involving only micro-organisms classified as Group I, the specified particulars for the purposes of paragraph (1) shall be those specified in Part I of Schedule 5.

(4) In the case of an activity which is -

(a) a Type A operation involving genetically modified micro-organisms classified as Group II; or

(b) an activity involving genetically modified organisms other than micro-organisms and which do not satisfy the criteria set out in Part III of Schedule 2,

the specified particulars for the purposes of paragraph (1) shall be those specified in Parts I and II of Schedule 5.

(5) In the case of an activity which is a Type B operation involving genetically modified micro-organisms classified as Group II, the specified particulars for the purposes of paragraph (1) shall be those specified in Parts I, II and III of Schedule 5 and the activity shall only be commenced with the consent of the Executive.

(6) In any case in which a consent is required under paragraph (5), the Executive shall communicate its decision on the application in writing within 90 days after the application was received.

(7) The Executive may accept as a single notification a connected programme of work covering more than one activity involving genetic modification at one site, or a single activity carried on by the same person at more than one site.

Additional provisions relating to notifications and consents

10.-(1) Where necessary for the purpose of evaluating a notification made under regulation 8 or 9 the Executive may require in writing the person making the notification to give such additional information relating to the proposal as is specified and in such a case the person making the notification shall not proceed with the activity involving genetic modification until the Executive gives its consent and the period between the time when the Executive requires the information and the notifier responds to the satisfaction of the Executive shall not be taken into account in calculating the periods of days referred to in the provisions concerned.

(2) The Executive shall not grant a consent under regulation 8 or 9 or paragraph (1) of this regulation, as it relates to the protection of the environment without the agreement of the Secretary of State.

(3) Any consent granted by the the Executive under regulation 8 or 9 or paragraph (1) of this regulation may be granted subject to conditions or to a limit of time and may be revoked or varied at any

time and in such a case the person undertaking the activity shall comply with those conditions.

(4) Where a person making a notification in pursuance of regulation 8 or 9 subsequently makes a significant change in any premises or activity to which the notification relates or becomes aware of any new information which would affect the particulars previously notified, he shall forthwith notify the Executive thereof.

(5) If information subsequently becomes available to the Executive which could have significant consequences for the risks imposed by an activity involving genetic modification which has been notified to it, it may require the notifier to modify the conditions of, suspend or terminate the activity.

(6) Notifications made in pursuance of regulations 8 and 9 shall be in a form approved by the the Executive.

Establishment of a genetic modification safety committee

11. A person who undertakes an assessment made for the purposes of regulation 7(1) shall establish a genetic modification safety committee to advise him in relation to that assessment.

PART III

CONDUCT OF ACTIVITIES INVOLVING GENETIC MODIFICATION

Standards of occupational and environmental safety and containment

12.-(1) For any activity involving genetically modified micro-organisms of Group I, the principles of good microbiological practice and the following principles of good occupational safety and hygiene shall apply -

(a) to keep workplace and environmental exposure to any physical, chemical and biological agent adequately controlled;

(b) to exercise engineering control methods at source and to supplement these with appropriate personal protective clothing and equipment where necessary;

(c) to test adequately and maintain control measures and equipment;

(d) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;

(e) to provide training of personnel; and

(f) to formulate and implement local rules for the safety of personnel.

(2) For the purpose of paragraph (1)(a) "adequate" in relation to the control of agents means adequate having regard only to the nature of the agent and the nature and degree of exposure to such agents and "adequately" shall be construed accordingly.

(3) For any activities involving genetically modified micro-organisms of Group II in Type A operations, in addition to the principles set out in paragraph (1) the containment measures shall be determined by a method approved by the Executive.

(4) For any activities involving genetically modified micro-organisms of Group II in Type B operations, in addition to the principles set out in paragraph (1) the containment measures set out in Schedule 6 shall be applied as appropriate so as to ensure a high standard of health and safety and environmental protection.

(5) For any activities involving genetically modified organisms, the principles set out in paragraph (1) shall be applied as far as they are appropriate.

Emergency plans

13.-(1) Where the assessment made in accordance with re)
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PART IV

DISCLOSURE OF INFORMATION NOTIFIED AND PUBLICITY

Disclosure of information notified

15.-(1) Subject to the following paragraphs of this regulation, in as far as any provision in regulations 8 to 10 is made under section 2 of the European Communities Act 1972, information notified under that provision shall be treated as relevant information for the purposes of section 28 of the Health and Safety at Work etc. Act 1974.

(2) Where a person making a notification in pursuance of regulations 8 to 10, indicates that it contains certain information the disclosure of which might harm his competitive position and should be kept confidential, full justification for that indication shall be given and in such a case after consulting the notifier the Executive shall decide which information shall be kept confidential and shall inform the notifier of its decision.

(3) Nothing in paragraph (2) shall apply to the following information which, where applicable, shall not be kept confidential -

(a) the name and address of the notifier and the location of the activity involving genetic modification;

(b) the purpose of the activity;

(c) the description of the genetically modified organism involved;

(d) methods and plans for monitoring the genetically modified organism and for emergency response; and

(e) the evaluation of foreseeable effects and in particular pathogenic effects and ecologically disruptive effects.

(4) It shall be functions of the Executive -

(a) where and to the extent that in its view it is appropriate, to make such of the information contained in a notification, which it has decided shall not be kept confidential in accordance with paragraph (3), available to the public; and

(b) to send information to the European Commission and to the competent authorities of the other Member States in accordance with the requirements of the contained use Directive.

Register of information

16.-(1) The Executive shall maintain a register of notifications to which regulations 8(3) or 9(5) relate (for which the consent of the Executive is required) and that register shall be open to inspection by members of the public at any reasonable time.

(2) The register referred to in paragraph (1) shall contain -

(a) the name and address of the notifier and the location of any activity involving genetic modification involved or intended to be involved;

(b) the purpose of the activity;

(c) the description of the genetically modified organism involved or intended to be involved;

(d) methods and plans for monitoring the genetically modified organism and for emergency response if any;

(a) to keep workplace and environmental exposure to any physical, chemical and biological agent adequately controlled;

(b) to exercise engineering control methods at source and to supplement these with appropriate personal protective clothing and equipment where necessary;

(c) to test adequately and maintain control measures and equipment;

(d) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;

(e) to provide training of personnel; and

(f) to formulate and implement local rules for the safety of personnel.

(2) For the purpose of paragraph (1)(a) "adequate" in relation to the control of agents means adequate having regard only to the nature of the agent and the nature and degree of exposure to such agents and "adequately" shall be construed accordingly.

(3) For any activities involving genetically modified micro-organisms of Group II in Type A operations, in addition to the principles set out in paragraph (1) the containment measures shall be determined by a method approved by the Executive.

(4) For any activities involving genetically modified micro-organisms of Group II in Type B operations, in addition to the principles set out in paragraph (1) the containment measures set out in Schedule 6 shall be applied as appropriate so as to ensure a high level of health and safety and environmental protection.

(5) For any activities involving genetically modified organisms other than micro-organisms, the principles set out in paragraph (1) shall be applied in as far as they are appropriate.

Emergency plans

13.-(1) Where the assessment made in accordance with regulation 7(1) shows that as a result of any reasonably foreseeable accident the health or safety of persons outside the premises in which an activity involving genetic modification is carried on is liable to be affected or there is a risk of damage to the environment, the person undertaking the activity shall ensure that a suitable emergency plan is prepared with a view to securing the health and safety of those persons and the protection of the environment.

(2) The person preparing the plan shall consult persons, bodies and authorities as are appropriate and shall inform the emergency services in writing of the plan.

(3) The person undertaking the activity involving genetic modification which is the subject of the emergency plan shall take appropriate measures to inform persons who are liable to be affected by an accident of the safety measures and the correct behaviour to adopt in the event of an accident.

(4) The information required to be given in pursuance of paragraph (3) shall be repeated and brought up to date at appropriate intervals and shall be made publicly available.

Notification of accidents

14.-(1) Where an accident occurs, the person undertaking the activity involving genetically modified organisms shall forthwith notify the Executive of it and shall provide the following information -

(a) the circumstances of the accident;

(b) the identity and quantity of genetically modified organisms released;

(c) any information necessary to assess the effects of the accident on the health of the general population and on the environment; and

(d) the emergency measures taken.

(2) Where the Executive receives a notification in pursuance of paragraph (1), the Executive shall -

(a) ensure that any emergency, medium and long term measures are taken;

(b) immediately inform any other member State that could be affected by the accident;

(c) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit their effects; and

(d) send to the European Commission the information provided for under paragraph (1), together with an analysis of the accident and details of any recommendations made to avoid similar accidents in the future and to limit their effects.

(e) the evaluation of foreseeable effects and in particular pathogenic effects and ecologically disruptive effects.

(4) It shall be functions of the Executive -

(a) where and to the extent that in its view it is appropriate, to make such of the information contained in a notification, which it has decided shall not be kept confidential in accordance with paragraph (3), available to the public; and

(b) to send information to the European Commission and to the competent authorities of the other Member States in accordance with the requirements of the contained use Directive.

Register of information

16.-(1) The Executive shall maintain a register of notifications to which regulations 8(3) or 9(5) relate (for which the consent of the Executive is required) and that register shall be open to inspection by members of the public at any reasonable time.

(2) The register referred to in paragraph (1) shall contain -

(a) the name and address of the notifier and the location of any activity involving genetic modification involved or intended to be involved;

(b) the purpose of the activity;

(c) the description of the genetically modified organism involved or intended to be involved;

(d) methods and plans for monitoring the genetically modified organism and for emergency response if any;

PART IV

DISCLOSURE OF INFORMATION NOTIFIED AND PUBLICITY

Disclosure of information notified

15.-(1) Subject to the following paragraphs of this regulation, in as far as any provision in regulations 8 to 10 is made under section 2 of the European Communities Act 1972, information notified under that provision shall be treated as relevant information for the purposes of section 28 of the Health and Safety at Work etc. Act 1974.

(2) Where a person making a notification in pursuance of regulations 8 to 10, indicates that it contains certain information the disclosure of which might harm his competitive position and should be kept confidential, full justification for that indication shall be given and in such a case after consulting the notifier the Executive shall decide which information shall be kept confidential and shall inform the notifier of its decision.

(3) Nothing in paragraph (2) shall apply to the following information which, where applicable, shall not be kept confidential -

(a) the name and address of the notifier and the location of the activity involving genetic modification;

(b) the purpose of the activity;

(c) the description of the genetically modified organism involved;

(d) methods and plans for monitoring the genetically modified organism and for emergency response; and

(e) the evaluation of foreseeable effects and in particular pathogenic effects and ecologically disruptive effects created by the genetically modified organism involved or intended to be involved; and

(f) a statement as to whether or not the consent of the Executive has been granted.

(3) The information referred to in paragraph (2) shall be entered in the register within seven days of its receipt by the Executive or in the case of a consent within seven days of a decision being made.

(4) Copies of the register shall be maintained at -

(a) the area office of the Executive in whose area the notifier is situated; and

(b) Baynards House, Chepstow Place, Westbourne Grove, London W2 4TF,

(c) Magdalen House, Stanley Precinct, Bootle, Merseyside, L20 3QZ.

PART V

ADDITIONAL DUTIES PLACED ON THE EXECUTIVE

Duties on receiving notifications

17. The Executive shall examine a notification under regulation 8 or 9 for -

(a) the conformity with the requirements of these Regulations;

(b) the accuracy and completeness of the information given;

(c) the correctness of the classification of the organisms to which the notification relates in accordance with Schedule 2;

(d) where appropriate, the adequacy of the waste management, safety and emergency response measures.

Information to be sent to the Secretary of State

18. Forthwith after receipt, the Executive shall send to the Secretary of State copies of -

(a) any notification received under regulation 8 or 9;

(b) any requirement for further information under regulation 10(1) and the response thereto; and

(c) any notification relating to an accident under regulation 14,

and if requested to do so by the Secretary of State, shall require additional information under regulation 10(1).

Reports to the European Commission

19. The Executive shall send to the European Commission reports of notifications for which a consent is required under regulation 9(5) and summary reports of the application of these Regulations in accordance with Article 18 of the contained use Directive.

PART VI

MISCELLANEOUS AND GENERAL

Exemption certificates

20.-(1) Subject to paragraph (2) and to any provisions imposed by the European Communities in respect of the control and regulation of genetically modified organisms, the Executive may, with the agreement of the Secretary of State in so far as the exemption relates to the environment, by a certificate in writing, exempt any person or class of persons, genetically modified organism or class of genetically modified organisms from all or any of the requirements or prohibitions imposed by these Regulations and any such exemption may be granted subject to conditions and to a limit of time and may be revoked by a certificate in writing at any time.

(2) The Executive shall not grant any such exemption unless, having regard to the circumstances of the case and in particular to -

(a) the conditions, if any, that it proposes to attach to the exemption; and

(b) any requirements imposed by or under any enactments which apply to the case,

it is satisfied that the health and safety of persons who are likely to be affected by the exemption or the protection of the environment will not be prejudiced in consequence of it.

Enforcement, civil liability and defence

21.-(1) In as far as any provision of these Regulations is made under section 2 of the European Communities Act 1972[8] that provision -

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([8]) 1972 c. 68.

(a) subject to the following paragraphs of this regulation, shall be treated as if it were a health and safety regulation made under section 15 of the Health and Safety at Work etc. Act 1974[9] and the provisions of that Act (including the provisions relating to enforcement, and notices) and of any health and safety regulations shall apply to that provision as it applies to health and safety regulations; and

(b) shall, in the event of a breach of duty imposed by that provision, confer a right of action in civil proceedings in so far as that breach of duty causes damage.

(2) Notwithstanding regulation 3 of the Health and Safety (Enforcing Authority) Regulations 1989[10], the enforcing authority for these Regulations shall be the Executive.

Fees for notifications

22.-(1) The Executive may charge a fee determined in accordance with paragraphs (2) and (3) in relation to any notification made to it under regulation 8 or 9 and that fee shall be payable by the person making the notification.

(2) The fee shall not exceed the sum of the costs reasonably incurred by the Executive in considering the notification and where appropriate granting or withholding its consent.

(3) The Executive may determine the cost of employing a graded officer for any period on work appropriate to his grade by reference to the average cost to it of employing officers of that grade for that period.

([9]) 1974 c. 37.

([10]) S.I. 1989/1903.

(4) When requiring payment the Executive shall send or give to the person making the notification a detailed statement of the work done and costs incurred including details of any visits made and the period to which the statement relates, and the fee shall be -

(a) payable whether or not any consent required under these Regulations is granted;

(b) payable one month after the statement had been sent or given; and

(c) only recoverable as a civil debt.

Transitional provisions

23.-(1) Where before [insert cif] a person had notified the Executive of his intention to undertake activities involving genetic modification which complied with regulation 5(1) and (2)(a) of the 1989 Regulations as then in force, that notification shall be treated as satisfying the requirements of regulation 8 of these Regulations, except that regulation 8(3) shall apply to that activity on or after [cif + 1 year].

(2) Until [insert cif + 90 days] it shall be a sufficient compliance with regulation 8 if the notifier commences the activity having notified his intention to do so 30 days in advance or such shorter time in advance as the Executive may approve and regulation 8(3) shall not apply to activities commenced before that date until [cif + 1 year].

(3) Where before [insert cif] a person had notified the Executive of his intention to undertake activities involving genetic modification which complied with regulation 5(1) and (2)(b) of the 1989 Regulations as then in force, that notification shall be treated as satisfying the requirements of regulation 9 of these Regulations, except that regulation 9(5) shall apply to that activity on or after [cif + 1 year].

(4) Until [insert cif + 60 days] it shall be a sufficient compliance with regulation 9 if the notifier of an activity involving genetic modification had notified it in accordance with that regulation 30 days in advance or such shorter time in advance as the Executive may approve and regulation 9(5) shall not apply to activities commenced before that date until [cif + 1 year].

(5) Regulation 10 shall apply to any notification made after [insert cif].

[Note. This note is not part of the Regulations. Cif means the date of coming into force of the Regulations and it is intended that calendar dates should be inserted once that date is settled.]

Extension outside Great Britain

24. These Regulations shall apply in relation to premises and activities outside Great Britain to which sections 1 to 59 and 80 to 82 of the Health and Safety at Work etc. Act 1974 apply by virtue of the Health and Safety at Work etc. Act 1974 (Application Outside Great Britain) Order 1989[11] as they apply to premises and activities within Great Britain.

Revocations

25. The 1989 Regulations are revoked.

([11]) S.I. 1989/840.

SCHEDULE 1 Regulations 2(1) and 3(3)

DEFINITION OF GENETIC MODIFICATION

PART I

Examples of techniques constituting genetic modification

1. Examples of the techniques which constitute genetic modification which are referred to in sub-paragraph (a) of the definition of genetic modification in regulation 2(1) are -

(a) recombinant DNA technique consisting of the formation of new combinations of genetic 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 occur naturally but in which they are capable of continued propagation;

(b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; and

(c) cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART II

Techniques which do not constitute genetic modification

2. The following techniques do not constitute genetic modification if they do not involve the use of recombinant-DNA molecules or genetically modified organisms -

(a) in vitro fertilization;

(b) conjugation, transduction, transformation or any other natural process; and

(c) polyploidy induction.

PART III

Techniques to which these Regulations do not apply

3. These Regulations shall not apply to the following techniques of genetic modification if they do not involve the use of genetically modified organisms as recipient or parental organisms -

(a) mutagenesis;

(b) the construction and use of somatic hybridoma cells (for example for the production of monoclonal antibodies);

(c) cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods; and

(d) self-cloning of non-pathogenic naturally occurring micro-organisms which fulfil the criteria of group I for recipient micro-organisms;

(e) self-cloning of non-pathogenic naturally occurring organisms other than micro-organisms which fulfil the criteria of Part III of Schedule 2.

SCHEDULE 2 Regulation 2(2)

CRITERIA FOR THE CLASSIFICATION OF ORGANISMS

PART I

Criteria for classification of micro-organisms in Group I

1. **Recipient or parental organism**

   (a) non-pathogenic;

   (b) no adventitious agents;

   (c) proven and extended history of safe use or built-in biological barriers, which, without interfering with optimal growth in the reactor or fermentor, confer limited survivability and replicability, without adverse consequences in the environment.

2. **Vectors/Insert**

   (a) well characterised and free from known harmful sequences;

   (b) limited in size as much as possible to the genetic sequences required to perform the intended function;

   (c) should not increase the stability of the construct in the environment (unless that is a requirement of intended function);

   (d) should be poorly mobilizable;

   (e) should not transfer any resistance markers to micro-organisms not known to acquire them naturally (if such acquisition could compromise use of drugs to control disease agents).

3. **Genetically modified micro-organisms**

(a) non-pathogenic;

(b) as safe in the reactor or fermentor as recipient or parental organism, but with limited survivability and/or replicability without adverse consequences in the environment.

4. **Other genetically modified micro-organisms that could be included in Group I if they meet the conditions in paragraph 3**

(a) those constructed entirely from a single prokaryotic recipient (including its indigenous plasmids and viruses) or from a single eukaryotic recipient (including its chloroplasts, mitochondria, plasmids, but excluding viruses);

(b) those that consist entirely of genetic sequences from different species that exchange these sequences by known physiological processes.

PART II

Guidelines for classification of micro-organisms in Group I

For classification into Group I the following guidelines should be used to further interpret Part I of this Schedule.

1. **Characteristics of the recipient or parental organism(s)**

(1) Non-pathogenic

The recipient or parental organisms can be classified as non-pathogenic if they satisfy the conditions of one of the following sub-paragraphs -

(a) the recipient or parental strain should have an established record of safety in the laboratory and/or industry, with no adverse effects on human health and the environment;

(b) the recipient or parental strain does not meet the conditions of sub-paragraph (a) above but it belongs to a species for which there is a long record of biological work including safety in the laboratory and/or industry, showing no adverse effects on human health and the environment;

(c) if the recipient or parental organism is a strain which does not satisfy the conditions of sub-paragraph (a) above and belongs to a species for which there is no record of biological work including safe use in the laboratory and/or industry, appropriate testing (including, if necessary, animals) must be carried out, in order to establish non-pathogenicity and safety in the environment;

(d) if a non-virulent strain of an acknowledged pathogenic species is used, the strain should be as deficient as possible in genetic material that determines virulence so as to ensure no reversion to pathogenicity. In the case of bacteria, special attention should be given to plasmid or phage-borne virulence determinants.

(2) **No adventitious agents**

The recipient or parental strain/cell line should be free of known biological contaminating agents (symbionts, mycoplasms, viruses, viroids, etc.), which are potentially harmful.

(3) The recipient or parental strain/cell line should have proven and extended history of safe use or built-in biological barriers, which, without interfering with optimal growth in the reactor or fermentor, confer limited

survivability and replicability, without adverse consequences in the environment (applicable only for type B operations).

2. **Characteristics of the vector**

(1) **The vector should be well characterized**

For this purpose the following characteristics should be taken into account.

(2) Information on composition and construction

(a) the type of the vector should be defined (virus, plasmid, cosmid, phasmid, transposable element, minichromosome, etc.);

(b) the following information on the constituent fragments of the vector should be available -

(i) the origin of each fragment (progenitor genetic element, strain of organism in which the progenitor genetic element naturally occurred),

(ii) if some fragments are synthetic, their functions should be known;

(c) the methods used for construction should be known.

(3) Information on vector structure

(a) the size of the vector should be known and expressed in basepairs or D;

(b) the function and relative positions of the following should be known -

(i) structural genes,

(ii) marker genes for selection (antibiotic resistance, heavy metal resistance, phage immunity, genes coding for degradation of xenobiotics, etc.),

(iii) regulatory elements,

(iv) target sites (nic-sites, restriction endonuclease sites, linkers, etc.),

(v) transposable elements (including provirus sequences),

(vi) genes related to transfer and mobilization function (eg with respect to conjugation, transduction or chromosomal integration),

(vii) replicon(s).

(4) **The vector should be free from harmful sequences**

The vector should not contain genes coding for potentially harmful or pathogenic traits (eg virulence determinants, toxins, etc.) unless for type A operations, such genes constitute an essential feature of the vector without, under any conditions or circumstances, resulting in a harmful or pathogenic phenotype of the genetically modified micro-organism.

(5) The vector should be limited in size as much as possible to the genetic sequences required to perform the intended function.

(6) The vector should not increase the stability of the genetically modified micro-organism in the environment (unless that is a requirement of the intended function).

(7) **The vector should be poorly mobilizable**

If the vector is a plasmid -

(a) it should have a restricted host-range;

(b) it should be defective in transfer-mobilization factors eg Tra−, Mob^+, for type A operations or Tra−, Mob−, for type B operations.

(8) If the vector is a virus, cosmid or phasmid -

(a) it should have a restricted host-range;

(b) it should be rendered non-lysogenic when used as a cloning vector (eg defective in the CI-lambda repressor).

(9) It should not transfer any resistance markers to micro-organisms not known to acquire them naturally (if such acquisition could compromise use of drug to control disease agents).

3. **Required characteristics of the insert**

(1) **The insert should be well characterised**

For this purpose, the following characteristics should be taken into account:

(2) The origin of the insert should be known (genus, species, strain).

(3) The following information on the library from which the insert originated, should be known -

(a) the source and method for obtaining the nucleic acid of interest (cDNA, chromosomal mitochondrial, etc.);

(b) the vector in which the library was constructed (eg lambda GT 11, pBR 322, etc.) and the site in which the DNA was inserted;

(c) the method used for identification (colony, hybridization, immuno-blot, etc.);

(d) the strain used for library construction.

(4) If the insert is synthetic, its intended function should be identified.

(5) The following information on the structure of the insert is required -

(a) information on structural genes, regulatory elements;

(b) size of the insert;

(c) restriction endonuclease sites flanking the insert;

(d) information on transposable elements and provirus sequences.

(6) The insert should be free from harmful sequences

(a) The function of each genetic unit in the insert should be defined (not applicable for type A operations);

(b) the inset should not contain genes coding for potential traits (eg virulence determinants, toxins, etc.), (unless for type A operations, such genes constitute an essential part of the insert without, under any circumstances resulting in a harmful or pathogenic phenotype of the genetically modified micro-organism).

(7) The insert should be limited in size as much as possible to the genetic sequences required to perform the intended function.

(8) The insert should not increase the stability of the construct in the environment (unless that is a requirement of intended function).

(9) **The insert should be poorly mobilizable**

For instance, it should not contain transposing or transferrable provirus sequences and other functional transposing sequences.

4. **Required characteristics of the genetically modified micro-organism**

(1) **The genetically modified micro-organism should be non-pathogenic**

This requirement is reasonably assured by compliance with all the requirements above.

(2) (a) the genetically modified micro-organism should be as safe (to man and the environment) as the recipient or parental strains (applicable only for type A operations);

(b) the genetically modified micro-organisms should be as safe in the reactor or fermentor as the recipient or parental strains, but with limited survivability and/or replicability outside the reactor or fermentor without adverse consequences in the environment (applicable only for type B operations).

5. Other genetically modified micro-organisms that could be included in Group 1 if they meet the conditions in C above:

(1) Those constructed entirely from a single prokaryotic recipient (including its indigenous plasmids and viruses) or from a single eukaryotic recipient (including its

chloroplasts, mitochondria, plasmids, but excluding viruses).

(2) Those that consist entirely of genetic sequences from different species that exchange these sequences by known physiological processes.

PART III

Criteria for the classification of organisms other than micro-organisms

An organism which satisfies the criteria of this Part is a genetically modified organism -

(a) which is not a genetically modified micro-organism: and

(b) which is as safe in the containment facility as any recipient or parental organism.

SCHEDULE 3 Regulation 7(3)

PARAMETERS TO BE TAKEN INTO ACCOUNT IN RISK ASSESSMENTS UNDER REGULATION 7

Characteristics of the donor, recipient or (where appropriate) parental organism

1. The following matters shall be investigated and assessed in relation to any organism which is or will be a donor, recipient or parental organism -

(a) the name, species, subspecies and strain of the organism;

(b) the degree of relatedness between the organism and the organism in relation to which the assessment is being carried out;

(c) the ecosystem, genetic source and supplier from which the organism originated;

(d) the reproductive cycle of the organism;

(e) history of prior genetic modifications to the organism;

(f) the stability of the genetic traits of the organism;

(g) the nature of the pathogenicity, virulence, infectivity, toxicity, and vectors of disease transmission of the organism;

(h) the base sequence, frequency of mobilisation and specificity of the organism's indigenous vectors;

(i) the presence in the organism of genes which confer resistance [antibiotics and environmental stresses];

(j) the host range of an organism which is a parasite or pathogen;

(k) the organism's other potentially significant physiological traits, and the stability of those traits;

(l) the organism's natural habitat and geographic distribution;

(m) the climactic characteristics of the organism's natural habitat;

(n) the significant involvement of the organism in environmental processes, including nitrogen fixation and pH regulation;

(o) the interaction of the organism with other organisms in the environment and its effect on those organisms, including its likely competitive or symbiotic properties;

(p) the ability of the organism to form survival structures, including seeds, spores or sclerotia.

Characteristics of the modified organism

2. The following matters shall be investigated and assessed in relation to an organism in relation to which a risk assessment under regulation 7 is carried out -

(a) the description of the modification, including the technique used or proposed to be used to introduce a vector or insert into the organism;

(b) the nature and source of the vector introduced into the organism;

(c) the function of the genetic modification and/or of the new nucleic acid;

(d) the structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organism;

(e) the stability of the genetic traits introduced into the organism;

(f) the frequency of mobilisation of inserted vector or genetic transfer capability;

(g) the rate and level of expression of the new genetic material in the organism, and the method and sensitivity of measurement of that rate and level;

(h) the activity of the expressed protein.

Health considerations

3. The following matters shall be investigated and assessed in relation to an organism in relation to which a risk assessment under regulation 7 is carried out -

(a) toxic or allergenic effects of non-viable organisms and/or their metabolic products;

(b) product hazards;

(c) comparison of the modified micro-organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(d) capacity for colonization;

(e) if the organism is pathogenic to humans who are immunocompetent -

(i) diseases caused and mechanism of pathogenicity including invasiveness and virulence,

(ii) communicability,

(iii) infective dose,

(iv) host range, possibility of alteration,

(v) possibility of survival outside of human host,

(vi) presence of vectors or means of dissemination,

(vii) biological stability,

(viii) antibiotic-resistance patterns,

(ix) allergenicity,

(x) availability of appropriate therapies.

Environmental considerations

4. The following matters shall also be investigated and assessed in relation to an organism in relation to which a risk assessment under regulation 7 is carried out -

(a) the factors affecting survival, multiplication and dissemination of the modified organism in the environment;

(b) the available techniques for detection, identification, and monitoring of the modified organism in the environment;

(c) the available techniques for detecting transfer of the new genetic material to other organisms;

(d) the known and predicted habitats of the modified organism;

(e) the ecosystems to which the modified organism could be disseminated as a result of an escape;

(f) the anticipated mechanism and result of interaction between the modified organism and the organisms which might be exposed in case of the escape of the organism;

(g) the known or predicted effects of the organism on plants and animals, including pathogenicity, infectivity, toxicity, virulence, vector or pathogen allergenicity, colonisation, predation, parasitism, symbiosis and competition;

(h) the known or predicted involvement of the organism in biogeochemical processes, including nitrogen fixation and pH regulation;

(i) the availability of methods for remedying harm caused to the environment by the escape of the organism

SCHEDULE 4 Regulation 8(1)

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 8(1)

1. A notification required for the purposes of regulation 8(1) shall include the following information -

(a) the name and address of the person responsible for carrying out the activity and the names of persons responsible for supervision, monitoring and safety together with details of their training and qualifications;

(b) address of the premises where the activity is to be carried on and its grid reference and, where appropriate, a description of the sections of the installation;

(c) a description of the nature of the activity to be undertaken, the likely scale of the operation and in particular, in the case of micro-organisms, their classification (whether in Group I or Group II);

(d) a summary of the risk assessment undertaken in accordance with regulation 7;

(e) the names and capacities of the members of the genetic modification safety committee;

(f) comments made by the genetic modification safety committee on the local arrangements for risk assessment;

(g) the names of the biological and deputy biological safety officers concerned with the intended activities (if any);

(h) the name of the supervisory medical officer (if any); and

(i) the arrangements for health surveillance (if any).

SCHEDULE 5 Regulation 9

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 9

PART I

Information required under regulation 9(3)

1. A notification required for the purposes of regulation 9(3) shall include the following information -

(a) the name and address of the person responsible for carrying out the activity;

(b) address of the premises where the activity is to be carried out;

(c) the date of the notification referred to in regulation 8(1);

(d) the parental organism used, or where applicable the host-vector system used;

(e) the source and the intended function of the genetic material involved in the modification;

(f) the identity and characteristics of the genetically modified organism;

(g) the purpose of the activity including the expected results;

(h) where appropriate the culture volumes to be used or the scale of the activity; and

(i) details of waste treatment including levels of live genetically modified micro-organisms in the waste; and

(j) a summary of the risk assessment required in accordance with regulation 7 and of the comments of the genetic modification safety committee on it.

(c) information about the installation -

(i) the activity in which the micro-organisms are to be used,

(ii) the technological processes used,

(iii) a description of the sections of the installation involved, and

(iv) the predominant meteorological conditions and specific hazards arising from the location of the installation;

(d) information about waste management -

(i) types, quantities and potential hazards arising from the use of the micro-organisms,

(ii) waste management techniques used including recovery of liquid or solid wastes and the inactivation techniques used, and

(iii) ultimate form and destination of inactivated wastes

(e) information about accident prevention and emergency response plans -

(i) the sources of hazards and conditions under which accidents might occur,

(ii) the preventive measures applied such as safety equipment, alarm systems, containment methods and procedures and available resources,

(iii) a description of information given to workers, and

(iv) the information necessary for the Executive to evaluate any emergency plan prepared in accordance with regulation 13; and

(f) the full risk assessment referred to in regulation 7.

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SCHEDULE 5 Regulation 9

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 9

PART I

Information required under regulation 9(3)

1. A notification required for the purposes of regulation 9(3) shall include the following information -

(a) the name and address of the person responsible for carrying out the activity;

(b) address of the premises where the activity is to be carried out;

(c) the date of the notification referred to in regulation 8(1);

(d) the parental organism used, or where applicable the host-vector system used;

(e) the source and the intended function of the genetic material involved in the modification;

(f) the identity and characteristics of the genetically modified organism;

(g) the purpose of the activity including the expected results;

(h) where appropriate the culture volumes to be used or the scale of the activity; and

(i) details of waste treatment including levels of live genetically modified micro-organisms in the waste; and

(j) a summary of the risk assessment required in accordance with regulation 7 and of the comments of the genetic modification safety committee on it.

PART II

Additional information required under regulation 9(4)

2. In addition to the information required under Part I a notification made for the purposes of regulation 9(4) shall contain the following information -

(a) a description of the sections of the installation involved and the methods for handling the organisms;

(b) a description of the predominant meteorological conditions and the potential sources of danger arising from the location of the installation;

(c) a description of the protective and supervisory methods to be applied throughout the duration of the activity; and

(d) in the case of micro-organisms, the containment level to which the micro-organism has been allocated in accordance with the risk assessment made in accordance with regulation 7(1) and in any case the safety precautions to be observed.

PART III

Additional information required under regulation 9(5)

3. In addition to the information required under Parts I and II a notification made for the purposes of regulation 9(5) shall contain the information specified in paragraph 5.

4. If it is not technically possible, or if it does not appear necessary to give the information specified in paragraph 5, the reason shall be stated. The level of detail required in response to each subset of considerations is likely to vary according to the nature and scale of the proposed activity. In the case of information already submitted to the Executive by the notifier under

these Regulations (or the 1989 Regulations) reference can be made to that information by him.

5. The additional information required is -

(a) information about the genetically modified micro-organism -

(i) the identity and characteristics of the genetically modified micro-organism,

(ii) the purpose of the contained use or the nature of the product,

(iii) the host-vector system to be used where applicable,

(iv) the culture volume to be used,

(v) behaviour and characteristics of the micro-organisms in the case of changes in the conditions of containment or release into the environment,

(vi) overview of the potential hazards associated with the release of the micro-organisms into the environment, and

(vii) substances which are or may be produced in the course of use of the micro-organisms other than the intended product;

(b) information about personnel -

(i) the maximum number of persons working in the installation, and

(ii) the number of persons who will work directly with the micro-organism;

(c) information about the installation -

(i) the activity in which the micro-organisms are to be used,

(ii) the technological processes used,

(iii) a description of the sections of the installation involved, and

(iv) the predominant meteorological conditions and specific hazards arising from the location of the installation;

(d) information about waste management -

(i) types, quantities and potential hazards arising from the use of the micro-organisms,

(ii) waste management techniques used including recovery of liquid or solid wastes and the inactivation techniques used, and

(iii) ultimate form and destination of inactivated wastes;

(e) information about accident prevention and emergency response plans -

(i) the sources of hazards and conditions under which accidents might occur,

(ii) the preventive measures applied such as safety equipment, alarm systems, containment methods and procedures and available resources,

(iii) a description of information given to workers, and

(iv) the information necessary for the Executive to evaluate any emergency plan prepared in accordance with regulation 13; and

(f) the full risk assessment referred to in regulation 7.

SCHEDULE 6 Regulation 12(4)

CONTAINMENT MEASURES FOR MICRO-ORGANISMS OF GROUP II

1. The containment measures for Type B operations using micro-organisms from Group II shall be chosen by the user from the levels in the Table below as appropriate to the micro-organism and the operation in question in order to ensure the protection of health of the general population and the environment.

2. Type B operations shall be considered in the terms of their unit operations. The characteristics of each operation will dictate the physical containment to be used at that stage. This will allow the selection and design of process, plant and operating procedures best fitted to ensure adequate and safe containment. Two important factors to be considered when selecting the equipment needed to implement the containment are the risk of, and the effects consequent on, equipment failure. Engineering practice may require increasingly stringent standards to reduce the risks of failure as the consequence of that failure becomes less tolerable.

SPECIFICATIONS	Containment Levels B1	B2	B3
1. Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system)	Yes	Yes	Yes
2. Exhaust gases from the closed system should be treated so as to:	Minimise release	Prevent release	Prevent release
3. Sample collection, addition of materials to a closed system and transfer of viable micro-organisms to another closed system, should be performed so as to:	Minimise release	Prevent release	Prevent release
4. Bulk culture fluids should not be removed from the closed system unless the viable micro-organisms have been	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to:	Minimise release	Prevent release	Prevent release
6. Closed systems should be located within a controlled area	Optional	Optional	Yes, and purpose-built
(a) Biohazard signs should be posted	Optional	Yes	Yes
(b) Access should be restricted to nominated personnel only	Optional	Yes	Yes, via airlock
(c) Personnel should wear protective clothing	Yes,work clothing	Yes	Yes A complete change
(d) Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes

SPECIFICATIONS	Containment Levels		
	B1	B2	B3
(e) Personnel should shower before leaving the controlled area	No	Optional	Yes
(f) Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes
(g) The controlled area should be adequately ventilated to minimise air contamination	Optional	Optional	Yes
(h) The controlled areas should be maintained at an air pressure negative to atmosphere	No	Optional	Yes
(i) Input air and extract air to the controlled area should be HEPA filtered	No	Optional	Yes
(j) The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Yes	Yes
(k) The controlled area should be sealable to permit fumigation	No	Optional	Yes
7. Effluent treatment before final discharge	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated physical means

[Draft - AUGUST 1992]

GUIDANCE NOTES ON THE CONTAINED USE OF GENETICALLY MODIFIED ORGANISMS REGULATIONS 199-

INTRODUCTION

1. This booklet gives practical guidance on the Contained Use of Genetically Modified Organisms Regulations 199- which are designed to ensure the safe use and handling of genetically modified organisms under containment.

2. The regulations are reproduced at Appendix 1. They repeal and replace the earlier legislation in this field, the Genetic Manipulation Regulations 1989, and implement within Great Britain EC Directive 90/219/EEC on the contained use of genetically modified micro-organisms, which was adopted on 23 April 1990, [OJ No L117, 8.5.90, P1]. The regulations come into force on.....

3. The regulations have been made under the powers of the Health and Safety at Work etc. Act 1974 (the HSW Act) and the European Communities Act 1972 and are concerned with protecting both human health and the environment. They provide that, with certain specified exceptions, no person should carry out any activity involving genetic modification unless this is done in conditions of contained use in accordance with the regulations ie the person has carried out a risk assessment, submitted a notification to the Health and Safety Executive, and, in certain circumstances, received the formal consent of the Executive.

4. The regulations cover both human health and environmental risks of genetically modified micro-organisms. They cover human health risks only of larger organisms, such as plants and animals, which are genetically modified. In this respect

they go beyond the requirements of the above directive. The 1989 Genetic Manipulation Regulations also covered the human health risks of genetically modified larger organisms.

5. The requirement to carry out an environmental risk assessment for work with larger organisms is covered by section 108(1)(a) of the Environmental Protection Act 1990 which also comes into force ..... Under this section anyone intending to make or acquire from another person a genetically modified organism which is not an approved product under the Deliberate Release Regulations (see below) would need to carry out an environmental risk assessment and make it available for inspection.

Other relevant legislation

6. It should be noted that this guidance does not cover other legislation which may also have a bearing on work with genetically modified organisms. Such legislation includes, for example, controls on: human and veterinary medicines, under the Medicines Acts 1968 and 1971; pesticides, under the Food and Environment Protection Act 1985; plant pathogens under the Plant Health (Great Britain) Order 1967; transgenic animals under the Animals (Scientific Procedures) Act 1986; genetically modified material and plants under the Plant Health (Great Britain) Order 1987; and the introduction of novel species under the Wildlife and Countryside Act 1981. [A list of Government contact points for this legislation will be included in an Appendix which will take the form of an update on current lists in guidance already published by the Health & Safety Commission's Advisory Committees on Genetic Modification and Dangerous Pathogens]. All such legislation remains in force and is not affected by the Contained Use regulations, which deal specifically with genetic modification. In addition, all work activities, including those concerned with genetic modification, are covered by the Health and Safety at Work etc Act 1974 and

relevant regulations made under that Act, including, where appropriate, the Control of Substances Hazardous to Health Regulations 1988.

Legislation on the deliberate release of genetically modified organisms

7. A second EC Directive, No 90/220/EEC, deals with the deliberate release of genetically modified organisms. Regulations to implement this directive have been introduced under the Environmental Protection Act 1990 (the EP Act), the regulations being entitled 'The Genetically Modified Organisms (Deliberate Release) Regulations 199-'. Guidance on the Act and regulations is provided in the booklet "Guidance on the regulatory control of the deliberate release of genetically modified organisms", HMSO, 199-, obtainable from .....

8. In this booklet the Contained Use of Genetically Modified Organisms Regulations 199- are referred to as the Contained Use Regulations and the Genetically Modified Organisms (Deliberate Release) Regulations 199- as the Deliberate Release Regulations.

Enquiries on the Contained Use Regulations

9. If, after reading this guidance, you need further advice on the procedures in the Contained Use Regulations for risk assessment, notification and consent, you should contact:

The Health and Safety Executive
Health Policy Division, Branch A,
Baynards House
1 Chepstow Place
London W2 4TF

Tel: 071 243 6120 or 6113
Fax:.....

Technical enquiries on matters such as containment practices and the reporting of accidents etc should be made to :

Health and Safety Executive
Branch THSD C6
Magdalen House
Stanley Precinct
Bootle
Merseyside L20 3QZ

Tel: 051 951 4831
Fax:.....

CONTENTS

The guidance is arranged as follows:

- Section 1 describes the main features of the Contained Use Regulations and the associated administrative arrangements;

- Section 2 contains detailed guidance on each requirement of the Contained Use Regulations;

- Section 3 explains the requirements of section 108(1)(a) of the EP Act as it applies to the contained use of genetically modified non micro-organisms in relation to environmental protection [to be added].

- Appendix 1 reproduces the Contained Use Regulations;

- Appendix 2 contains a flow chart summarising the notification requirements [to be added].

- Appendix 3 lists current titles in the ACGM Guidance Note series

- Appendix 4 sets out the format for information which must be supplied with an accident notification under Regulation 14.

- Appendix 5 lists the abbreviations used in this guidance [to be added]

1. MAIN FEATURES OF THE CONTAINED USE REGULATIONS

1. The main requirements of the Contained Use Regulations provide for:

- human health and environmental risk assessment;

- the need to keep records of risk assessments;

- the need to establish a local safety committee to advise on risk assessments;

- categorisation of work on the basis of risks to human health and safety and of damage to the environment, taking into account the nature of the organism and the type of activity;

- advance notification to the Health and Safety Executive of an intention to use premises for activities involving genetic modification for the first time and, in prescribed circumstances, specific consent from the Executive and for such use;

- notification to the Health and Safety Executive of individual activities involving genetic modification, in advance where specified, and, in prescribed circumstances, specific consent from the Executive before such activities can proceed;

- standards of occupational and environmental safety and levels of containment;

- notification of accidents and, where appropriate, the drawing up of emergency plans;

- provisions relating to confidentiality, disclosure of information and public registers;

- provision for fees for notifications.

2. The provisions apply to all activities involving genetically modified organisms (GMOs) except for their deliberate release or marketing as described in Paragraph 4 below. The activities covered by the Contained Use Regulations include laboratory operations, housing and/or breeding of modified animals in animal houses, farm animals restrained by appropriate fencing, the use of growth rooms and glasshouses of appropriate specification, and the use of fermenters. All such activities are prohibited unless they are carried out in contained use conditions in accordance with the regulations.

3. 'Contained use' is defined as any operation in which organisms are genetically modified or in which GMOs are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers or a combination of physical barriers with chemical or biological barriers or both are used to limit their contact with the general population and the environment. Note that physical barriers appropriate to the GMO must always be present. In some cases, although physical barriers are present, they may not provide an adequate limitation to contact with the environment eg, some designs of glasshouse may not adequately contain plant pollen.

4. The Contained Use Regulations cover the breeding on of a transgenic plant or animal, as well as activities involving modified organisms supplied by others. They do not cover however, the deliberate release of GMOs to the environment for experimental purposes nor the marketing of products consisting of or containing GMOs. These activities are covered by the EP Act and the Deliberate Release Regulations.

5. So long as the use of a product is as specified under the Deliberate Release Regulations in the conditions for marketing, and no further genetic modification is undertaken, it will also not be covered by the Contained Use Regulations. Breeding on from such 'approved products' may be allowed under the conditions for marketing and in such cases would not be further regulated under the Deliberate Release Regulations or the Contained Use Regulations.

6. Waste streams from contained facilities are also regulated under the Contained Use Regulations. They are not regulated by the Deliberate Release Regulations.

Administrative Arrangements

7. The Contained Use Regulations are administered jointly by the Health and Safety Executive (HSE) and the Department of the Environment (DOE), under integrated arrangements. Those with duties under the legislation have a single point of contact in the HSE. All notifications under the Contained Use Regulations should thus be made to the HSE, which is under a duty to pass copies to the Secretary of State for Environment. Where further information is required by either the Secretary of State or the HSE this will be requested by the HSE. Where the work activity concerned is subject to consent by the Secretary of State and HSE, then the results of their consideration will be transmitted to the applicant by the HSE and, where appropriate, both consents will be forwarded to the applicant together.

8. [Arrangements for fees charged, to be finalised after consultation. See the covering consultation paper to this draft guidance]

9. Notifications and consent applications must be made in a form approved by the Executive and submitted to:

The Health and Safety Executive
Health Policy Division, Branch A,
Baynards House
1 Chepstow Place
London W2 4TF
(Tel 071-243 6120 or 6113)

Model forms for the applications can be obtained free from the above address.

Enforcement

10. Enforcement of the Contained Use Regulations is the responsibility of HSE under the powers of the HSW Act. HSE Inspectors have extensive powers under this Act, including powers to enter premises and to require the provision of information relevant to their purposes and the production of documents.

Guidance from the Advisory Committee on Genetic Modification

11. The Advisory Committee on Genetic Modification (ACGM) has issued, for centres concerned with genetic modification, a series of guidance notes (ACGM/HSE Notes 1-11) on individual subjects related to the contained use of GMOs. The guidance notes are referred to where appropriate in the regulation-by-regulation guidance that follows and a list of current titles is at Appendix 3. The notes will be updated from time to time. Updates will, in future, be issued jointly by HSE and DOE but the numbering in relation to the subjects covered will be retained. Copies of the notes may be obtained from HSE at the address given at paragraph 9 above.

2 - GUIDANCE ON INDIVIDUAL REQUIREMENTS OF THE REGULATIONS

[The draft guidance below needs to be read with the regulations referred to. In the final version, each regulation commented on will be reproduced in full at the start of the relevant passage, and the guidance will be edited accordingly]

Note The guidance given below reflects discussions in the Committee of National Competent Authorities set up by the European Commission under the terms of the Contained Use Directive. (The UK Competent Authorities are HSE and DOE). The European Commission has issued guidelines on the interpretation of a number of issues arising from the directive, which has been discussed and agreed by the Committee. Where the following notes draw on or are based on such guidelines, this is indicated by an asterisk. The guidelines themselves are published in .....

Regulation 1 - Citation and commencement

12. There are special transitional arrangements for activities which were already notified under the Genetic Manipulation Regulations 1989 or are notified in the period immediately after the new regulations come into force. These are in regulation 23 (see note on that regulation below).

Regulation 2 - Interpretation

13. This regulation deals with definitions. Particular points to note are

- "contained use" covers any operation involving GMOs under conditions of containment.

- the containment must be provided by physical barriers, which may be supplemented by chemical or biological barriers;

- the containment must limit the contact of the genetically modified organism with the general population and the environment;

- the "genetic modification" definition is similar to that for genetic manipulation contained in the Genetic Manipulation Regulations 1989 (now repealed). Techniques included in the definition are listed in Schedule 1 Part I. However:

  the list in Schedule 1 Part I is not exhaustive;

  gene deletions or the insertion of multiple copies of a gene are considered to be genetic modification if they are brought about using any listed technique (see also "self cloning" below);

  cell fusion is considered to be a technique of genetic modification. This represents a change from the 1989 Regulations (but see note on Regulation 3 below).

- Schedule 1 Part II contains techniques which are not considered to fall within the definition of genetic modification if they do not involve the use of recombinant DNA molecules or genetically modified organisms. Schedule 1 Part III lists techniques which <u>are</u> considered to be genetic modification but which are also excluded if they do not involve the use of genetically modified organisms as recipient or parental organisms. The transformation of cells with DNA or the transformation of cells with viruses are thus not considered to be genetic modification unless modified DNA or modified viruses are employed or the recipient is itself genetically modified;

- "micro-organism" covers all micro-organisms. The term include viruses and viroids, the [uncharacterised] agent responsible for transmissible spongiform

encephalopathy, cell cultures and tissue cultures, including those from plants, animals and humans. It does not cover naked DNA or naked plasmids;*

- **"organism"** covers, in addition to all micro-organisms, all multicellular organisms not defined as micro-organisms, thus including plants and animals;

- **"self-cloning"** is one of the techniques referred to in Schedule 1 Part III. This term, as defined, covers the re-insertion of an organism's nucleic acid into the same species. Such nucleic acid may have been subject to modification by enzymic, chemical or mechanical steps so as to produce a novel order, to remove sequences, to produce multiple gene copies, etc., but may not contain foreign gene sequences beyond short oligonucleotide linker sequences such as those used for the purpose of introducing restriction endonuclease sites. Self-cloning which meets the following criteria is exempt from the Regulations:

  - only non-pathogenic micro-organisms which meet the criteria for Group I status or non-pathogenic organisms which are as safe as any recipient or parental organism are used. Both the donor and recipient must meet the criteria for Group I status. Guidance on Group I status is given below;

  - vector sequences are derived from only poorly mobilisable vectors and are well characterised and free from harmful sequences;

  - the modified nucleic acid does not contain genes known to affect pathogenicity, toxicity or which could affect the capacity of the organism to harm human health or the environment.

- **"Type A operation"** - to qualify as a Type A operation, an activity must fulfil two conditions:

  (1) it must be for teaching, research or development, or for non-industrial or non-commercial purposes,

  (2) it must be on a scale at which operations related to culture volume and numbers of organisms are such that

    a) the containment system reflects good microbiological practice and good occupational safety and hygiene;

    b) the organism can easily be rendered inactive by standard laboratory decontamination techniques.

  In determining whether these conditions are fulfilled the following should be taken into account:

  - the system of operations used to contain the organisms should comply with the methods set out in ACGM/HSE/NOTE 8 taking into account ACGM/HSE/NOTE 6 where appropriate;

  - it should be possible to limit the possibility of contact with man and the environment both in the event of spillage and in the removal of waste for safe disposal. A figure of 10L is given in the EC Directive 90/219/EEC as indicative of appropriate volume, but it is recognised that this cannot be used as a fixed figure.

- **Type B operation** - classified as any operation which does not fulfil the criteria for Type A

- **Classification of micro-organisms** The regulations define two hazard groups of genetically modified micro-organism,

Group I and Group II. All persons undertaking any contained use with a genetically modified micro-organism must classify it into one of these groups.

Schedule 2 Part I sets out the criteria that a micro-organism must meet (to the extent the criteria are applicable) to be classified as Group I. Part II of this schedule sets out the guidelines published in a European Commission Decision, No 91/448/EEC, for the further interpretation of the criteria in Part I.

Group I organisms may not be based upon recipients with pathogenic characteristics or those which may harm the environment. As a general guide, the following recipient micro-organisms will not qualify for Group I status and are therefore automatically considered to be Group II:

micro-organisms listed in hazard groups 2,3 or 4 in the Advisory Committee on Dangerous Pathogens (ACDP) guidance document "Categorisation of pathogens according to hazard and categories of containment", 1990, 2nd Ed;

organisms listed in the Plant Health Order 1987, 1989 or any other plant pathogen;

pathogens of animals, poultry, fish, or bees controlled by the Agriculture Departments (listed in Appendix N of the above ACDP publication);

any other micro-organism capable of harming the environment by any means including the production of metabolites;

Disabled strains of pathogenic species such as E coli K12, disarmed Agrobacterium tumefaciens etc., may satisfy the host/vector criteria for Group I status set out in Schedule 2. MAFF/SOAFD licence requirements under plant

health legislation are independent of Group I/Group II status.

- classification of organisms other than micro-organisms Part III of Schedule 2 sets out the criteria for classification of higher organisms. In effect there are two groups on the basis of whether or not the genetically modified organism is as safe to man or the environment as the parental organism.

Regulation 3 - Application

14. This regulation specifies that the regulations apply both to risks to human health and protection of the wider environment, and that they apply to all activities involving the contained use of genetically modified organisms with the following exceptions:

- the transport of genetically modified organisms is subject only to the requirements for risk assessment in Regulation 7 and the provisions of Regulation 13 onwards. The requirements for notification in Regulations 8-12 do not apply to transport.

- the regulations do not apply to GMO activities involving solely the techniques of genetic modification listed in Schedule 1, Part III. This lists techniques which are excluded so long as the parental or recipient organism is not itself a genetically modified organism. Such techniques include self-cloning (see guidance to Regulation 2) and cell fusion of plant cells where the resulting organism could be produced using traditional breeding methods. Interpretation of the term "traditional breeding methods" has been agreed by the Competent Authorities of EC member states to mean:

Traditional breeding refers to practices which use one or more of a number of methods, including physical and/or chemical means and control of physiological processes, which can lead to successful crosses between plants of the same botanical family.*

15. The regulations do not apply in Northern Ireland [where separate complementary provisions will implement the EC Directive].

Regulation 4 - Meaning of 'work' and 'at work'

16. This regulation extends the meaning of `work' and `at work' in the HSW Act so as to include all activities involving the contained use of genetically modified organisms, whether the person concerned is an employer, an employee, a self-employed person, or is non-employed. All such activities are covered both by the general duties in Part I of the Act and by the Contained Use Regulations.

Regulation 5 - Modification of Section 3(2) of the Health and Safety at Work etc Act 1974

17. This regulation modifies Section 3(2) of the HSW Act which requires self employed persons to conduct their undertakings in such a way as to ensure, so far as is reasonably practicable, that persons other than employees are not exposed to risks to their health and safety. Under regulation 5, this requirement is extended, in relation to an activity involving genetic modification, to anyone who is not an employer or an employee.

Regulation 6 - Prohibition of work with genetically modified organisms outside containment

18. Regulation 6 prohibits any work with genetically modified organisms unless:

- the work is carried out under contained conditions in accordance with the Contained Use Regulations, or

- the organisms are or are contained in an 'approved product' under the Deliberate Release Regulations, or

- the activity is a deliberate release to the environment carried out under a consent issued under the Deliberate Release Regulations

Regulation 7 - Risk assessment

19. This regulation requires that a risk assessment, taking account of the parameters set out in Schedule 3 to the Regulations so far as they are relevant, must be made before any premises can be used for genetic modification activities or any such activities are undertaken. Under regulation 7(2) part of the purposes of such risk assessment is to classify the organisms involved, in accordance with Schedule 2, and make decisions about appropriate levels of containment. The figure belows shows how risk assessment relates to classification and decisions about control measures:-

RISK ASSESSMENT (using parameters set out in Schedule 3 where relevant)



CLASSIFICATION of genetically modified micro-organisms (Group I/II) and other genetically modified organisms (Reg 2) by application of Schedule 2 <——————> ASSIGNMENT to levels of containment (Reg 12)

20. Risk assessments made for the purpose of notifying a general intention to use premises will necessarily be less specific than those made for the purpose of notifying individual activities.

Guidance on risk assessment is contained in :

ACGM/HSE Note 6, ACGM/HSE Note 7 [revision to be issued in 1992] and, in relation to eukaryotic viral vectors, ACGM/HSE/Note 5

21. Under regulation 7(4), it is necessary to review the assessment where there is reason to suspect that the original assessment is no longer valid or where there has been a significant change in the activity to which the assessment relates. In this context significant change would include:

- change of scale of operation;

- change in containment conditions used;

- change of waste treatment procedures;

- new data on the behaviour of the organism eg data on the toxicity of the gene product; on the level of gene expression; on the ability of the organism to cause harm in the environment etc.

22. Under Regulation 7(5), records of risk assessments are required to be kept for at least 10 years from the date on which use of the premises or activity to which the assessment related has ceased.

23. Under Regulation 11, any persons undertaking a risk assessment for the purposes of the Regulations must establish a Genetic Modification Safety Committee to advise them in relation to that assessment. See paragraph 34 for further guidance on such committees.

Regulation 8 - Notification of intention to use premises for activities involving genetic modification for the first time

24. Under both this regulation and Regulation 9 which follows notification is required by the person undertaking or intending to to undertake the activity involving genetic modification. In practice, the 'person' will generally be a body corporate such as a company, university or research institute.

25. Notification under Regulation 8 is required when it is intended that premises be used for the first time for activities involving genetic modification. The extent to which, for example, different laboratories within the same research institution or university may be the subject of a single notification will depend largely on the way in which the management structure of the body making the notification is organised. Advice in individual cases can be obtained from the Health and Safety Executive.

26. Notification is required 90 days in advance of any intended activities or later with the agreement of the Health and Safety Executive. Under Regulation 10(5), notification under Regulation 8 must be made in a form approved by the Health and Safety Executive and a model form for this purpose (ref) can be obtained free from the Executive at the address given at paragraph 9 above. The information to be notified consists of the information specified in Schedule 4 to the Regulations.

27. In the case of activities involving micro-organisms, notifiers must indicate whether it is intended that Group I or Group II micro-organisms will be used and separate notifications are required in respect of an intention to undertake activities involving each Group. Where a notification of intention to undertake activities involving Group I micro-organisms has been made and it is subsequently the intention to undertake activities involving Group II micro-organisms, or vice versa, then a further notification of intention is required.

28. For activities with Group I micro-organisms, or organisms other than micro-organisms, the activities may proceed at the end of 90 days or any shorter time that the Executive may have approved provided that no objection is raised by the Executive. For notification of intention of activities with Group II micro-organisms, the activities may proceed only with the consent of the Executive, which will be granted only with the agreement of the Secretary of State for Environment in relation to environmental protection. Notifiers will be informed of the outcome of consideration of consent applications within 90 days of the receipt of the application.

29. The regulation also provides that notification of intention to use premises for the first time under Regulation 8 and notification of individual activities under Regulation 9 (see below) can be submitted at the same time. Such notification will be considered together with relevant time periods running concurrently. In accordance with Regulation 8, individual activities, if notified at the same time as an intention to use premises for the first time, can only be commenced after a period of 90 days unless the Executive approves a shorter time.

Regulation 9 - Notification of individual activities involving genetic modification

30. This regulation deals with notification of specific activities involving genetic modification. Under Regulation 9(7), the Executive may accept as a single notification a connected programme of work covering more than one activity. [Example to be added]. To avoid the need for renotification in respect of different phases or elements of a particular activity careful consideration should therefore be given by the notifier to the project as a whole and the notification should, where appropriate, cover all foreseeable aspects of the intended work.

31. Under Regulation 10(5) notification under Regulation 9 must be made in a form approved by the Health and Safety Executive and a

model form for this purpose (ref ...) can be obtained free from the Executive at the address given at paragraph 9 above. The information to be notified, the time period for notification, and whether a consent is required depends on the nature of the activity and can be summarised as follows:

Type A operations involving Group I micro-organisms or operations involving organisms other than micro-organisms which satisfy the criteria in Schedule 2, Part III - Regulation 9(2)

In these cases, advance notification is not required. Instead, records of activities need to be kept available for inspection. At the end of each calendar year the Health and Safety Executive should be notified as soon as reasonably practicable of the total number of risk assessments required under regulation 7 undertaken during that year, whether the activities are to be continued and details of changes to any particulars previously notified.

Type B operations involving Group I micro-organisms - Regulation 9(3)

The information specified in Part I of Schedule 5 should be notified 60 days in advance of the proposed activity or later with the agreement of the Health and Safety Executive. The activity may proceed at the end of the notification period provided that no objection is raised by the Executive, and in accordance with any conditions imposed by the Executive.

It should be noted that the summary of the risk assessment submitted with Group I, Type B notifications should give sufficient information to demonstrate that environmental harm will not be caused as a result of effluent discharge. Failure to provide such information will result in further information being requested by the Executive (see Regulation 10). If the additional information provided indicates that

contact of genetically modified micro-organisms with man or the environment is not sufficiently limited, the notification will be subject to consent before it can proceed and discharge conditions may be imposed.

Type A operations involving Group II micro-organisms and operations involving organisms other than micro-organisms which do not satisfy the criteria in Schedule 2, Part III - Regulation 9(4)

The information specified in Parts I and II of Schedule 5 should be notified 60 days in advance of the proposed activity or later with the agreement of the Health and Safety Executive. The activity may proceed at the end of the notification period provided that no objection is raised by the Executive, and in accordance with any conditions imposed by the Executive.

Type B operations involving Group II micro-organisms - Regulation 9(5)

The information specified in Parts I, II and III of Schedule 5 should be notified. The activity can proceed only with the consent of the Executive. The Executive will not grant a consent relating to environmental protection without the agreement of the Secretary of State. Notifiers will be informed of the outcome of their consideration of applications within 90 days of their receipt.

Regulation 10 - Additional provisions relating to notifications and consents

32. This regulation, which is largely self-explanatory, deals with:

- requests by the Executive for additional information, which stop the clock as far as the specified time periods are

concerned, and make the activity subject to consent (Regulation 10(1));

- provision for conditions to be specified as part of a consent (Regulation 10(2));

- the need for notification of any significant changes in premises or activities or new information which would affect the particulars previously notified (Regulation 10(3));

- provision for the Executive to require modification, suspension or termination of activities in the light of new information (Regulation 10(4); and

- the need to make notifications under regulations 8 and 9 in a form approved by the Executive (Regulation 10(5)) - see paragraphs 27 and 32 above.

33. For guidance on what would constitute a `significant' change in relation to Regulation 10(3), the guidance in paragraph 21 above also applies. The Executive should also be informed of changes in notified personnel and it is particularly important that the Executive is informed of cessation of work involving genetic modification.

Regulation 11 - Establishment of Genetic Modification Safety Committee

34. There needs to be a properly constituted and representative genetic modification safety committee at each centre where activities involving genetic modification are undertaken. As with regulations 8 and 9, the person setting up the safety committee will be the "body corporate". In considering notifications under the regulations the Executive will take into account comments made by such committees. Advice on the constitution and functions of such committees is contained in ACGM/HSE/NOTE 11.

Regulation 12 - Standards of occupational and environmental safety and containment

35. Regulation 12 sets out standards of occupational and environmental safety and containment which must be achieved for all work with genetically modified organisms. Requirements for each group of organism and type of operation are detailed in turn.

36. For work with Group I micro-organisms, control measures must be taken in accordance with principles of good microbiological practice and good occupational safety and hygiene, as set out in Regulation 12(1) and (2). These principles are intended to protect both human health and safety and the environment. ACGM/HSE/NOTE 8 contains relevant advice on safe systems of work in laboratories and ACGM/HSE/Note 6 deals with safe operation of scale-up work.

37. For work with Group II micro-organisms in Type A operations, Regulation 12 (3) requires, in addition to observance of the above principles, containment measures, determined by a method approved by the Executive. The approved method is that currently contained in ACGM/HSE/NOTE 8.

38. Additional containment provisions to be used for work with Group II micro-organisms in Type B operations are set out in Schedule 6: B1, B2, B3. (These were previously in use under the 1989 Regulations for large scale categories LS1, LS2 and LS3 and they are set out in ACGM/HSE/NOTE 6). For genetically modified organisms other than micro-organisms, the principles set out in Regulation 12(1) must be applied as appropriate. Standards for physical containment for work with transgenic animals are contained in ACGM/HSE/Note 9 and ACGM/HSE/Note 10 contains standards for glasshouse work.

Regulation 13 - Emergency plans

39. Regulation 13 contains a requirement to draw up an emergency plan if the risk assessment undertaken in accordance with

Regulation 7 (1) indicates that, as a result of any foreseeable accident, the health and safety of persons outside the premises may be affected or if there is any risk to the environment. In practice the drawing up of an emergency plan is unlikely to be necessary for any operations other than for those Type B operations involving Group II micro-organisms.

40. For those Group II Type B operations where an emergency plan is produced, it should be a written document, kept up to date to reflect changes in risks procedures and personnel. The plan should be drawn up in consultation with appropriate organisations including Local Authority Emergency Planning arrangements. The Emergency Services [to be specified] should be informed in writing of the plan's existence. The plan should include the following <u>where appropriate</u>:

(i) the types of incidents to people or the environment to be taken into account and the immediate steps to be taken;

(ii) organisations involved, including key personnel, their responsibilities and liaison arrangements between them;

(iii) communication links including arrangements for giving information to persons liable to be affected by any accident and for making such information publicly available;

(iv) special equipment, including damage control and repair items;

(v) technical information such as nature of the organism, characteristics of the plant and other hazards which may be present;

(vi) information about the site including likely locations of hazardous organisms and personnel;

(vii) evacuation arrangements;

(viii) contacts and arrangements for obtaining further advice and assistance, eg meteorological information, medical services, water and agricultural authorities;

(ix) arrangements for dealing with the media;

(x) longer-term clean up.

Regulation 14 - Notification of accidents

41. This regulation requires notification to HSE of an accident, defined in Regulation 2 as any incident involving a significant and unintended release of GMOs which present a risk of harm, immediate or delayed, to either human health and safety or to the environment.

The regulation specifies that the notification should be made forthwith and that it should contain the following information

(a) the circumstances of the accident;

(b) the identity and quantity of genetically modified organisms released;

(c) any information necessary to assess the effects of the accident on the health of the general population and on the environment;

(d) the emergency measures taken.

In accordance with Community wide guidelines agreed by Member States, the information should be set out as an Appendix 4.

The notification should be made to:-

Health and Safety Executive
Branch THSD C6
Magdalen House
Stanley Precinct
Bootle
Merseyside L20 3Q2
Tel: 051 951 .....
Fax: ....

42. Spillages of Group I micro-organisms are unlikely to have involve a significant release of genetically modified organisms which have the potential for harm. These will not routinely require notification.

43. On receipt of an accident notification, the Health and Safety Executive is required to

(a) ensure that appropriate emergency measures are taken,

(b) inform any other member State that could be affected by the accident.

(c) carry out an analysis of accidents and make recommendations to avoid similar occurrences and to limit their effects, and

(d) send to the European Commission accident details as specified above together with an analysis and any recommendations.

Regulation 15 - Disclosure of information notified

44. This regulation ensures that the provisions of Section 28 of the Health and Safety at Work etc. Act 1974 in relation to disclosure of information apply to all notifications made under

- **the purpose of the contained use;**

  For each contained use, the type of operation, the purpose and objectives.

- **methods and plans for monitoring and emergency response;**

  In principle, all the information submitted to the competent authority on this aspect;

- **the evaluation of foreseeable effects in respect of human health and environmental impact.**

  The intention here is that the summary of the risk assessment carried out under Regulation 7 and the conclusions reached as regards foreseeable effects are not to be considered confidential.

  More specifically, as regards pathogenic effects, information not to be kept confidential should include the ability of the GMM and its extracellular products to be pathogenic or harmful in any other way to humans, plants or animals. The information mentioned under Schedule 3 Part 3, section C is particularly pertinent.

  As regards possible ecologically disruptive effects, information not to be kept confidential should include any information on the likelihood of selection for the GMM in the environment, its survival and dissemination, and characteristics outside the contained systems, the significant potential interactions with other organisms, the likelihood of genetic exchange in vivo, and the relevant information on potential ecological impact mentioned under Schedule 3 Part 4.

Such information in relation to activities requiring consent will be contained in public registers (see paragraphs 48-50 below).

Access to non-confidential material in notifications not requiring consent can also be obtained through contact with the address at paragraph 9 above.

Regulation 16 - Register of information

48. This regulation requires the Executive to maintain a public register of notifications requiring consent (ie notifications of intention to use premises for activities involving Group II micro-organisms for the first time and individual Type B operations involving Group II micro-organisms). The information required to be placed on the register is specified in Regulation 16(2) and is the same as that specified in Regulation 15 as information which cannot be kept confidential, together with a statement as to whether or not consent has been granted. The model notification form for such consent applications contains a section on the information to be placed on the register as well as guidance on the amount of detail required. Information from notifiers is required to be placed on the register within 7 days of its receipt. The decision of the Executive and the Secretary of State for the Environment is required to be added within 7 days of the decision being made.

49. Copies of the register are maintained at the area office of the Executive in whose area the notifier is situated (addresses of HSE's local offices are given in general telephone directories, under 'Health and Safety Executive') and at Head Offices of the Executive. The Head Office addresses are:

The Health and Safety Executive
Health Policy Division, Branch A,
Baynards House
1 Chepstow Place
Westbourne Grove
London W2 4TF
Tel: 071-243 ----

the regulations. Under Section 28 a duty is placed on the Executive as the recipient of relevant information not to disclose such information without the agreement of the notifier. However, this is qualified by Section 28(3) of the Act which allows the Executive to disclose relevant information required by statutory provisions to a Government Department or any enforcing authority or to any person for the purposes of the Executive's functions. Under Regulation 15(4) it is a function of the Executive to make information contained in notifications publicly available to the extent that it considers appropriate. Under Regulation 18 the Executive must disclose notifications to the Secretary of State. Under Regulation 19 the Executive must send to the European Commission reports of applications for consents under Regulation 9(5) and summary reports of the application of these regulations.

45. Information is circulated within Government Departments on a `need to know' basis. Where it is necessary to disclose confidential information to advisers outside Government service such as members of the Advisory Committee on Genetic Modification (ACGM), the `need to know' principle will be observed. ACGM will normally be asked to review and advise on notifications of: intentions to use premises for the first time for activities involving Group II micro-organisms (Reg 8(3)); individual activities involving Group I micro-organisms in Type B operations (Reg 9(3)); Group II micro-organisms in Type A operations (Reg 9(4)); and Group II micro-organisms in Type B operations (Reg 9(5)).

46. Under Regulation 15(2) the notifier may indicate when notifying that certain information is commercially sensitive and any disclosure beyond that indicated above would harm his competitive position. An example is information which if disclosed would prejudice the possibility of a successful patent application. Justification for such an indication must be given and the Executive will inform the notifier of its decision in relation to such information before disclosing it to any other person other than those indicated in paragraph 45 above.

47. Under Regulation 15(3) certain specified items of notified information cannot be claimed to be commercially sensitive. Guidance on each of these is given below

- **the corporate name and address of the notifier and the location of the activity involving genetic modification;**

  This means the name and official address of the research institute/company/manufacturer. Names of individual persons can be kept confidential. Where there are fears about security, the main address of the company, institution or university etc can be disclosed but the specific location of the laboratory etc can remain confidential.

- **the description of the genetically modified organisms;**

  It is not possible to lay down generally applicable guidance here, as there may be specific conditions applicable in certain cases. However, the following principles apply: identity of GMO including trait; complete name of the recipient or of each parental organism; information relating to the method of genetic modification; (for Type B operations only) name(s) of donor organisms(s) and broad description of inserted sequences; and in relation to genetically modified micro-organisms (GMMs), group into which the GMM has been classified.

  As far as possible, the following information should also be regarded as non-confidential for all activities: name of the donor organism, description of the function of each inserted DNA or RNA sequence or of deleted sequences; for modifications where base substitution occurs, description of original function of the gene in which the base substitution occurred and the function of the modified gene.

and

The Health and Safety Executive
Branch THSD C6
Magdalen House
Stanley Precinct
Bootle
Merseyside L20 3QZ
Tel: 051 951 ----

50. Registers are open to inspection by members of the public during normal office hours but those wishing to inspect them are advised to telephone first.

Regulation 17 - Duties of Health and Safety Executive on receiving notifications

51. This regulation, which is largely self-explanatory, places requirements on HSE to scrutinise notifications received to ensure:

- conformity with the requirements of the Contained Use Regulations;

- accuracy and completeness of notified information;

- the correctness of classifications of organisms and micro-organisms; and

- where appropriate, adequacy of waste management, safety and emergency response measures.

Regulation 18 - Information to be sent to the Secretary of State

52. This regulation requires HSE to pass to the Secretary of State copies of notifications, any requests it makes for further information and responses to such requests, and accident

notifications. HSE is also required to make a request for further information if asked to do so by the Secretary of State.

Regulation 19 - Reports to the European Commission

53. Regulation 19 requires HSE to send reports to the European Commission in accordance with Article 18 of the Contained Use Directive (90/219/EEC). Under Article 18, Member States are required to send to the Commission summary reports of notifications of individual activities for which a consent is required ie Type B operations involving Group II organisms. These reports include the description, proposed uses and risks of the micro-organisms. In addition, every three years, Member States are required to submit a report on their experience of the operation of the Directive. The Commission publishes a summary based on these reports.

Regulation 20 - Exemption certificates

54. This regulation sets out the powers of HSE to make exemptions from the requirements of the regulations. Before making any such exemption HSE will consider the circumstances of the case and will need to be satisfied that the health and safety of persons and the protection of the environment will not be prejudiced by it. Exemptions will also be subject to any provisions imposed by the European Communities in respect of the control and regulation of genetically modified organisms.

Regulation 21 - Enforcement and civil liability

55. The effect of Regulation 21(1) is that insofar as any provisions of the regulations are made under the European Communities Act 1972, including provisions in relation to the protection of the environment, they are treated as if they were made under HSW Act. The provisions of the HSW Act in relation to matters such as enforcement and serving of notices therefore apply, and rights of action in civil proceedings are conferred, as in the case of regulations made under the HSW Act.

56. Under Regulation 21(2) HSE is the enforcing authority for the Contained Use Regulations both in respect of human health and environmental protection in all premises concerned, including those where local authorities enforce other HSW Act regulations.

Regulation 22 - Fees for notifications

57. [Guidance to be inserted on arrangements for fees in the light of consultation].

Regulation 23 - Transitional provisions

58. The aim of the transitional provisions is to ensure that those who have notified under the 1989 Genetic Manipulation Regulations may continue with as little disturbance as possible but also to ensure that those activities notified under the 1989 Regulations which are subject to consent are brought within the new regime.

59. Under Regulations 23(1) and 23(3) where a notification of intention to use premises or a notification of an individual activity was made under the 1989 Regulations while they were in force then no further notification is required in respect of the premises or the individual activity unless, under the terms of the Contained Use Regulations, a consent would have been required ie premises used or intended to be used for activities involving Group II organisms or individual activities involve Group II organisms in Type B operations. In those cases where consent is required, those undertaking the activities have until one year after the new regulations come into force either to obtain a consent or to cease the activity.

60. Where a notification of intention to use premises or a notification of an individual activity is made after the Contained Use Regulations come into force, then Regulations 23(2) and 23(4) provide for notification to be made 30 days in advance to avoid placing what would in effect be a moratorium on new

genetic modification activities and to ensure that there is no period during which it would not be possible for new activities involving genetic modification to commence. In such cases where the activities concerned would normally be subject to consent then the notifier has until one year after the Contained Use Regulations come in to obtain that consent.

61. Where notifiers are given up to one year to obtain consents under transitional arrangements, they will need to ensure that consent applications are submitted within 9 months of the regulations coming into force to ensure that work does not have to cease while waiting up to 90 days for consents to be granted.

Regulation 24 - Extension outside Great Britain

62. The Regulations apply to those premises and activities specified in the Health and Safety at Work etc Act 1974 (Application Outside Great Britain) Order 1989 (S.I. 1989/840) as they apply within Great Britain. Notification is therefore required of any activity which takes place on an offshore installation which is in territorial waters or areas designated under the Continental Shelf Act 1964 which includes the British North Sea oil fields. The Order, and therefore the Regulations, does not however apply to vessels in or aircraft flying over territorial waters or designated areas.

Regulation 25 - Revocations and savings

63. This regulation revokes the Genetic Manipulation Regulations 1989.

APPENDIX 3

CURRENT TITLES IN THE ACGM GUIDANCE NOTE SERIES

ACGM/HSE/NOTE 1. (2ND Revision) - Guidance on construction of recombinants containing potentially oncogenic nuclei acid sequences.

ACGM/HSE/NOTE 2. Disabled host/vector systems (now incorporated in Note 7)

ACGM/HSE/NOTE 3. The intentional introduction of genetically manipulated organisms into the environment.

ACGM/HSE/NOTE 4. Guidelines for the health surveillance of those involved in genetic manipulation at laboratory and large-scale.

ACGM/HSE/NOTE 5. Guidance on the use of eukaryotic viral vectors in genetic manipulation.

ACGM/HSE/NOTE 6. Guidelines for the large-scale use of genetically manipulated organisms.

ACGM/HSE/NOTE 7. Guidelines for the categorisation of genetic manipulation experiments.

ACGM/HSE/NOTE 8. Laboratory containment facilities for genetic manipulation.

ACGM/HSE/NOTE 9. Guidelines on work with transgenic animals.

ACGM/HSE/NOTE 10. Guidelines on work involving the genetic manipulation of plants and plant pests.

ACGM/HSE/NOTE 11. Genetic manipulation safety committees.

APPENDIX 4

FORMAT FOR INFORMATION TO BE SUPPLIED WITH ACCIDENT NOTIFICATION*
(REGULATION 14)

1. General data

Date and time of the accident:
Name and address of person responsible for carrying out the activity:
Address of premises where activity is carried out:
Grid reference:
Principal Activity of installation .....
.....
Type of activity (Type A or Type B):
Classification of organism (Group I or Group II)

2. Type of accident

Failure of equipment (breakage/leakage etc.)
Fire
Explosion
Maloperation of equipment (human/mechanical)
Other (specify) .....

3. Organisms released

Identity of genetically modified organisms released:
Quantity of genetically modified organisms released:
Form and/or concentration in which organisms released:

4. Description of the circumstances of the accident

5. Was there any emergency plan drawn up in advance?

yes ☐ no ☐

If yes by whom? .....

* As agreed by the Committee of National Competent Authorities

6. Emergency measures taken

(a) Inside the installation .....
.....

(b) Outside the installation .....
.....

7. Assumed or established cause(s) of accident (If not know information should be supplied as soon as possible)

8. Nature and extent of exposure

(a) Within the installation: provide information on the following

- persons exposed to the accident
- casualties
- damage to health
- material damage
- damage affecting the containment equipment
- whether the danger is still present
- if danger still exists it should be specified

(b) Outside the installation/to the environment: provide information on the following

- persons exposed to the accident
- casualties
- damage to health
- types of environments exposed (water, sewage systems, agricultural land, natural environments)
- material damage
- damage affecting the containment equipment
- damage to the environment
- whether the danger is still present
- if danger still exists it should be specified

9. Member States already informed bilaterally of the accident

DRAFT 12 August 1992

S T A T U T O R Y I N S T R U M E N T S

1992 No.

ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Deliberate Release) Regulations 1992

Made	1992
Laid before Parliament	1992
Coming into force	1992

ARRANGEMENT OF REGULATIONS

PART I
General
1. Citation and commencement
2. Interpretation
3. Artificial techniques of genetic modification
4. Capacity of organisms for causing harm

PART II
Releasing organisms
5. Consent to release organisms
6. Information to be contained in application for consent to release
7. Exemptions from regulation 6
8. Advertisement of application for consent to release
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PART III
Marketing organisms
10. Consent to market products
11. Information to be contained in application for consent to market
12. Transitional provision for marketing

PART IV
Duties placed on Secretary of State
13. Duties on receiving applications for consent to release
14. Decisions on applications for consent

15. Duties in relation to applications for consent to market

PART V
Register of Information
16. Information to be included in register
17. Keeping of the register

SCHEDULES

1. Consent to release or market
2. Consent to market

The Minister of Agriculture, Fisheries and Food, the Secretary of State for the Environment and the Secretary of State for Employment acting jointly, as respects England, the Secretary of State for Wales, as respects Wales, and the Secretary of State for Scotland, as respects Scotland, in exercise of the powers conferred on them by section 2(2) of the European Communities Act 1972 (a), being the Ministers designated (b) for the purposes of that subsection in relation to the control and regulation of genetically modified organisms, and sections 106(4) and (5), 107(8), 111, 122, 123, 126 and 156 of the Environmental Protection Act 1990 (c), and of all other powers enabling them in that behalf, hereby make the following Regulations:-

PART I

GENERAL

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) Regulations 1992 and shall come into force on [date of coming into force].

(a) 1972 c.68.

(b) S.I. 1991/ .

(c) 1990 c.43.

Interpretation

2. In these Regulations: -

"the Act" means the Environmental Protection Act 1990;

"the Committee" means the Committee appointed by the Secretary of State under section 124 of the Act;

"the Deliberate Release Directive" means Council Directive 90/220/EEC(a) on the deliberate release into the environment of genetically modified organisms;

"genetically modified organism" means a genetically modified organism or a combination of genetically modified organisms;

"heritable genetic material" means genes or other genetic material, in any form, whether in cellular or sub-cellular entities, which are capable of being replicated or transferred by any means;

"product" means a product consisting of or containing a genetically modified organism or a combination of genetically modified organisms, and "approved product" means a product marketed in pursuance of a consent granted by the Secretary of State under section 111(1) of the Act or a written consent given by another competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive.

Artificial techniques of genetic modification

3. The following techniques are prescribed as artificial techniques for the purpose of section 106(4) of the Act:

(a) the insertion by any method into a virus, bacterial plasmid or other vector system of a nucleic acid molecule, which has been produced by any method outside that virus,

---

(a) OJ No. L 117, 15.4.90, p.15.

bacterial plasmid or other vector system, so as to produce a new combination of genetic material which is capable of being inserted into an organism in which that combination does not occur naturally and within which it will be heritable genetic material;

(b) the insertion into an organism, by micro-injection, macro-injection, micro-encapsulation or other direct means, of heritable genetic material prepared outside that organism;

(c) the fusion (including protoplast fusion) or hybridization, by any method that does not occur naturally, of two or more cells to form cells which have new combinations of heritable genetic material, and which (if derived solely from plant cells) cannot be produced by traditional breeding methods;

(d) where they involve the use of recombinant DNA molecules- (i) in vitro fertilisation,

(ii) conjugation, transduction, transformation or any other natural process,

(iii) polyploidy induction.

Capacity of organisms for causing harm

4.-(1) For the purposes of sections 110(1), 112(5)(a) and (c) and (7)(a) and 117(1) of the Act there shall be disregarded -

(a) the capacity of genetically modified organisms of the description specified in paragraph (2) below for causing harm of the description specified in paragraph (3) below, and

(b) harm which is of the description so specified and which has been caused by organisms of the description so

specified.

(2) The genetically modified organisms specified in this paragraph are genetically modified organisms which control -

(a) the number or activity (or both) of any organisms, or

(b) toxic wastes.

(3) The harm specified in this paragraph is harm caused to any organisms by genetically modified organisms which have been released or marketed in pursuance of -

(a) a consent granted by the Secretary of State under section 111(1) of the Act, or

(b) a written consent given by another competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive.

PART II

RELEASING ORGANISMS

Consent to release organisms

5.-(1) Subject to paragraph (3), no person shall release any genetically modified organisms, other than an approved product which is released in accordance with the conditions and limitations to which the release of the product is subject, except in pursuance of a consent granted by the Secretary of State under section 111(1) of the Act.

(2) An application for a consent to release genetically modified organisms must be made in writing to the Secretary of State, and must be made either -

(a) for one or more releases of one or more descriptions of genetically modified organism on the same site within a limited period, or

(b) for one or more releases of one description of genetically modified organisms on one or more sites for the same purpose within a limited period.

(3) Paragraph (1) shall not apply to a person who -

(a) has notified the Health and Safety Executive, under regulation 5(1)(a) of the Genetic Manipulation Regulations 1989 **(a)**, of his intention to carry out an activity involving an intentional introduction into the environment, and

(b) carries out the activity in accordance with that notification before [date 90 days after date Regulations come into force].

(a) S.I. 1989/1810.

Information tc be contained in application for consent to release

6. - (1) Subject to regulation 7 (Exemptions from regulation 6), an application for a consent to release genetically modified organisms must contain -

(a) the information prescribed in Schedule 1 to these Regulations, to the extent that such information is appropriate to the proposed release,

(b) information on data or results from any previous releases of the organisms, or of organisms of the same description, which have been carried out by the applicant, and information from any previous application for the release of the organisms, or of organisms of the same description, which the applicant has made to the Secretary of State in accordance with the Act and these Regulations or to the competent authority of another member State in accordance with Article 5 of the Deliberate Release Directive,

(c) a statement evaluating the impacts and risks posed to human health and the environment by the release of the organisms.

(2) The information prescribed in Schedule 1 shall be included in the application at the level of detail which is appropriate to the nature and scale of the proposed release.

(3) Where the applicant considers, on the basis that it is not technically possible or it does not appear to the applicant to be necessary, that it is not appropriate for the application to contain the information prescribed in one or more of the paragraphs of Schedule 1, the application shall contain a statement of the reasons why the inclusion of the information is not appropriate.

(4) The application must contain the description of the methods

used to obtain the information contained in the application and a bibliographic reference, or, where standardised or internationally recognised methods are used, a reference to which method was used to obtain the information and its bibliographic references, together with the name of the body or bodies responsible for carrying out the studies.

(5) The application may in addition refer to data or results from applications for consent to release genetically modified organisms previously submitted by other applicants, provided that the latter have given their agreement in writing and their agreement is contained in the application.

Exemptions from regulation 6

7. An application for a consent to the release of genetically modified organisms need not contain the information prescribed in regulation 6(1)(a) and (b) if -

(a) the information was contained either -

(i) in an application which was made by the same person in relation to a previous release of those organisms or of the same description of organisms, or

(ii) in an application which was made by some other person in relation to a previous release of those organisms or of the same description of organisms,

(b) the application refers to the previous application in which the information was contained, and

(c) where paragraph (a)(ii) applies, the application contains the agreement in writing of the person who made the previous application to a reference to that application being made.

Advertisement of application for consent to release

8.- (1) Subject to paragraph (2), a person who makes an

application for a consent to release genetically modified organisms shall, not less than fourteen days and not more than twenty-eight days after the date of acknowledgment of receipt of that application by the Secretary of State, cause to be published in a newspaper or newspapers circulating in the areas likely to be affected by the proposed release a notice containing the following information -

(a) the name and address of the applicant,

(b) the description of the organisms to be released,

(c) the location and purpose of the release; and

(d) the date or dates of the release.

(2) The information on the location of the release shall be the same as the information on its location which is placed on the register kept by the Secretary of State under section 122 of the Act.

(3) A person who makes an application for a consent to release genetically modified organisms shall, not less than fourteen days and not more than twenty-eight days after the date of acknowledgment of receipt of that application by the Secretary of State, send a notice containing the information set out in paragraph (1)(a) to (d) above to -

(a) the local environmental health officer,

(b) the owner of the site of the proposed release, if a person other than the applicant,

(c) the Nature Conservancy Council for England, [Scottish Natural Heritage] and the Countryside Council for Wales, according to whether the release will be in the locality of a site notified under section 28 of the Wildlife and Countryside Act 1981(a) in England, Scotland or Wales,

(d) the Forestry Commission,

(e) the Countryside Commission,

(f) the National Rivers Authority or, in Scotland, the

(a) 1981 c.69.

River Purification Board for the area of the proposed release,

(g) the company appointed for the water supply area in which the proposed release will take place,

(h) the members of the genetic modification safety committee established by the applicant under regulation 11 of the Contained Use of Genetically Modified Organisms Regulations 1992(a).

General condition on consents to release organisms

9. In section 112 of the Act there shall be substituted for paragraph (b) of subsection (5) the following paragraph -

"(b) notify the Secretary of State of -

(i) any new information which becomes available with regard to any such risks, and

(ii) the result of the release in respect of any risk to human health or the environment, with particular reference to any kind of product for which the holder of the consent intends to apply for consent to market at a later stage;".

(a) S.I. 1992/

PART III

MARKETING ORGANISMS

Consent to market products

10.-(1) No person shall market any genetically modified organisms, other than a product which is marketed in accordance with a written consent given by the competent authority of another member State in accordance with Article 13(4) of the Deliberate Release Directive, except in pursuance of a consent granted by the Secretary of State under section 111(1) of the Act.

(2) An application for a consent to market genetically modified organisms must be made in writing to the Secretary of State, and must be made either -

(a) in a case where the product has not previously been marketed, or

(b) in a case where the product is intended for a use for which it has not previously been marketed.

Information to be contained in application for consent to market

11. - (1) An application for a consent to market genetically modified organisms must contain -

(a) the information prescribed in Schedule 1 to these Regulations, to the extent that such information is appropriate to the nature and scale of the release which may result from the marketing,

(b) information on data or results from any previous release of the organisms, or of organisms of the same description, which have been carried out by the applicant, and information from any previous application for the release of the organisms, or of organisms of the same description, which the applicant has made to the Secretary of State in accordance with the Act and these Regulations

or to the competent authority of another member State in accordance with Article 5 of the Deliberate Release Directive,

(c) subject to paragraph (5), the information prescribed in Schedule 2 to these Regulations.

(2) The information prescribed in Schedule 1 shall be included in the application at the level of detail which is appropriate to the nature and scale of the release which may result from the marketing, and shall take into account the diversity of sites of use of the product, including -

(a) information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product, and

(b) an assessment of any risks for human health or the environment related to the genetically modified organisms contained in the product, including information obtained from the research and development stage on the impact of the release on the environment.

(3) Where the applicant considers, on the basis that it is not technically possible or it does not appear to the applicant to be necessary, that it is not appropriate for the application to contain the information prescribed in one or more of the paragraphs of Schedule 1, the application shall contain a statement of the reasons why the inclusion of the information is not appropriate.

(4) The application must contain the description of the methods used to obtain the information prescribed in Schedule 1 and a bibliographic reference or, where standardised or internationally recognised methods are used, a reference to which method was used to obtain the information and its bibliographic references,

together with the name of the body or bodies responsible for carrying out the studies.

(5) Where the applicant considers, on the basis of the results of any release in pursuance of a consent granted under section 111(1) of the Act or a written consent given by the competent authority of another member State in accordance with Article 13(4) of the Deliberate Release Directive, or on substantive, reasoned scientific grounds, that the placing on the market and use of the product do not pose a risk to human health or the environment, he may propose not to supply the information prescribed in Part II of Schedule 2.

(6) An application for a consent to market genetically modified organisms may in addition contain data or results from notifications previously submitted by other applicants, provided that the latter have given their agreement in writing, and that a copy of that agreement is contained in the application.

Transitional provision for marketing

12.-(1) This Part of these Regulations shall not apply to a person marketing a product which -

(a) was marketed by him before [date on which Regulations come into force], and

(b) is not an approved product,

until [date one year after regulations come into force].

(2) Part II of these Regulations shall not apply to a person who releases, in accordance with any conditions and limitations to which its use is subject, a product to which paragraph (1) applies.

PART IV

DUTIES PLACED ON SECRETARY OF STATE

Duties on receiving applications for consent to release

13. -(1) The Secretary of State shall within 30 days of receiving an application for a consent under regulation 5 forward to the European Commission a summary of that application in the format established by the Commission in accordance with the procedure laid down in Article 21 of the Deliberate Release Directive.

(2) The Secretary of State shall -

(a) examine an application for a consent under regulation 5 for its conformity with the requirements of the Act and of these Regulations,

(b) evaluate the risks posed by the proposed release,

(c) if necessary, carry out such tests or inspections as may be necessary for control purposes,

(d) take into account any comments from member States made following the circulation to them by the European Commission of the summary referred to in paragraph (1) above, and

(e) record his conclusions in writing.

Decisions on applications for consent

14.-(1) The Secretary of State shall not grant a consent for the release of genetically modified organisms as it relates to the protection of human health without the agreement of the Health and Safety Executive.

(2) The Secretary of State shall communicate his decision on an application for a consent under regulation 5 before the end of a period of 90 days beginning with the day on which the

application was made.

(3) The period referred to in paragraph (1) shall not include any period beginning with the day on which the Secretary of State gives notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending with the day on which that information is given to the Secretary of State.

(3) The Secretary of State shall inform each member State and the European Commission of his decision on each application for the release of genetically modified organisms.

Duties in relation to applications for consent to market

15. -(1) The Secretary of State shall examine an application for consent under regulation 10 for its conformity with the requirements of the Act and of these Regulations, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.

(2) Before the end of a period of 90 days beginning with the day on which he receives an application under regulation 10 the Secretary of State shall either -

(a) forward to the European Commission -

(i) the application,

(ii) a summary of the application in the format established by the Commission in accordance with the procedure laid down in Article 21 of the Deliberate Release Directive,

(iii) a statement of the conditions under which he proposes to consent to the marketing of the product,

(iv) where acceded to by the Secretary of State, details of any proposal by the applicant under

regulation 11(5) not to comply with any of the requirements of regulation 11(1)(c), and

(v) his favourable opinion on the application, or

(b) inform the applicant that the proposal does not fulfil the conditions of the Act and these Regulations and is rejected.

(3) The Secretary of State shall not forward his favourable opinion on the application as it relates to the protection of human health where the Health and Safety Executive has informed him that it does not fulfill the conditions of the Act and these Regulations.

(4) The period referred to in paragraph (2) shall not include any period beginning with the day on which the Secretary of State gave notice in writing under section 111(6) of the Act that further information in respect of the application was required and ending with the day on which that information was given to the Secretary of State.

(5) The Secretary of State shall immediately inform the competent authority of each member State and the European Commission of any other information he receives from the applicant before or after the granting of the consent.

(6) Where no objection has been raised by the competent authority of another member State the Secretary of State shall, within a period of 60 days beginning with the day on which the documents referred to in paragraph (2)(a) were forwarded to those member States by the European Commission, give the applicant consent in writing to the application to market the product and inform those member States and the Commission that he has done so.

(7) Where an objection has been raised by the competent authority of another member State and the European Commission has taken a favourable decision under Article 13(3) of the Deliberate Release Directive, the Secretary of State shall give the applicant consent in writing to the application to market the product and inform those member States and the Commission that he has done so.

PART V

REGISTER OF INFORMATION

Information to be included in register

16. (1) The register kept by the Secretary of State under section 122 of the Act shall contain the particulars set out in paragraphs (2) to (6).

(2) In relation to a prohibition notice served under section 110 of the Act -

(a) the name and address of the person on whom the notice is served,

(b) the description of the genetically modified organisms in relation to which the notice is served,

(c) the location at which the genetically modified organisms are proposed to be released or marketed, and the purpose for which they are being released or marketed,

(d) the reason the notice is served,

(e) the day specified in the notice as the day on which the prohibition is to take effect.

(3) In relation to an application for a consent under section 111(1) of the Act -

(a) the name and address of the applicant,

(b) the description of the genetically modified organisms in relation to which the application is being made,

(c) the location at which, and the purpose for which, the genetically modified organisms will be released,

(d) the foreseen dates of the release,

(e) the methods and plans for monitoring the genetically modified organisms and for emergency response,

(f) the evaluation of the environmental impact of the genetically modified organisms, in particular any pathogenic and/or ecologically disruptive effects,

(g) the conditions or limitations in accordance with which the Committee has advised that the consent should be

granted,

(h) a summary of the reasons why the Committee has advised that the consent should not be granted.

(4) In relation to consents granted under section 111(1) of the Act -

(a) the fact that the consent has been granted, and a reference to the application in respect of which it was granted,

(b) the conditions or limitations to which the consent is subject,

(c) any information supplied to the Secretary of State in accordance with those conditions or limitations,

(d) any variation or revocation.

(5) In relation to information furnished under section 112(3)(b), (4)(b) or (5)(b) of the Act, the description of the risks which are considered to be more serious than was apparent when the consent was granted.

(6) In relation to convictions for any offence under section 118 of the Act -

(a) the name and address of the person convicted,

(b) the description of any genetically modified organisms in relation to which the conviction was obtained,

(c) the offence which was committed,

(d) the penalty imposed and any order made by the court under section 120 of the Act.

Keeping of the register

17. (1) The information prescribed in regulation 16(2) shall be placed on the register within fourteen days of the prohibition notice being served.

(2) The information prescribed in regulation 16(3), (5) and (6) shall be placed on the register within fourteen days of its

receipt by the Secretary of State.

(3) The information prescribed in regulation 16(4) shall be placed on the register within fourteen days of the granting of the consent.

(4) The register is to be kept at the following offices of Her Majesty's Inspectorate of Pollution:

[Romney House, 43 Marsham Street, London SW1P 3PY,]

[addresses of divisional offices]

and at [Scottish equivalent].

In witness whereof the Official Seal of the Ministry of Agriculture, Fisheries and Food is hereunto affixed on [ ] 1992.

LS

Minister of Agriculture,
Fisheries and Food

Secretary of State
1992 for the Environment

Secretary of State
1992 for Employment

1992 Secretary of State for Wales

1992 Parliamentary Under Secretary of State, Scottish Office

SCHEDULE 1

Regulations 6 and 11

CONSENT TO RELEASE OR MARKET

PART I

GENERAL INFORMATION

1. The name and address of the applicant, and the name, qualifications and training of the responsible scientist and of every other person who will be responsible for planning and carrying out the release of the organisms, for carrying out the release and for the supervision, monitoring and safety of the release.

PART II

INFORMATION RELATING TO THE ORGANISMS

Characteristics of donor, parental and recipient organisms

2. Scientific name and taxonomy.

3. Usual strain, cultivar or other name.

4. Phenotypic and genetic markers.

5. The degree of relatedness between the donor and recipient organisms or between the parental organisms.

6. The description of identification and detection techniques.

7. The sensitivity, reliability (in quantitive terms) and specificity of detection and identification techniques.

8. The description of the geographic distribution and of the natural habitat of the organism including information on natural predators, prey, parasites, competitors, symbionts and hosts.

9. The potential of the organism for genetic transfer and exchange with other organisms.

10. Verification of the genetic stability of the organisms and factors affecting that stability.

11. The following pathological, ecological and physiological traits:

(a) the classification of hazard according to [existing Community rules] concerning the protection of human health and the environment;

(b) the generation time in natural ecosystems, and sexual and asexual reproductive cycle;

(c) survivability, including seasonability and the ability to form survival structures, including seeds, spores and sclerotia;

(d) pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses), and ability to colonise other organisms;

(e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

(f) involvement in environmental processes, including primary production, nutrient turnover, decomposition of organic matter and respiration.

12. The sequence, frequency of mobilisation and specificity of indigenous vectors, and the presence in those vectors of genes which confer resistance to environmental stresses.

13. The history of genetic modification and of any application of additional techniques to the organism.

Characteristics of the vector

14. The nature and source of the vector.

15. The sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organism and to make the introduced vector and insert function in that organism.

16. The frequency of mobilisation, genetic transfer capabilities and/or methods of determination of the inserted vector.

17. The degree to which the vector is limited to the DNA required to perform the intended function.

Characteristics of the modified organism

18. The methods used for the modification.

19. The methods used -

(a) to construct inserts and to introduce them into the recipient organism

(b) to delete a sequence;

20. The description of any insert and/or vector construction.

21. The purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function.

22. The sequence, functional identity and location of the altered, inserted or deleted nucleic acid segments in question, and in particular any known harmful sequence.

Characteristics of the genetically modified organism

23. The description of the genetic traits or phenotopic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

24. The structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organism.

25. The stability of the organism in terms of genetic traits.

26. The rate and level of expression of the new genetic material in the organism, and the method and sensitivity of measurement of that rate and level.

27. The activity of the gene product.

28. The description of identification and detection techniques, including techniques for the identification and detection of the inserted sequence and vector.

29. The sensitivity, reliability (in quantitive terms), and specificity of detection and identification techniques.

30. The history of previous releases or uses of the organism.

31. In relation to human health -

(a) the toxic or allergenic effects of the non-viable organism and/or its metabolic products,

(b) the product hazards,

(c) the comparison of the organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity,

(d) the capacity of the organism for colonisation, and

(e) if the organism is pathogenic to humans who are immunocompetent -

(i) diseases caused and mechains of pathogenicity including invasiveness and virulence,

(ii) communicability,

(iii) infective dose,

(iv) host range and possibility of alteration,

(v) possibility of survival outside of human host,

(vi) presence of vectors or means of dissemination,

(vii) biological stability,

(viii) antibiotic-resistance patterns,

(ix) allergenicity, and

(x) availability of appropriate therapies.

PART III

CONDITIONS OF RELEASE

The release

32. The description of the proposed deliberate release, including the purpose or purposes of the release and the foreseen products of the release.

33. The foreseen dates of the release and time planning of the experiment including frequency and duration of releases.

34. The preparation of the site before the release.

35. The size of the site.

36. The methods to be used for the release.

37. The quantity of organisms to be released.

38. The disturbance of the site, including the type and method of calculation, and mining, irrigation, or other activities.

39. The worker protection measures taken during the release.

40. The post-release treatment of the site.

41. The techniques foreseen for elimination or inactivation of the organisms at the end of the experiment or other purpose of the release.

42. Information on results of previous releases of those organisms, or of organisms of the same type as those which are to be released, and in particular releases on a different scale

or into different ecosystems.

The environment (both on the site and in the wider environment)

43. The geographical location and national grid reference of the site onto which the release will be made, or the foreseen areas of use of the product.

44. The physical or biological proximity of the site of the organisms to humans and other significant biota.

45. The proximity to significant biotopes or protected areas.

46. The size of the local human population.

47. The local economic activities which are based on the natural resources of the area.

48. The distance to the nearest drinking water supply zone and/or areas protected for environmental purposes.

49. The climatic characteristics of the region or regions likely to be affected.

50. The geographical, geological and pedological characteristics.

51. The flora and fauna, including crops, livestock and migratory species.

52. The description of the target and non-target ecosystems likely to be affected.

53. The comparison of the natural habitat of the recipient organism with the proposed site or sites of release.

54. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

PART IV

THE ORGANISM AND THE ENVIRONMENT

Characteristics affecting survival etc.

55. The biological features which affect survival, multiplication and dispersal.

56. The known or predicted environmental conditions which may affect survival, multiplication and dissemination, including wind, water, soil, temperature and pH.

57. The sensitivity to specific agents.

Interactions with the environment

58. The predicted habitat of the organism.

59. The studies on the behaviour and characteristics of the organism and its ecological impact carried out in simulated natural environments, such as microcosms, growth rooms and greenhouses.

60. The capability of post release transfer of genetic material -

(a) from the genetically modified organisms into organisms in affected ecosystems,

(b) from indigenous organisms to the genetically modified organisms.

61. The likelihood of post release selection leading to the expression of unexpected or undesirable traits in the genetically modified organism.

62. The measures employed to ensure and to verify genetic stability, the description of genetic traits which may prevent or minimise dispersal of genetic material, and methods to verify genetic stability.

63. The routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact and burrowing.

64. The description of ecosystems to which the organism could be disseminated.

Potential environmental impact

65. The potential for excessive population increase of the organisms in the environment.

66. The competitive advantage of the organisms in relation to the unmodified recipient or parental organism.

67. The identification and description of the target organisms.

68. The anticipated mechanism and result of interaction between the released organisms and the target organism.

69. The identification and description of non-target organisms which may be affected.

70. The likelihood of post release shifts in biological interactions or in the host range.

71. The known or predicted effects on plants and animals and non-target organisms in the environment, impact on population levels of competitors, prey, hosts, symbiont, predators, parasites and pathogens.

72. The known or predicted involvement of the organism in biogeochemical processes.

73. Any other potentially significant interactions of the organisms with the environment.

PART V

MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY PLANS

Monitoring techniques

74. Methods for tracing the organisms, and for monitoring their effects.

75. Specificity (to identify the organisms, and to distinguish them from the donor, recipient or the parental organisms), sensitivity and reliability of the monitoring techniques.

76. Techniques for detecting transfer of the donated genetic material to other organisms.

77. Duration and frequency of the monitoring.

Control of the release

78. Methods and procedures to avoid and/or minimise the spread of the organisms beyond the site of release or the designated area for use.

79. Methods and procedures to protect the site from intrusion by unauthorised individuals.

80. Methods and procedures to prevent other organisms from entering the site.

Waste treatment

81. Type of waste generated.

82. Expected amount of waste.

83. Possible risks.

84. Description of treatment envisaged.

Emergency response plans

85. Methods and procedures for controlling the organisms in case of unexpected spread.

86. Methods, such as eradication of the organisms, for decontamination of the areas affected.

87. Methods for disposal or sanitation of plants, animals, soils, and any other thing exposed during or after the spread.

88. Methods for the isolation of the area affected by the spread.

89. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

SCHEDULE 2

Regulation 11

CONSENT TO MARKET

PART I
GENERAL INFORMATION

1. The name of the product and the name of the genetically modified organisms in the product.

2. The name and address in one of the member States of the manufacturer or distributor of the product.

3. The specificity of the product and the exact conditions of use including, where appropriate, the type of environment and/or the geographical areas within the member States for which the product is suited.

4. The type of expected use of the product and the description of the persons who are expected to use the product.

PART II
ADDITIONAL RELEVANT INFORMATION

5. The measures to be taken in the event of the escape of the organisms in the product or misuse of the product.

6. Specific instructions or recommendations for storage and handling of the product.

7. The estimated level and amount of production of the product within the member States and the estimated level and amount of imports of the product into the member States.

8. Information regarding the proposed packaging for the product and its appropriateness so as to avoid the escape of genetically modified organisms during storage or at a later stage.

9. Information regarding proposed labelling including the proposals for stating, in full or summarised form, the information prescribed in paragraphs 1 to 3, 5 and 6 above.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, together with Part VI of the Environmental Protection Act 1990, give effect to Council Directive 90/220/EEC (OJ No. L117, 8.5.90, p.15) on the deliberate release into the environment of genetically modified organisms.

Part I of the Regulations makes provision as to interpretation of the regulations and the application of the Act, and provides that the Secretary of State shall have the consent of the Health and Safety Executive to any consents granted under section 111 of the Act.

Part II of the Regulations makes provision as to when consents for the release of genetically modified organisms to the environment are required, and makes provision as to applications for consents and the conditions on which consents are held.

Part III of the Regulations makes provision as to when consents for the marketing of genetically modified organisms are required, and makes provision as to applications for consents to market.

Part IV of the Regulations places duties on the Secretary of State following receipt of applications for consents. Part V makes provision as to the registers of information required to be kept by the Secretary of State under section 122 of the Act.

GUIDANCE TO THE REGULATORY CONTROL OF THE DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS

This is a preliminary draft of the guidance. It will be extensively revised before being issued when the Regulations come into force.

Although the consultation exercise is directed specifically to the draft Regulations, comments on this draft guidance would also be welcomed.

DRAFT DATED 10 AUGUST 1992

GUIDANCE TO THE REGULATORY CONTROL OF THE DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS

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GUIDANCE TO THE REGULATORY CONTROL OF THE DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS

PREFACE

The legal framework for the control of work with genetically modified organisms (GMOs) has recently been changed to keep pace with technical progress, increasing environmental concerns and the need to implement two Directives which lay down common safety standards for such work in the European Community (EC).

The Environmental Protection Act 1990 (EPA) introduced new and specific provisions on the environmental safety of GMOs which complement requirements under the Health and Safety at Work etc. Act 1974 which have been in place since 1978.

The two EC Directives require Member States to implement common measures and procedures on the contained use of genetically modified micro-organisms (Directive 90/219/EEC) and on the deliberate release into the environment of genetically modified organisms (Directive 90/220/EEC).

Two new sets of Regulations have been made to implement the detailed requirements of the EC directives. The Contained Use of Genetically Modified Organisms Regulations 1992 implement Directive 90/219/EEC. Separate guidance on contained uses is provided in [title of HSE guidance].

Together with certain provisions in Part VI of the Environmental Protection Act 1990 and the European Communities Act 1972, the Genetically Modified Organisms (Deliberate Release) Regulations 1992 implement Directive 90/220/EEC.

The purpose of this booklet is to give guidance on how The Genetically Modified Organisms (Deliberate Release) Regulations 1992 will operate in practice.

INTRODUCTION

Regulatory control and administrative procedures before [October 1992]

Until [October 1992] all activities involving genetically modified organisms were notified to the Health and Safety Executive (HSE) under the Genetic Manipulation Regulations 1989. The purpose of these regulations was to ensure human health and safety.

Anyone wishing to release a genetically modified organism had to notify the HSE at least 90 days in advance. Notifications were examined by both HSE and the Department of the Environment in the context of human health and safety and environmental protection. In addition, the advice of the Advisory Committee on Releases to the Environment and of other interested Government departments was sought before a letter of clearance was issued to the notifier. This letter usually set out recommendations about the way in which the release should be conducted and arrangements for reporting to the authorities on the results of the release.

Background to regulatory structure applying after [October 1992]

In 1990, agreement was reached in the European Community about a directive (90/220/EEC) which would ensure that the deliberate release of GMOs into the environment and the marketing of GMO products would only take place if there were adequate provisions to protect human health and safety and the environment. The directive also put into place a system for EC-wide clearance of products via a single competent authority.

The provisions of the directive were closely in line with most of the recommendations in the 13th report published in 1989 by the Royal Commission on Environmental Pollution (RCEP) on the Deliberate Release of Genetically Engineered Organisms to the Environment.

The adoption of the directive and the RCEP report led to the inclusion, in the Environmental Protection Act 1990 (EPA), of a part specifically providing for protection of the environment from, inter alia, the release and marketing of genetically modified organisms.

The current regulations are made under the EPA and the European Communities Act 1972 to achieve full implementation of the EC directive, which required implementation in October 1991.

Implementation and effects of new regulatory structure

There is, in practice, little change from the way in which notifications of releases were handled previously. Under the directive, the information requirements are somewhat greater than before, but only that information which is relevant to any particular case must be submitted. Decisions on applications for consents to release are made in the same 90 day time frame as

previously. Advice from ACRE and other departments will continue to be sought as under the previous regime. As more experience is gained, it will be increasingly possible to streamline the consideration of applications. The objective is to have in place a system which is robust and ensures protection of the environment and human health and safety but which is also pragmatic and efficient.

The new regulations bring the added advantage of allowing products which are cleared in the UK to be marketed throughout the European Community without further regulatory hurdles. The objective here is the same: to have an efficient system which provides for safety to people and the environment.

About this guidance

This booklet offers detailed guidance about how to apply for a consent to release or to market genetically modified organisms. It also provides guidance to the associated legislation and the ways in which certain aspects, such as public registers, will be implemented. However, this guidance is not intended to be an authoritative interpretation of the law, which is a matter for the national courts or the European Court of Justice.

Section 1 (pps.....)is a "route map" to the main requirements. Its purpose is to help those who wish to release or market GMOs to find their way around the regulatory control system and to tell them where to find additional and more detailed information.

Section 2 (pps.....) explains, step by step, how to apply for a consent to release or market genetically modified organisms. This section should be used by anyone actually intending to carry out such activities.

Section 3 (.....) contains detailed guidance on the Environmental Protection Act 1990 and the Regulations based on the structure and sequence of the Regulations. Its main purpose is as a reference document for those who wish to know more comprehensively what the law is and what it covers.

SECTION 1: "ROUTE MAP" TO THE MAIN REQUIREMENTS AND THEIR OPERATION

The following is a brief guide to the main requirements of the law and how it will work in practice. Its purpose is to help those who wish to release or market GMOs to find their way around the regulatory control system and to tell them where to find additional and more detailed information.

The three summary "route maps" on pps.....set out the main features. **Figure 1** (p) describes how to find out whether a particular activity requires a consent. **Figure 2** (p) traces the steps leading to the issue of a consent to release GMOs and **Figure 3** (p)those leading to a consent to market GMOs.

The questions answered below describe the broader framework of the control system and where to find out more about particular aspects.

To which activities do the Regulations apply?

They apply to the deliberate release of any genetically modified organism in the environment and to the placing on the market of any product consisting of or containing one or more genetically modified organisms (GMOs). There are some exceptions, set out in Regulations 5, 10 and 12.

Part II of the Regulations (Regulations 5-9) covers the main requirements relating to release and Part III (Regulations 10-12) those relating to marketing. See pps....and.....for further guidance.

What is a "genetically modified organism" for these purposes?

For the purposes of the Regulations, a genetically modified organism is an organism whose genes or genetic material has been modified by any of the techniques prescribed in **Regulation 4.**

The definition of "organism" and the power to prescribe techniques which are regarded to result in "genetically modified organisms" are contained in S.106 of the Environmental Protection Act 1990. See pps.....for further guidance.

What authority is required to release or market GMOs?

Anyone wishing to release or market GMOs, apart from GMOs covered by the exceptions in Regulations 5, 10 and 12, needs to obtain a consent. Consents will be issued jointly on behalf of the Secretary of State and the Health and Safety Executive.

The power to require consents is contained in S.111 of the Environmental Protection Act 1990 and Regulations 5, 10 and 12. Regulations 14 and 15 make clear that consents will be issued jointly by the Secretary of State and HSE. See pps.....for further guidance.

How should an application for consent be made?

The applicant should write to the Department of Environment giving the information set out in **Schedules 1 and 2** at the level of detail which is relevant to the proposed experimental or product release and a statement evaluating the impact and risks to the environment. There is a specified format for applications, based on Schedules 1 and 2, which is available from the Department on request [from the address given below]. **The information requirements are prescribed in Regulations 6, 7 and 11 under powers in S.111 of the Environmental Protection Act 1990. See pps.....on how to apply for a consent and pps.....for further guidance on the information requirements and the way in which the risk assessment should be approached.**

Is a fee or charge or payable?

The EPA 90 makes provision for the recovery of costs associated with granting consents. Annex [5] sets out the [proposed] bands of fees applicable to applications for consents to release and market.

Where should an application for consent be sent?

Applications should be sent to The Department of the Environment, Biotechnology Unit, Room A347, Romney House, 43 Marsham Street, London SW1P 3PY. DOE will co-ordinate consideration of the application with the Health and Safety Executive and, as necessary, with other interested government departments such as the Ministry of Agriculture Fisheries and Food, and the Scottish and Welsh Offices. The applicant need deal only with DOE.

Should anyone else be informed?

Yes. Applicants for release (but not marketing) should put an advertisement in the press and, as appropriate, inform the bodies listed in Regulation 8(3).

The requirement to inform the public and other bodies is contained in S.111 of the Environmental Protection Act 1990. Regulation 8 sets out who should be informed and how. See pps.....for further guidance.

How will an application for consent be decided?

Applications will be circulated in confidence by DOE to HSE, to other interested government departments and to members of the Advisory Committee on Releases to the Environment (ACRE). ACRE will give their advice on whether the consent should be granted and on any appropriate conditions. [In cases where it will help consideration, applicants will be invited to explain their proposal to a meeting of ACRE.] Officials will consider ACRE's advice on behalf of the Secretary of State, inform the applicant of the outcome and issue any consent granted.

ACRE is appointed under S.124 of the Environmental Protection Act 1990. For further guidance on its functions see pps.....

How long will it take to decide an application for consent?

Applications for release must be decided within 90 days and those for marketing within 150 days. In each case, the clock will stop for any period during which DOE is awaiting any additional information required to decide the application. In the case of marketing, a decision on whether to grant the consent will be made by DOE within 90 days. The application will then be sent to the European Commission for circulation to other EC member states for comment within 60 days. Consents will then be issued and will be valid in any country in the EC.

The Secretary of State's powers to ask for additional information are contained in S.111 of the Environmental Protection Act 1990. His duties to consider applications within certain timescales are prescribed in Part IV of the Regulations (Regulations 13-15) made under the European Communities Act 1972. See pps.....for further guidance.

Will any information be disclosed to the public?

Yes. The information prescribed in Regulation 16 will be placed on a register which will be available for public inspection in England and Wales at HMIP offices. In Scotland registers will be held at HSE offices. The Secretary of State may decide to exclude information on grounds of commercial confidentiality (following any representations made by the applicant), of national security or of the possibility that its disclosure will lead to damage to the environment.

The Secretary of State's duty to set up a public register is contained in S.122 of the Environmental Protection Act 1990. His powers to exclude certain information are set out in S.123. See pps.....for further guidance.

Is any other information required in connection with applications for consent?

Yes. For the purposes of assisting information exchange between EC member states on R&D releases and the clearance of products for the market, applicants are requested to complete the relevant Summary Notification Information Format (SNIF) [at - to be inserted.....] and submit it with their application.

The Secretary of State is required under Regulations 13 and 15 to send this information to the European Commission and/or to other Member States. Without information in this format, it is not possible to clear the release of products for marketing throughout the EC. See pps.....for further guidance.

What rules apply after a consent has been issued?

All consent holders must comply with the conditions of the consent and are subject to the certain general duties which are a condition of all consents. Holders of consents to release GMOs are required to inform DOE of the outcome. Holders of consents to market GMOs are required to abide by any conditions and limitations attached to the marketing of approved products. A consent may, if justified by the circumstances, be revoked, varied or expressed to expire after a limited period.

The power of the Secretary of State to attached conditions to consents, including general duty conditions are set out in S.112 of the Environmental Protection Act 1990 and Regulation 9. See pps.....and.....for further guidance.

What are the arrangements for enforcement?

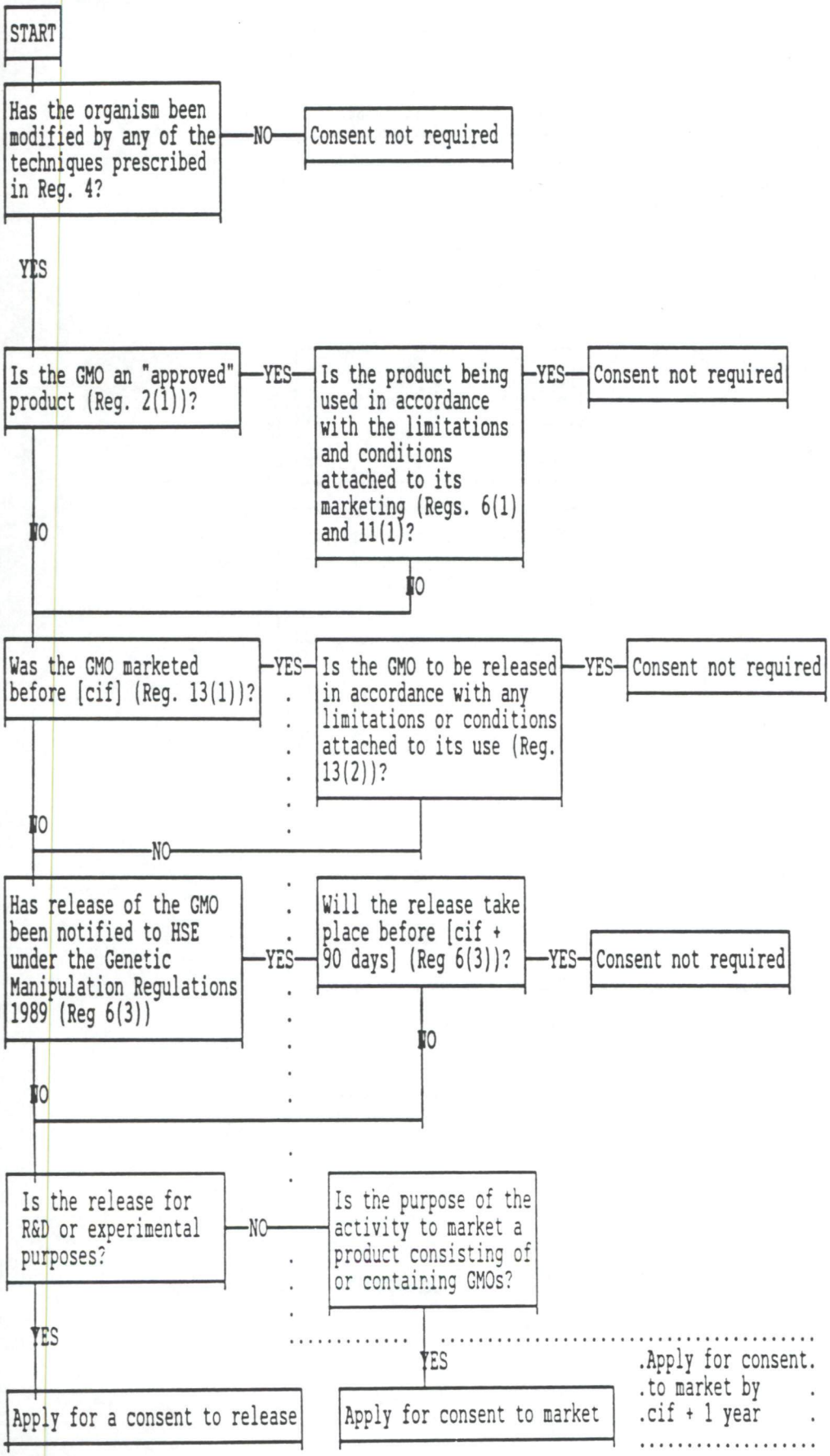
The Secretary of State has appointed inspectors to enforce the new regulatory control system. Their main function is to ensure that the conditions attached to consents are adhered to. To this end, they have rights of entry and inspection to premises and sites, powers to obtain information relevant to the conduct of their duties, to deal with any cause of imminent danger of damage to the environment and to remedy any harm caused.

The Secretary of State's power to appoint inspectors is in S114 of the Environmental Protection Act 1990. The powers of inspectors and the functions which the Secretary of State may delegate to them are set out in S.114, 116, 118 and 121. [Under S.125 of the Act, the Secretary of State has delegated the appointment of inspectors and his enforcement functions to.....].

What are the penalties for breaking the law.

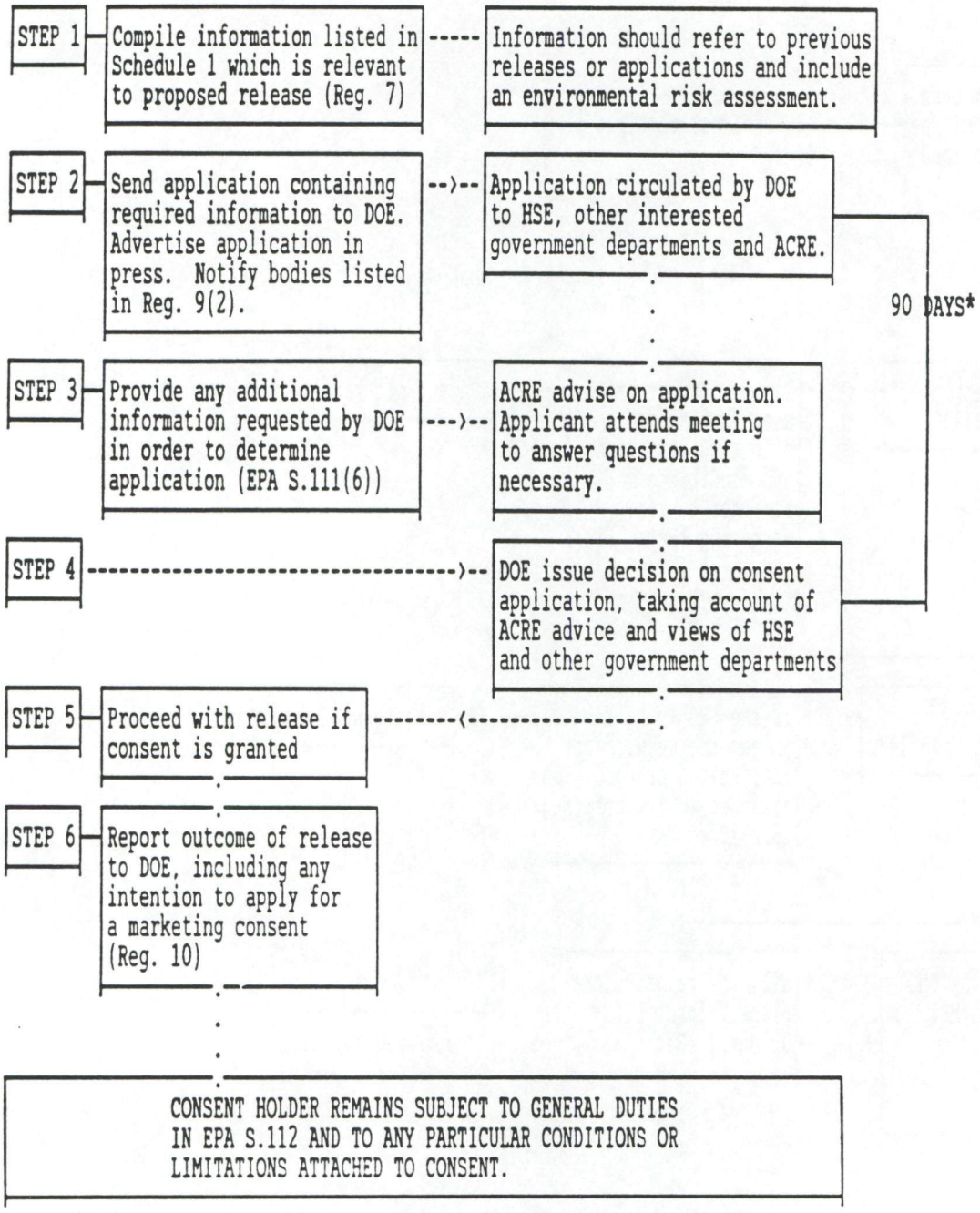
The offences and penalties associated with the new control regime are set out in S.118 of the Environmental Protection Act 1990. Persons who fail to comply with the requirements relating to applications for consents or any conditions attached to them are liable, on summary conviction, to a fine not exceeding £20,000 or imprisonment for a term not exceeding six months, or to both. On conviction on indictment, such persons are liable to a fine or to imprisonment for a term not exceeding five years, or to both.

ACTIVITIES WHICH REQUIRE A CONSENT UNDER THE REGULATIONS Figure 1



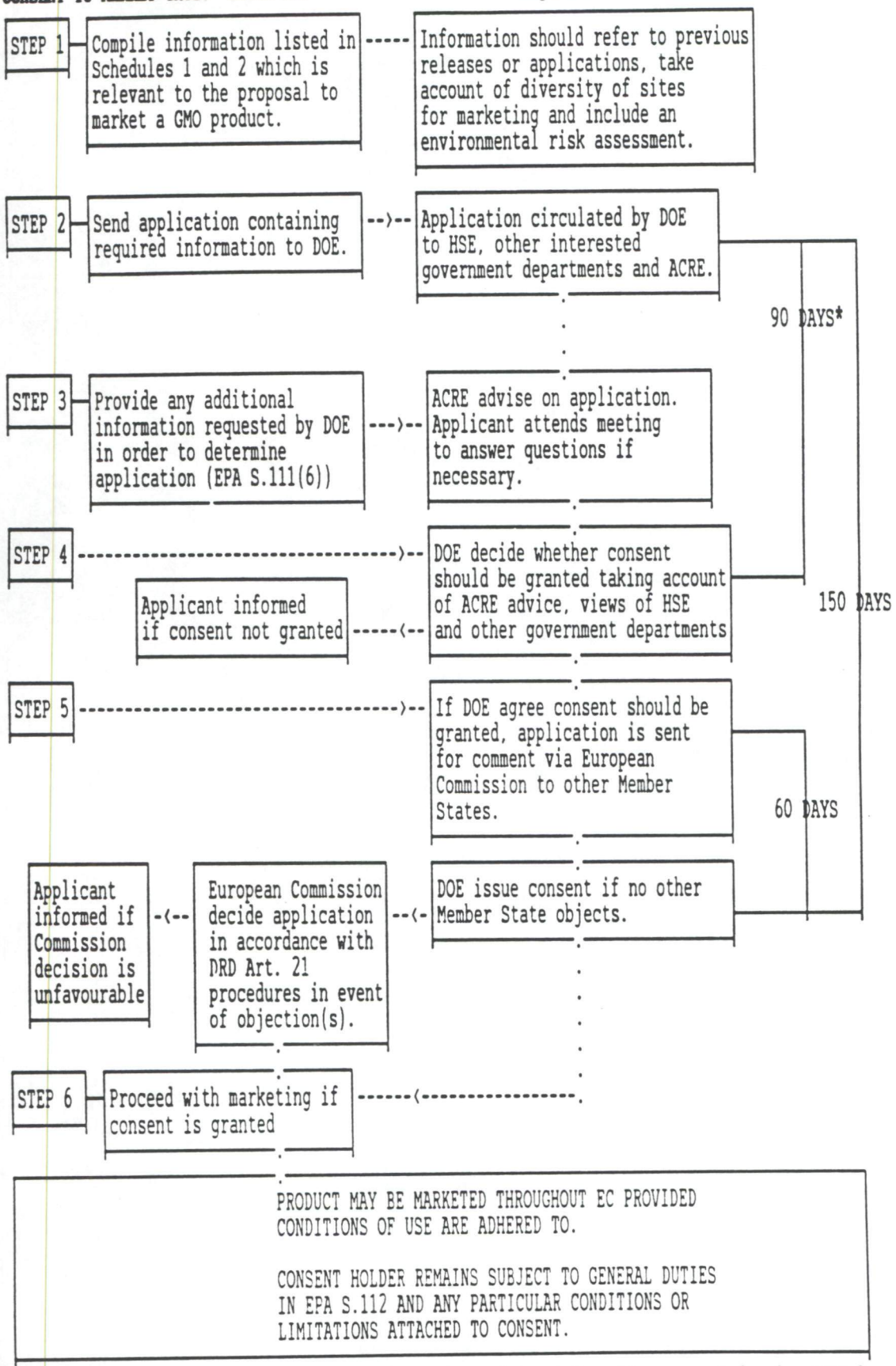
CONSENT TO RELEASE GMOs: "ROUTE MAP"

Figure 2



* 90 days excludes any period during which DOE is awaiting information requested under STEP 3

CONSENT TO MARKET GMOs: "ROUTE MAP" Figure 3



* 90 days excludes any period during which DOE is awaiting information requested under STEP 3
DRD = Deliberate Release Directive

SECTION 2: HOW TO APPLY FOR A CONSENT TO RELEASE OR MARKET A GENETICALLY MODIFIED ORGANISM

This section tells practitioners what they need to do to apply for a consent to release or market GMOs. It should be used by anyone who intends to carry out either or both of these activities. Applicants may find it helpful to use the figures on pages 10 and 11 as a checklist of the steps leading to the issue of any consent granted.

Consent to release

To apply for a consent to release genetically modified organisms for experimental purposes or research and development purposes, do the following:

1. **Get from DOE a copy of the format for applications.** The address is [..... ; telephone....]. The format is based on Schedule 1 to the Regulations. Detailed guidance on each point listed in the format is given on pps.....

2. **Make a statement under each of the points listed in the format.** Statements should be provided at the level of detail which is appropriate to the proposed released. If you consider that it is technically impossible or unnecessary to provide a detailed response to any particular point, say as briefly as possible why this is so. It may be sufficient to state that a particular point is "not applicable", but you may be asked to justify your response or be asked for further information.

3. **Also include with your application statements covering the following additional items of information:**

   (a) any data or results from any previous releases of the GMO or GMOs for which you are seeking a consent to release;

   (b) any previous applications for the release of the GMO or GMOs which you have made to the Secretary of State under the 1992 Regulations or to another EC Member State under the Deliberate Release Directive; and

   (c) an evaluation of the impacts and risks posed to the environment [and human health] by the release of the GMO or GMOs for which you are seeking a consent.

In answer to (b) it is sufficient to give an appropriate reference to any previous application made. This will enable the authorities to trace your earlier application from their records. Guidance on the risk assessment statement requested at (c) is give on pps.....

4. Also enclose with your application:

(a) a summary of the information requested at 2 [in the SNIF format at....]; and

(b) a summary of the risk assessment requested at 3(c) [in the format set out at....]

The summary requested at 4(a) will be used for the purposes of information exchange between EC Member States. The summary requested at 4(b) will be placed on the register of public information, on which there is further guidance on pps.....

5. Put an advertisement containing the following information in a newspaper or newspapers circulating in the areas likely to be affected by the proposed release:

(a) Your name and address;
(b) A description of the GMO or GMOs to be released.
(c) The location and purpose of the release; and
(d) The proposed date or dates of the release

[Enclose a copy of your advertisement(s) with your application.]

6. Give notice of your application to the following bodies:

(a) the local environmental health officer,
(b) the owner of the site of the proposed release, if a person other than the applicant,
(c) the Nature Conservancy Council for England, [Scottish Natural Heritage] and the Countryside Council for Wales, according to whether the release will be in the locality of a site notified under section 28 of the Wildlife and Countryside Act 1981 in England, Scotland or Wales,
(d) the Forestry Commission,
(e) the Countryside Commission,
(f) the National Rivers Authority or, in Scotland, the River Purification Board for the area of the proposed release,
(g) the company appointed for the water supply area in which the proposed release will take place.
(h) the genetic modification safety committee responsible for the premises where the GMO or GMOs are being kept in containment prior to release.

You are advised in all cases to inform and seek the views of the relevant genetic modification safety committee.

7. Send your application, with the required fee, to the address listed at 1.

Additional Notes:

(i) Your application may cover the proposed release of one or more GMOs of different descriptions on the same site; or of several GMOs of the same description on several sites for the same purpose.

(ii) Your application may relate to a proposed programme of work which is intended to be phased over a specified period. Make clear what the proposed phases of the programme are, what you intend to do in them, and when you plan each phase to start and finish. A consent may be issued for the initial phase of the programme and contain conditions requiring additional information, results or data to be supplied before the next phase may begin. Although a single consent may be issued for the whole programme, it may be varied or revoked at as a result of additional information, etc supplied during the course of the programme.

(iii) Your statements in support of your application should make clear the methods you have used to obtain the information requested, together with a bibliographic reference. Where standardised or internationally recognised methods have been used, say what they were, who carried them out and give a bibliographic reference or references.

(iv) You may support your application by referring to data or results from applications for consent to release made by other persons. However, you must enclose with your application evidence that the persons concerned have given their agreement in writing to your using such information.

(v) Consideration of your application will be held up until any further information requested to justify, clarify or amplify your statements is supplied.

(vi) Your application will be acknowledged on receipt and you will be given the name, address and telephone number of an official who will be your contact point for all enquiries. You may be asked to attend a meeting of the Advisory Committee on Releases to the Environment to answer questions about your proposal. This is not compulsory, but in most cases attendance, where requested, will speed up processing of your application.

(vii) Your application will be circulated to other regulatory bodies with an interest in one or more aspects of your proposed release. Although not part of the requirements for obtaining a consent under the 1992 regulations, you should consider whether other approvals may be necessary before your proposed release may go ahead. For example, separate approval

under the Plant Health Order 1987 is required from [MAFF or SOAFD] for the release of a plant pest or pathogen. Further guidance on these considerations is given on pps.....

Consent to market

To apply for a consent to market a product consisting of or containing GMOs, do the following:

1. **Get from DOE a copy of the format for applications.** The address is [..... ; telephone....]. The format is based on Schedules 1 and 2 to the Regulations. Detailed guidance on each point listed in the format is given on pps.....

2. **Make a statement under each of the points listed in the format.** See note under point 2 of consent to release. The information given under Schedule 1 should take into account the diversity of sites of use of the product. You may propose not to supply statements on the points listed in Part II of Schedule 2. To do so you must be able to demonstrate, on scientific grounds or on the basis on the results of an earlier product release cleared under the Deliberate Release Directive, that the marketing and use of the product do not pose a risk to human health or the environment.

3. **Also include with your application statements covering the following additional items of information:**

   (a) data or results from research and development concerning the ecosystems which could be affected by the use of the product;

   (b) any previous applications for the release of the GMO or GMOs which you have made to the Secretary of State under the 1992 Regulations or to another EC Member State under the Deliberate Release Directive; and

   (c) an assessment of any risks for the environment related to the genetically modified organisms contained in the product, including information obtained from the research and development stage on the impact of the release on the environment.

In answer to (b) it is sufficient to give an appropriate reference to any previous application made. This will enable the authorities to trace your earlier application from their records. Guidance on the risk assessment statement requested at (c) is give on pps.....

4. Also enclose with your application:

(a) a summary of the information requested at 2 [in the SNIF format at....]; and

(b) a summary of the risk assessment requested at 3(c) [in the format set out at....]

The summary requested at 4(a) will be used for the purposes of clearing your product for marketing via other EC Member States. The summary requested at 4(b) will be placed on the register of public information, on which there is further guidance on pps.....

5. Send your application [with the required fee] to the address listed at 1.

Additional notes (iii) to (vii) on applying for consent to release apply. In addition, your application will be circulated via the European Commission for clearance by other EC Member States. Following such clearance, you will be able to market your product in any EC Member State without further consent provided the product is used in accordance with any limitations and conditions attached to the consent to market granted by the Secretary of State.

SECTION 3: GUIDANCE TO THE ENVIRONMENTAL PROTECTION ACT 1990 AND THE GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) REGULATIONS 1992

PART I
GENERAL

The guidance in this Part describes the general scope and purpose of the Environmental Protection Act 1990 (Part VI) and the Regulations, explains the definition of key terms required for their understanding, and makes clear the techniques of genetic modification to which they apply.

Part VI of the EP Act, the relevant parts of which are reproduced at Annex...., aims to prevent or minimise any damage to the environment which may arise from the escape or release from human control of GMOs. It imposes a number of general duties on anyone carrying out activities involving GMOs and empowers the Secretary of State to prescribe various detailed requirements in regulations. Various key terms are defined in s 107 (2) - (7):

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(2) The "environment" consists of land, air and water or any of those media.

(3) "Damage to the environment" is caused by the presence in the environment of genetically modified organisms which have (or of a single such organism which has) escaped or been released from a person's control and are (or is) capable of causing harm to the living organisms supported by the environment.

(4) An organism shall be regarded as present in the environment notwithstanding that it is present in or on any human or other organism, or any other thing, which is itself present in the environment.

(5) Genetically modified organisms present in the environment are capable of causing harm if-

(a) they are individually capable, or present in numbers such that together they are capable, of causing harm; or

(b) they are able to produce descendants which will be capable, or which will be present in numbers such that together they will be capable, of causing harm;

and a single organism is capable of causing harm either if it is itself capable of causing harm or if it is able to produce descendants which will be so capable.

(6) "Harm" means harm to the health of humans or other living organisms or other interference with the ecological systems of which they form part and, in the case of man, includes offence caused to any of his senses or harm to his property.

(7) "Harmful" and "harmless" mean respectively, in relation to genetically modified organisms, their being capable or their being incapable of causing harm.

"Damage to the environment" is caused by potentially harmful GMOs having escaped or been released into the environment. GMOs which may be capable of causing harm either directly or through their descendants. Thus, GMOs have to be held in effective containment to prevent harm, or, in the case of a deliberate release, appropriate precautions have to be taken to minimise harm.

> Example: A crop plant is genetically modified to be pest resistant by expressing a chemical in its leaves which is toxic to insects. If the plant is then deliberately released, any risk that it may cause harm to the environment by the transfer of the gene to wild or feral relatives (for example, by cross-pollination) must be minimised. This might involve planting away from sites where there are such wild relatives or by not allowing flowers to develop.

Harm, and damage to the environment, are considered to result only if there is a significant impact on humans or ecosystems. For example, although oil seed rape has a smell, it is generally not considered to offend peoples' senses significantly. Other examples are:

> (i) If a crop plant is genetically modified to express a toxin so that it becomes resistant to lepidopteran pests but the toxin is not specific for the target pests, then other non-target insects may also be affected. Under the above definition, this would constitute harm to the health of living organisms.
>
> (ii) A crop plant modified for a complex of agronomic traits which resulted in improved ecological performance might be able to establish a self-sustaining weed population where this was previously unknown. If this new weed were to displace a native member of the flora then this would constitute harm to the environment by dint of interference with the ecological system of which the affected native plant formed part.
>
> (iii) If a micro-organism modified to decompose lignin and cellulose were to spread from a release site to an adjacent housing estate and result in the destruction of wooden joists, this would be seen as harm in the context of harm to man's property.

CITATION AND COMMENCEMENT

Regulation 1

These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) Regulations) 1992 and shall come into force on [date of coming into force].

A transitional arrangement has been made for those who have notified an intention to release under the Genetic Manipulation Regulations 1989 but who have not yet conducted the release. Also, those who have marketed a product before the coming into force of these regulations are subject to a transitional provision. Details are given under the relevant sections.

INTERPRETATION

Regulation 2

2. -(1) In these Regulations: -

"the Act" means the Environmental Protection Act 1990;

"the Committee" means the Committee appointed by the Secretary of State under section 124 of the Act;

The Committee appointed by the Secretary of State is the Advisory Committee on Releases to the Environment (ACRE). The functions of the Committee are set out in s 124(1) of the 1990 Act:

The Secretary of State shall appoint a committee to provide him with advice-

(a) on the exercise of his powers under sections 111, 112 and 113 above;

(b) on the exercise of any power under this Part to make regulations;

and on such other matters concerning his functions under this Part as he may from time to time direct.

The Committee advises the Secretary of State on applications for consents to release or market genetically modified organisms (s 111) and on the conditions which may be attached to such consents (s 112). The Secretary of State is also required to seek the Committee's advice on any proposal to make a scheme of fees and

charges for consents (s 113) or to make new Regulations. The Secretary of State may also seek the Committee's advice on any other matters which are relevant to the conduct of his functions under Part VI.

The Committee's full terms of reference, which go wider than these specific functions, are:

> "To advise the Health and Safety Commission and Executive, Secretaries of State, the Minister of Agriculture, Fisheries and Food, and other bodies as appropriate, on all aspects of human and environmental health and safety of the introduction in to the UK environment of genetically modified and other novel organisms; and in particular to advise on proposals for specific introductions, research needs, and on proposed regulations and written guidance."

All applications for consent to release and market are subject to the Committee's advice. For certain cases, however, streamlined procedures are being developed: for example, repeat applications to release GMOs will be circulated by post for consideration by committee members without necessarily a full discussion in committee. This is an administrative arrangement that does not require specific reference in the regulations. It is distinct from any "simplified procedures" that might be agreed under the EC directive on Deliberate Release by competent authorities of EC Member States.

"the Deliberate Release Directive" means Council Directive 90/220/EEC[1] on the deliberate release into the environment of genetically modified organisms;

The full title of the Directive is "Council Directive of 23 April 1990 on the deliberate release into the environment of genetically modified organisms".

"genetically modified organism" means a genetically modified organism or a combination of genetically modified organisms;

A single GMO, such as a genetically modified tomato may be released, or, for example, a formulated microbial biopesticide which contains but does not consist entirely of GMOs or consists of several GMOs. Only one consent is required for the release or marketing of several GMOs combined together.

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[1] OJ No. L 117, 15.4.90, p.15.

"heritable genetic material" means genes or other genetic material, in any form, whether in cellular or sub-cellular entities, which are capable of being replicated or transferred by any means;

The term "heritable genetic material" arises in **Regulation 4**, which prescribes the techniques which are regarded to result in genetic modification. The ability to replicate genes or other genetic material is essential to consideration of whether or not something is a GMO: for example, bread made from genetically modified wheat would not itself be regarded as a GMO.

"product" means a product consisting of or containing a genetically modified organism or a combination of genetically modified organisms, and "approved product" means a product marketed in pursuance of a consent granted by the Secretary of State under section 111(1) of the Act or a written consent given by the competent authority of a member State of the Communities in accordance with Article 13(4) of the Deliberate Release Directive.

The procedures by which consents are granted to market products are set out in the guidance to regulations 11 - 13. A product is an article, preparation, plant, diagnostic kit etc consisting of or containing GMOs that is being considered for marketing. After a consent to market has been issued, it becomes an approved product. "Approved products" are products which have been cleared for marketing by the Secretary of State or the competent authority of another EC Member State.

ARTIFICIAL TECHNIQUES OF GENETIC MODIFICATION

The EP Act (s 106(2),(3)) sets out what is meant by "organism" and "biological matter":

(2) In this Part the term "organism" means any acellular, unicellular or multicellular entity (in any form), other than humans or human embryos; and unless the context otherwise requires, the term also includes any article or substance consisting of or including biological matter.

(3) For the purposes of subsection (2) above "biological matter" means anything (other than an entity mentioned in that subsection) which consists of or includes-

(a) tissue or cells (including gametes or propagules) or subcellular entities, of any kind, capable of replication or of transferring genetic material, or

(b) genes or other genetic material, in any form, which are so capable,

and it is immaterial, in determining if something is or is not an organism or biological matter, whether it is the product of natural or artificial processes of reproduction and , in the case of biological matter, whether it has ever been part of a whole organism.

"**Organism**" includes all acellular, unicellular or multicellular entities and their populations and biological lines or strains, except for humans and human embryos. It thus covers: micro - organisms, including viruses and viroids; plants and animals, including ova, seeds, pollen and cell cultures; and tissue cultures from plants and animals.

"Organism" also includes any article or substance consisting of "**biological matter**", ie anything other than a discrete organism (as defined above) which consists of or includes material which is capable of replication or of transferring genetic material. Biological matter will therefore include (not exclusively) tissues, cells, sub-cellular organelles, and cytoplasm. Also included will be biological matter constructed by artificial means, which need never have been part of any whole organism. However, since naked DNA and plasmids are themselves not capable of transferring or replicating genetic material, they are not included. As a result, recombinant naked DNA and recombinant plasmids are not considered to constitute genetically modified organisms in the meaning of the regulations.

The EP Act (s 106(4)) then defines the ways in which an organism is genetically modified:

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(4) For the purposes of this Part an organism is "genetically modified" if any of the genes or other genetic material in the organism-

(a) have been modified by means of an artificial technique prescribed in regulations by the Secretary of State; or

(b) are inherited or otherwise derived, through any number of replications, from genes or other genetic material (from any source) which were so modified.

(5) The techniques which may be prescribed for the purposes of subsection (4) above include-

(a) any technique for the modification of any genes or other genetic material by the recombination, insertion or deletion of, or of any component parts of, that material from its previously occurring state, and

(b) any other technique for modifying genes or other genetic material which in the opinion of the Secretary of

State would produce organisms which should for the purposes of this Part be treated as having been genetically modified,

but do not include techniques which involve no more than, or no more than the assistance of, naturally occurring processes of reproduction (including selective breeding techniques or in vitro fertilisation).

(6) It is immaterial for the purposes of subsections (4) and (5) above whether the modifications of genes or other genetic material effected by a prescribed technique are produced by direct operations on that genetic material or are induced by indirect means(including in particular the use of viruses, microbial plasmids or other vector systems or of mutation inducing agents).

(7) In this Part, where the context permits, a reference to "reproduction", in relation to an organism, includes reference to its replication or its transferring genetic material.

Genetic modification is the collective term for a wide variety of established and developing **techniques** which are used to alter the genetic material of organisms. But the term is not a fixed and static concept. To avoid doubt about which techniques are subject to regulation and to allow for updating or revision in the light of technical developments, the EPA provides for the prescription in regulations of "**artificial techniques**" which are to be regarded as genetic modification for the purposes of the control regime. Only those techniques set out in regulation 4 are subject to the regime:

Regulation 3

The following techniques are prescribed as artificial techniques for the purpose of section 106(4) of the Act:

(a) the insertion by any method into a virus, bacterial plasmid or other vector system of a nucleic acid molecule, which has been produced by any method outside that virus, bacterial plasmid or other vector system, so as to produce a new combination of genetic material which is capable of being inserted into an organism in which that combination does not occur naturally and within which it will be heritable genetic material;

(b) the insertion into an organism, by micro-injection, macro-injection, micro-encapsulation or other direct means, of heritable genetic material prepared outside that organism;

(c) the fusion (including protoplast fusion) or hybridization, by any method that does not occur naturally, of two or more cells to form cells which have new

combinations of heritable genetic material, and which (if derived solely from plant cells) cannot be produced by traditional breeding methods;

(d) where they involve the use of recombinant DNA molecules-

(i) in vitro fertilisation,

(ii) conjugation, transduction, transformation or any other natural process,

(iii) polyploidy induction.

Mutagenesis is not included as an artificial technique of genetic modification and nor are in vitro fertilisation, conjugation, transduction, transformation and other natural processes, and polyploidy induction **(but see guidance under general duties, pp ...., for application of these techniques to existing GMOs).**

Products of the fusion of plant cells which cannot be produced by "traditional breeding methods" fall within the control regime, but those which can be produced by these methods are not controlled.

The term "traditional breeding methods" is not defined in the regulations, but an appropriate interpretation, agreed by competent authorities of EC member states is:

Traditional breeding refers to practices which use one or more of a number of methods, including physical and/or chemical means and control of physiological processes, which can lead to successful crosses between plants of the same botanical family.

Traditional breeding methods defined in this way is thus in terms of the taxonomic relatedness between the organisms involved in the cross rather than in terms of specifically named techniques.]

Examples:

(i) The protoplast fusion of cells from Brassica rapa with Raphanus sativa would be exempt from the control regime. Even though cells came from plants of different genera, they are from the same botanical family (Cruciferaceae). It may be that viable progeny could only be produced if specialised breeding (eg hand pollination, embryo rescue) and tissue culture techniques were used, but this would be irrelevant when deciding whether the operation fell within the scope of the regime.

(ii) Transfer of a gene involved in (for example) susceptibility to Rhizobium infection from Trifolium repens (Leguminosae) to Triticum aestivum (Gramineae) would involve fusion between cells of plants from quite different botanical families and thus would be controlled.

Self-cloning is covered by the artificial techniques of genetic modification prescribed in Regulation 3:

Self-cloning involves the removal of nucleic acid from a cell, alteration (by enzymic, chemical or mechanical means) of the nucleic acid outside the cell followed by re-insertion of this nucleic acid back into the cell using, in most cases, a vector system. Using this procedure it is possible to produce a cell which has a new combination of heritable genetic material as compared with the parental organism. An anti-sense gene may be inserted, or multiple copies of genes. This procedure is clearly covered by Regulation 3 a) and/or b).

The release of any self-cloned organism therefore requires a consent.

The Genetic Modification (Contained Use) Regulations 1992 exempt from control self-cloned non-pathogenic, naturally occurring organisms which fulfil the criteria of Group I genetically modified microorganisms and the construction and use of somatic animal hybridoma cells. However, Regulation 3 makes clear that such organisms are not exempt from the control regime for releases and marketing.

CAPACITY OF ORGANISMS FOR CAUSING HARM

Section 107(8) of the EPA empowers the Secretary of State to disregard harm caused by prescribed organisms in prescribed circumstances:

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(8) The Secretary of State may by regulations provide, in relation to genetically modified organisms of any description specified in the regulations, that-

(a) the capacity of those organisms for causing harm of any description so specified, or

(b) harm of any description so specified,

shall be disregarded for such purposes of this Part as may be so specified.

The types of operation and harm which will be disregarded under these regulations is set out below:

Regulation 4:

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(1) For the purposes of sections 110(1), 112(5)(a) and (c) and (7)(a) and 117(1) of the Act there shall be disregarded -

(a) the capacity of genetically modified organisms of the description specified in paragraph (2) below for causing harm of the description specified in paragraph (3) below, and

(b) harm which is of the description so specified and which has been caused by organisms of the description so specified.

(2) The genetically modified organisms specified in this paragraph are genetically modified organisms which control - ✱
the number or activity (or both) of any organisms, or
(b) toxic wastes.

(3) The harm specified in this paragraph is harm caused to any organisms by genetically modified organisms which have been released or marketed in pursuance of -
(a) a consent granted by the Secretary of State under section 111(1) of the Act, or

(b) a written consent given by the competent authority of a member State of the Communities in accordance with Article 13(4) of the Deliberate Release Directive.

Damage to the environment is likely to be caused by the destruction of pests by GMOs. However, it is important that useful, new preparations of pesticides, for example, can be developed. Therefore the harm caused by GMOs used in certain approved preparations to control the numbers and activity of other organisms is disregarded. This means that in this case, prohibition notices preventing the release of the GMOs cannot be served by the Secretary of State (s 110(1)); the general condition implied in all consent applications that a releaser keep himself informed about the risks of damage to the environment and to use the best available techniques not entailing excessive cost to prevent such damage does not apply (s 112(5)(a) and (c) and 112(7)(a)); and inspectors do not have the power to destroy or otherwise bring the GMOs under control because of imminent danger to the environment.

Anyone releasing GMOs which are, for example, bio-control agents will need to ensure that they are targeted as closely as possible on the pest species and to take care to minimize any potentially harmful effects on other organisms.

PART II
RELEASING ORGANISMS

This Part contains guidance on the release of GMOs for research and development purposes or their release for any purposes other than placing on the market.

DEFINITION OF "RELEASE"

Section 107 (9) of the EPA sets out what is meant by a person having a GMO under his control:

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(9) Organisms of any description are under the "control" of a person where he keeps them contained by any system of physical, chemical or biological barriers (or combination of such barriers) used for either or both of the following purposes, namely-

(a) for ensuring that the organisms do not enter the environment or produce descendants which are not so contained; or

(b) for ensuring that any of the organisms which do enter the environment, or any descendants of the organisms which are not so contained, are harmless.

The terms "release" and "escape" are then defined in terms of control, or lack of control (s 107(10)):

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(10) An organism under a person's control is "released" if he deliberately causes or permits it to cease to be under his control or the control of any other person and to enter the environment; and such an organism "escapes" if, otherwise than being released, it ceases to be under his control or that of any person and enters the environment.

The accidental entry of GMOs into the environment, ie GMOs which **unintentionally** cease to be kept under a person's control, is therefore regarded as an "escape".

The term "release" thus covers:

i) the deliberate entry of GMOs into the environment as a result of R&D trials conducted in the open and

ii) any other intentional introduction of GMOs into the environment by whatever means where the organisms are no longer contained by a system of barriers.

The appropriate system of containment for keeping GMOs under control will vary from case to case. In most cases, physical

barriers are likely to consist of a building - such as a laboratory, production plant or storage facility - with walls and a roof and windows and doors that can be securely closed with, as appropriate, the assistance of filters, special entrances, etc. In other cases, it may be necessary to consider whether the proposed form of containment is sufficient to ensure that the activity being undertaken should not be regarded as a deliberate release.

Some forms of containment may or may not offer an adequate form of control depending on the circumstances in which they are used. For example, a growth chamber located in a building and subject to laboratory procedures is more likely to meet the requirements of appropriate containment than a growth chamber located in more open facilities for the purposes of mass propagation on a large scale.

Similarly, the degree of protection offered by pens, ponds, fences, mounds, ditches, etc is likely to vary depending on the nature and numbers of organisms being used. For example, a genetically modified domestic animal surrounded by a fence in a field may be adequately contained if there is no possibility of the animal's escape. On the other hand, the use in experiments in the open environment of modified organisms in microcosms such as soil cores in containers with limited openings is likely to be more difficult to contain and will thus be likely to constitute a deliberate release.

In some cases an organism will have an in-built barrier which prevents its survival in the environment. Genetically modified microorganisms fulfilling the criteria of Group I have such limited survivability. Therefore in some cases, the effluent from Group I Type B contained operations will not present any significant risk of damage to the environment; this will need to be borne out by the risk assessment submitted to the Health and Safety Executive under the Contained Use regulations.

Examples of the types of considerations that should be applied in order to decide whether GMOs are being contained, or released i.e. are under control or not, are: the possibility of spread to the exterior by ventilation systems, visiting insects or other animals, and by personnel and equipment; the number of organisms and their familiarity, and their size and degree of domestication (for plants and higher animals); whether the organism is likely to survive and/or be disseminated and whether it originates in the UK or is a non-indigenous organism.

CONSENT TO RELEASE ORGANISMS

The powers which enable the Secretary of State to grant a consent to release or market organisms are set out in s 111 EPA:

(1) Subject to subsection (7) below, no person shall ... release ... any genetically modified organisms-

(a) in such cases or circumstances as may be prescribed in relation to that act ....

except in pursuance of a consent granted by the Secretary of State and in accordance with any limitation and conditions to which the consent is subject.

GENERAL DUTIES

The EPA imposes a general condition on everyone holding a consent to release or market a GMO (s 112 (1)(2)(5)(6)(7)):

112(1) The Secretary of State may include in a consent such limitations and conditions as he may think fit; but no limitations or conditions shall be imposed for the purpose only of securing the health of persons at work (within the meaning of Part I of the Health and Safety at Work etc. Act 1974 or, in relation to Northern Ireland, Part II of the Health and Safety at Work (Northern Ireland) Order 1978.

(2) Without prejudice to the generality of subsection (1) above, the conditions included in a consent may-

(a) require the giving of notice of any fact to the Secretary of State, or

(b) prohibit or restrict the ... releasing or marketing of genetically modified organisms under the consent in specified cases or circumstances;

.....

(5) Subject to subsection (6) below, there is implied in every consent for releasing or marketing genetically modified organisms a general condition that the holder of the consent shall-

(a) take all reasonable steps to keep himself informed (by reference to the nature of the organisms and the extent and manner of the release and marketing) of any risks there are of damage to the environment being caused as result of their being release or, as the case may be, marketed;

(b) if any time it appears that any risks are more serious than were apparent when the consent was granted, notify the Secretary of State forthwith; and

(c) use the best available techniques not entailing excessive cost for preventing any damage to the environment being caused as a result of their being released or, as the case may be, marketed.

(6) The general condition implied into a consent under subsection .... (5) above has effect subject to any conditions imposed under subsection (1) above; and the obligations imposed by virtue of subsection ..... (5)(c) above shall not apply to any aspect of an act authorised by a consent which is regulated by such condition.

(7) There shall be implied in every consent for .... releasing or marketing genetically modified organisms of any description a general condition that the holder of the consent-

> **(a) shall take all reasonable steps to keep himself informed of developments in the techniques which may be available in his case for preventing damage to the environment being caused as a result of the doing of the act authorised by the consent in relation to organisms of that description; and**
>
> **(b) if it appears at any time that any better techniques are available to him than is required by any condition included in the consent under subsection (1) above, shall notify the Secretary of State of that fact forthwith.**

But this general condition shall have effect subject to any conditions imposed under subsection (1) above.

Section 112 allows the Secretary of State to impose conditions on a consent:

> Example: A person proposing to plant out genetically modified sugar beet in East Anglia where there are populations of the related sea beet might be required to ensure that cross pollination is prevented by removing flowers from the plants.

It also allows him to require in a consent that certain events are notified:

> Example: if the techniques of mutagenesis, cell fusion, in vitro fertilisation, conjugation, transduction, transformation or any other natural process, or polyploidy induction are to be used on an existing GMO for which a consent to release has already been obtained, the Secretary of State must be notified.

BATNEEC, or, the best available techniques not entailing excessive cost, can best be interpreted by examining its three constituents "best available", "techniques" and "excessive cost". In essence BATNEEC means that the risks involved in a particular operation should be weighed against the benefits. A balance

should be attained between the risks of damage to the environment and the use of any techniques or technologies which are available to minimize those risks; but the cost involved should not be excessive in comparison with the degree of risk.

> Example: A person is proposing to release a genetically modified oil seed rape which expresses insect resistance. This is part of a development programme, and constitutes the first small scale release during which flowering will be allowed to take place. BATNEEC might best be applied to monitoring aspects by use of a marker gene that permits simple phenotypic characterization rather than application of PCR techniques.

[Further example to follow.]

"Excessive cost" therefore depends on the risk of damage to the environment, on the degree of that damage, and on the cost of the technology in relation to the benefit obtainable. It does not depend in any way on the financial resources of the person who is responsible for the GMOs. Anyone proposing to carry out GMO activities who is unable to afford appropriate BATNEEC may not lawfully engage in those activities.

CONSENT TO RELEASE ORGANISMS

Regulation 5:

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(1) Subject to paragraph (3), no person shall release any genetically modified organisms, other than an approved product which is released in accordance with the conditions and limitations to which the release of the product is subject, except in pursuance of a consent granted by the Secretary of State under section 111(1) of the Act.

Regulation 5(1) means that a consent is required for all GMO releases apart from releases of products which have received the approval of the UK authorities or the authorities of another EC member state under the terms of the Deliberate Release Directive.

The requirement to have a consent means that an applicant may only proceed with the release after he has received the written consent from the Secretary of State.

If the release is planned to take place in another country, notification of proposals to carry out a GMO release must be submitted prior to the release to the competent authority appointed for the purpose in the Member State where the release is planned. Annex XXX lists, for information, the authorities [so far] formally notified to the EC Commission.

(2) An application for a consent to release genetically modified organisms must be made in writing to the Secretary of State, and must be made either -

(a) for one or more releases of one or more descriptions of genetically modified organism on the same site within a limited period, or

(b) for one or more releases of one description of genetically modified organisms on one or more sites for the same purpose within a limited period.

"One description" of a genetically modified organism might cover a single clone containing a specific construct or several clones containing that construct, even if the introduced gene(s) is/are expressed at different levels in the clones. It may also be possible to include slightly different constructs containing identical functional gene(s) in the same description as long as the modification is designed for the same purpose.

In order to facilitate the procedures and reduce possible costs, a number of proposed releases falling within the same experimental programme at the same time or within a specified period can be treated as one application for consent. For example, a person may be proposing to release on the same site plants which have been genetically modified to express different characteristics. Alternatively, the proposal may be to release on different sites plants which have been modified to express the same characteristics. In either case, the proposal could be treated in the same consent application provided the requirements in the application form for specific information on the different sites or the different GMOs are met.

The "limited period" will relate to the nature of the proposed release. In some cases, when one-off releases are envisaged, the period may be weeks or months: for example, a proposal to carry out a one-off release of a virus with insecticidal properties as a first step to evaluating future options. Alternatively, a single consent may cover a complete programme of work. For example, one consent may be appropriate for a plant breeding programme for a specific purpose, covering early research trials, development trials, statutory (DUS) and other (VCU) performance trials, provided that a single risk assessment would cover the whole programme. The consent would then cover all sites and all years in a programme. In such a case, the consent might be of the order of 5-10 years, but there would be likely to be specific requirements on reporting back annually during this period as one of the conditions of the consent. Consent holders would always have to comply with the general duty and report to the Secretary of State if the risks became more serious than originally expected. These could lead to a variation in the consent conditions, or if the risks were highly significant and could not be appropriately managed, to revocation of the consent.

(3) Paragraph (1) shall not apply to a person who -
(a) has notified the Health and Safety Executive, under regulation 5(1)(a) of the Genetic Manipulation Regulations 1989 (a), of his intention to carry out an activity involving an intentional introduction into the environment, and

(b) carries out the activity in accordance with that notification before [date 90 days after date Regulations come into force].

(a) S.I. 1989/1810

This transitional provision is designed to protect the position of persons who, before the present Regulations came into force, properly notified the Health and Executive under the Genetic Modification Regulations 1989 of their intention to carry out a proposed release. Since many releases are dependent on specific climatic or seasonal conditions, it would be unreasonable to require people to submit another application to release and have to wait for its consideration by the authorities. Therefore these people do not require a consent under the present Regulations provided the proposed release notified to the HSE is made by [date 90 days after date Regulations come into force.] If the release is intended to be carried out after that date, a consent will be needed.

INFORMATION TO BE CONTAINED IN APPLICATION FOR CONSENT TO RELEASE

The EPA (s 111(4) and (6)) provides that an applicant for a consent supply the Secretary of State with certain information:

(4) An application for a consent must contain such information .... as may be prescribed .....

(6) The Secretary of State may by notice to the applicant require him to furnish such further information specified in the notice, within such period as may be so specified, as he may require for the purpose of determining the application; and if the applicant fails to furnish the information within the specified period the Secretary of State may refuse to proceed with the application.

Regulation 6:

(1) Subject to regulation 7 (Exemptions from regulation 6), an application for a consent to release genetically modified organisms must contain -

(a) the information prescribed in Schedule 1 to these Regulations, to the extent that such information is appropriate to the proposed release,

(b) information on data or results from any previous releases of the organisms, or of organisms of the same description, which have been carried out by the applicant, and information from any previous application for the release of the organisms, or of organisms of the same description, which the applicant has made to the Secretary of State in accordance with the Act and these Regulations or to the competent authority of another member State of the Communities in accordance with Article 5 of the Deliberate Release Directive,

(c) a statement evaluating the impacts and risks posed to human health and the environment by the release of the organisms.

Schedule 1 sets out information which will comprise the technical dossier necessary for evaluating the risks which the proposed release could present to human health and the environment. On the advice of ACRE, the Secretary of State uses this information, together with the statement of impacts and risks required at (c), to decide whether a release consent should be issued and any conditions which should be attached to a consent issued.

Guidance on the way in which the Schedule 1 information should be supplied is at ..... **Only information which is appropriate to the proposed release need be given.**

Experimental releases of GMOs often form part of a programme of work which may be carried out over a period of months or even years. Data or results from releases which have been made in an earlier phase of a programme may often be relevant to consideration of releases proposed at a later stage in the programme. Similarly, information from earlier applications for proposed releases may also be relevant, whether or not the application was granted or carried through to an actual release. Such data, results and information form part of the information required in support of consent applications. However, in many cases a reference to the previous application will be sufficient to enable the Secretary of State to use this information in considering the current consent application. **Regulation 7** specifically provides for information from previous releases to be supplied in this way.

Reference to earlier releases may mean that the consent applications can be considered using streamlined procedures because less official and advisory committee time is likely to be involved.

Information of this type which may be cited in support of an application is not confined to earlier releases made by the applicant in the United Kingdom or to earlier applications made to the Secretary of State. Information from applications made to another EC country in accordance with the Deliberate Release Directive or from releases made in any other country outside the EC may also be taken into account. The relevance of such information to a current application will, however, vary from case to case according to such factors as the geographical location, climatic conditions, etc of the site of the earlier release or application.

Risk Assessment

Regulation 7(1)(c) requires the applicant to submit a statement evaluating the impacts and risk posed to the environment by the release of the organisms. This statement will be assessed by the Secretary of State in making his decision on whether the release will cause damage to the environment. It will also be placed on the public registers established under regulation 17. The statement should thus include a summary of the risks written, as far as possible, in non technical terms.

In preparing the statement the applicant should assess the hazards, including the impact on the environment identified as a result of the information provided (in schedules 1 and 2) and then evaluate the likelihood that specific hazardous events will be realised; this is the risk.

The hazard is the characteristic (biological, chemical or physical) which if manifested would cause harm to the environment, ie the potential for harm. For example pathogenicity or ability to exchange genetic material with related species, [more examples]. The nature and magnitude of the hazards must be assessed.

The risk is the likelihood of the realisation of the hazard, ie the likelihood that a specified undesired event will occur within a specified period or in specified circumstances. For example the likelihood that genetically modified insect resistant oil seed rape plant adjacent to normal rape crops and other wild crucifers will transfer genetically modified pollen to the normal plants is high; the likelihood or risk that a storm force wind which would increase the pollination distances would occur in June is low.

Having considered each of the hazards and risks associated with a particular proposal, the applicant should submit a statement which evaluates the risk overall of the release causing damage to the environment. The type and magnitude of the overall risk will form part of the Secretary of State considerations in making his decision on the consent. Further guidance on the approach to risk assessment is included in an annex to the guidance to Schedules 1 and 2.

(2) The information prescribed in Schedule 1 shall be included in the application at the level of detail which is appropriate to the nature and scale of the proposed release.

Some of the information required under Schedule 1 may not be relevant to the proposed release. Furthermore, the amount of detail required will vary from case to case but it should be sufficient to allow the competent authorities to verify the statement evaluating the risks of damage to the environment.

(3) Where the applicant considers, on the basis that it is not technically possible or it does not appear to the applicant to be necessary, that it is not appropriate for the application to contain any of the information prescribed in one or more of the paragraphs of Schedule 1, the application shall contain a statement of the reasons why the inclusion of the information is not appropriate.

An applicant's statement of why particular information cannot or need not be provided in support of an application for consent to release will again vary from case to case. Sometimes it will be sufficient to indicate very briefly why the information is not applicable to the proposed release. Where the requested information is relevant to a proposed release but there are technical difficulties in providing it, sufficient reason should be given to satisfy the Secretary of State that the application can be determined without it.

(4) The application must contain the description of the methods used to obtain the information contained in the application and a bibliographic reference, or, where standardised or internationally recognised methods are used, a reference to which method was used to obtain the information and its bibliographic references, together with the name of the body or bodies responsible for carrying out the studies.

Although there are no international standards in this area as yet, many methods, such as polymerase chain reaction (PCR) techniques, are internationally recognized, in which case reference only is necessary.

It is important that unnecessary animal experimentation is avoided and that Directive 86/609/EEC of 24.11.1986 on the protection of animals used for experimental and other scientific purpose is adhered to. Animal experimentation that may be required in order to supply data under this Directive should be minimised as far as possible by avoiding repetition of experiments. It may also be appropriate to consider whether a licence is needed under the Animals (Scientific Procedures) Act 1986.

(5) The application may in addition refer to data or results from applications for consent to release genetically modified organisms previously submitted by other applicants, provided that the latter have given their agreement in writing and their agreement is contained in the application.

Applicants are encouraged to refer to data both from their own previous releases and from those of other applicants.

EXEMPTIONS FROM REGULATION 6

Regulation 7:

An application for a consent to the release of genetically modified organisms need not contain the information prescribed in regulation 6(1)(a) and (b) if -

(a) the information was contained either -

(i) in an application which was made by the same person in relation to a previous release of those organisms or of the same description of organisms, or

(ii) in an application which was made by some other person in relation to a previous release of those organisms or of the same description of organisms,

(b) the application refers to the previous application in which the information was contained, and

(c) where paragraph (a)(ii) applies, the application contains the agreement in writing of the person who made the previous application to a reference to that application being made.

As made clear in the guidance to Regulation 6(1) and (5), information required may be supplied by referring to earlier releases or applications. Regulation 8 ensures that a reference to an earlier application rather than a copy of that application or related material will suffice. The agreement of the person concerned should be obtained where reference is made to an earlier application which was submitted by someone else.

ADVERTISEMENT OF APPLICATION FOR CONSENT TO RELEASE AND TO NOTIFY

The powers to require applicants to advertise and to notify certain authorities are in section 111 of the EPA:

(4) An application for a consent must .... be advertised in such manner as may be prescribed .....

(5) The applicant shall, in prescribed circumstances, give such notice of his application to such persons as may be prescribed.

Regulation 8:

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(1) Subject to paragraph (2), a person who makes an application for a consent to release genetically modified organisms shall, not less than fourteen days and not more than twenty-eight days after the date of acknowledgement of receipt of that application by the Secretary of State, cause to be published, in a newspaper or newspapers circulating in the areas likely to be affected by the proposed release a notice containing the following information -

(a) the name and address of the applicant,
(b) the description of the organisms to be released,
(c) the location and purpose of the release; and
(d) the date or dates of the release.

Within 14 and 28 days of acknowledgement of receipt of the application, the applicant should place an advertised in the press in the area or areas likely to be affected by the proposed release. What this means in practice will depend on the circumstances of particular cases. For example, it is likely that advertisements in newspapers circulating widely would be required for a release of a genetically modified insect. In most cases of small scale experimental releases of genetically modified plants, however, advertisements in the local press are likely to suffice.

In placing the advertisement, the name and address of the institute/company/research establishment should be given. We also recommend that proposers supply a telephone number which can be used for readers to obtain further information if required.

The level of detail in the advertisement may vary depending on the case, but it should give sufficient information to allow the reader to understand the basic purpose of the release. We recommend that detailed scientific information is not given.

As regards location, this might be the nearest village or town. If there is an spread of the organism expected, this "wider site" might be indicated.

[Example of advertisement to be provided.]

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(2) The information on the location of the release shall be the same as the information on its location which is placed on the register kept by the Secretary of State under section 122 of the Act.

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(3) A person who makes an application for a consent to release genetically modified organisms shall, not less than fourteen days and not more than twenty-eight days after the date of acknowledgement of receipt of that application by the Secretary of State, send a notice containing the information set out in paragraph (1)(a) to (d) above] to -

(a) the local environmental health officer,
(b) the owner of the site of the proposed release, if a person other than the applicant,
(c) the Nature Conservancy Council for England, [Scottish Natural Heritage] and the Countryside Council for Wales, according to whether the release will be in the locality of a site notified under section 28 of the Wildlife and Countryside Act 1981[2] in England, Scotland or Wales,
(d) the Forestry Commission,
(e) the Countryside Commission,
(f) the National Rivers Authority or, in Scotland, the River Purification Board for the area of the proposed release,
(g) the company appointed for the water supply area in which the proposed release will take place.
(h) the members of the genetic modification safety committee established by the applicant under regulation 11 of the Contained Use of Genetically Modified Organisms Regulations 1992 (a).

GENERAL CONDITION ON CONSENTS TO RELEASE ORGANISMS

Regulation 9:

In section 112 of the Act there shall be substituted for paragraph (b) of subsection (5) the following paragraph -

"(b) notify the Secretary of State of -

(i) any new information which becomes available with regard to any such risks, and

(ii) the result of the release in respect of any risk to human health or the environment, with particular reference to any kind of product for which the holder of the consent intends to apply for consent to market at a later stage;".

The purpose of this requirement is to obtain information about any change in the assessment of the risks associated with a particular release and the outcome of a release. This will assist the Secretary of State in developing criteria for the approval of subsequent releases, particularly where this involves the marketing of a product.

[2] 1981 c.69.

PART III
MARKETING ORGANISMS

DEFINITION OF "MARKET"

"Market" is defined in Section 107(11) of the Act:

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(11) Genetically modified organisms of any description are "marketed" when products consisting of or including such organisms are placed on the market.

The term "placing on the market" means that a product is being marketed through external distribution channels. Examples of situations that are not considered to require a marketing consent are:

- If GMOs are specifically developed for a user on a bilateral agreement between a supplier and a user and are to be used for research and development purposes;

- GMMs exchanged for non-commercial purposes between two research institutions but which will be used only for "contained use" provided that both the research institutions in such an exchange have duly notified under the Contained Use regulations.

- The exchange of a GMM within subsidiaries of the same company or the research company in the UK, and the production company within the same group of companies provided that the GMM is not to be made more widely available to others as a product, and provided that the receiving company/section has notified under the Contained Use regulations.

- The supply of cultures to and from national and international culture collections.

In some cases such as in Denmark, transportation of GMOs to other EC Member States or within that State may be subject to additional national controls.

CONSENT TO MARKET PRODUCTS

The powers to require a person to apply for a consent to market are in section 111 of the EPA:

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(1) Subject to subsection (7) below, no person shall ... market ... any genetically modified organisms-

(a) in such cases or circumstances as may be prescribed in relation to that act ....

except in pursuance of a consent granted by the Secretary of State and in accordance with any limitation and conditions to which the consent is subject.

The general duties on everyone holding a consent also apply to consents to market organisms, see pp.....

Regulation 10:

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(1) No person shall market any genetically modified organisms, other than a product which is marketed in accordance with a written consent given by the competent authority of another member State of the Communities in accordance with Article 13(4) of the Deliberate Release Directive, except in pursuance of a consent granted by the Secretary of State under section 111(1) of the Act.

Part C of the Deliberate Release Directive provides a procedure which enables GMO products which are cleared for the market in one Member State to be marketed in any other Member State. The importer or manufacturer of the product need deal only with the competent authority of the Member State where the product will be marketed for the first time. The authority chosen by the importer or manufacturer will then act as a "gateway" to the entire EC market by receiving and processing the information required and issuing the consent.

The EC requirements are built into the Regulations. The process of seeking clearance for proposed new GMO products via the EC Commission and other Member States therefore follows automatically from the submission of an appropriate consent application to the Secretary of State.

The clearance procedures for marketing GMO products does not apply to products which are subject to EC product legislation which provides for a risk assessment similar to that specified in the Deliberate Release Directive. The EC Commission, in consultation with Member States, has determined that no currently operative product legislation falls into this category (ref. 1991).

The Regulations will be amended to provide appropriate exclusions as and when Member States and the Commission decide that particular product directives do provide for a risk assessment similar to that specified in the Deliberate Release Directive. UK policy is to encourage such provisions to be incorporated in product directives.

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(2) An application for a consent to market genetically modified organisms must be made in writing to the Secretary of State, and must be made either -

(a) in a case where the product has not previously been marketed, or

(b) in a case where the product is intended for a use for which it has not previously been marketed.

Products entering the market will in many cases consist of or contain GMOs which have not been used commercially before even though they may have been used for experimental or research and development purposes. However, as commercial uses of the technology expand, it is possible that GMOs which are or form part of cleared products will be put to novel uses, including the development of new products. A new consent to market is required in such cases.

Examples:

(i) A micro-organism approved for use as a bioremediative agent in soil might show potential for similar activity in polluted rivers. This new application of the product would require a further consent.

(ii) Tomatoes genetically modified for enhanced fruit flavour might be particularly susceptible to infection by vesicular arbuscular mycorrhizal fungi and the harvested root material used as a source of inocula for these fungi. The use of the product as a biofertiliser would be subject to a new consent.

However, in some cases it may be possible for the Secretary of State to impose conditions on consents which will permit the use of products in new product development without further regulatory oversight being necessary. An appropriate risk assessment will nevertheless always have had to have been carried out at the time of applying for a consent to market and/or there could be a requirement to provide further risk assessment data during subsequent development of the product.

Example: It may be desirable to introduce approved products containing genetically modified organisms from a plant breeding programme into further breeding programmes as a novel germplasm source. The use of the GMO in new breeding programmes could be exempt from further regulatory scrutiny by the imposition of appropriate positive conditions on the marketing consent.

INFORMATION TO BE CONTAINED IN APPLICATION FOR CONSENT TO MARKET

The EPA (s 111(4) and (6)) provides that an applicant for a consent supply the Secretary of State with certain information:

(4) An application for a consent must contain such information .... as may be prescribed .....

(6) The Secretary of State may by notice to the applicant require him to furnish such further information specified in the notice, within such period as may be so specified, as he may require for the purpose of determining the application; and if the applicant fails to furnish the information within the specified period the Secretary of State may refuse to proceed with the application.

Regulation 11:

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(1) An application for a consent to market genetically modified organisms must contain -

(a) the information prescribed in Schedule 1 to these Regulations, to the extent that such information is appropriate to the nature and scale of the release which may result from the marketing,

(b) information on data or results from any previous release of the organisms, or of organisms of the same description, which have been carried out by the applicant, and information from any previous application for the release of the organisms, or of organisms of the same description, which the applicant has made to the Secretary of State in accordance with the Act and these Regulations or to the competent authority of another member State of the Communities in accordance with Article 5 of the Deliberate Release Directive,

(c) subject to paragraph (5), the information prescribed in Schedule 2 to these Regulations.

Schedules 1 and 2 set out information which will comprise the technical dossier necessary for evaluating the risks which the proposed release could present to human health and the environment.

Guidance on the way in which the Schedule 1 and 2 information should be supplied is at ..... **Only information which is appropriate to the proposed release need be given.**

All GMO products are covered by the regulations. For example, human and veterinary live vaccines, transgenic plants and animals, including those intended for containment such as experimental animals, test kits containing live genetically modified microorganisms will all require a consent to market under these regulations.

Product applications will usually be made after pre-product trials have been conducted. These may be experimental releases of GMOs, in which case the data or results may often be relevant; applicants are encouraged to use existing data wherever possible. If these trials were conducted in the UK and notified to the UK authorities under these regulations, a reference to the previous application will suffice. If the trials were elsewhere in the European Community, a clear reference [notification number] should be given. Data and results from previous releases will be required if the GMO was tested outside the European Community. The information may not always be directly transferable to the UK and the Community however, if there are differences in, for example, the climatic conditions.

(2) The information prescribed in Schedule 1 shall be included in the application at the level of detail which is appropriate to the nature and scale of the release which may result from the marketing, and shall take into account the diversity of sites of use of the product, including -

(a) information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product, and

(b) an assessment of any risks for human health or the environment related to the genetically modified organisms contained in the product, including information obtained from the research and development stage on the impact of the release on the environment.

In providing the information under Schedule 1, it is important that the likely use of the product be taken into account in order to identify the ecosystems that might be affected. This should then be linked to the type of ecosystems found throughout the Community in order to give an indication of whether restrictions should be placed on the use of the product.

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(3) Where the applicant considers, on the basis that it is not technically possible or it does not appear to the applicant to be necessary, that it is not appropriate for the application to contain the information prescribed in one or more of the paragraphs of Schedule 1, the application shall contain a statement of the reasons why the inclusion of the information is not appropriate.

An applicant's statement of why particular information cannot or need not be provided in support of an application for consent to market may vary from case to case, but it is likely that a number of information requirements under Schedule 1 will be found not to be applicable to an application to market. In such cases, a very brief reason only need be given.

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(4) The application must contain the description of the methods used to obtain the information prescribed in Schedule 1 and a bibliographic reference or, where standardised or internationally recognised methods are used, a reference to which method was used to obtain the information and its bibliographic references, together with the name of the body or bodies responsible for carrying out the studies.

Although there are no international standards in this area as yet, many methods, such as polymerase chain reaction (PCR) techniques, are internationally recognized, in which case reference only is necessary.

It is important that unnecessary animal experimentation is avoided and that Directive 86/609/EEC of 24.11.1986 on the protection of animals used for experimental and other scientific purpose is adhered to. Animal experimentation that may be required in order to supply data under this Directive should be minimised as far as possible by avoiding repetition of experiments. Consideration may also need to be given to a possible requirement for a licence under the Animals (Scientific Procedures) Act 1986.

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(5) Where the applicant considers, on the basis of the results of any release in pursuance of a consent granted under section 111(1) of the Act or a written consent given by the competent authority of another member State in accordance with Article 13(4) of the Deliberate Release Directive, or on substantive, reasoned scientific grounds, that the placing on the market and use of the product do not pose a risk to human health or the environment, he may propose not to supply the information prescribed in Part II of Schedule 2.

If the applicant, as a result of the trials he has conducted, considers that the proposed marketing poses no risk to human health and to the environment, he may choose not to make a proposal for labelling and packaging and not to give other information. The reasons for this proposal will need to be substantiated by the assessment of the risks to human health and the environment.

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(6) An application for a consent to market genetically modified organisms may in addition contain data or results from notifications previously submitted by other applicants, provided that the latter have given their agreement in writing, and that agreement is contained in the application.

Applicants are encouraged to refer to data both from their own previous releases and from those of other applicants. This may in some cases, have the positive effect of reducing the necessity for animal experimentation. It is important that unnecessary animal experiments are avoided and the Directive 86/609/EEC of 24.11.86 on the protection of animals used for experimental and other scientific purposes is adhered to. Animal experimentation that may be required in order to supply data under this Directive should be minimised as far as possible by avoiding repetition of experiments. Maximum use of available data should be made.

TRANSITIONAL PROVISION FOR MARKETING

Regulation 12:

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(1) This Part of these Regulations shall not apply to a person marketing a product which -

(a) was marketed by him before [date on which Regulations come into force], and

(b) is not an approved product,

until [date one year after regulations come into force].

(2) Part II of these Regulations shall not apply to a person who releases, in accordance with any conditions and limitations to which its use is subject, a product to which paragraph (1) applies.

Anyone who had placed a product on the UK market before the Regulations came into force may continue to market <u>in the UK</u> for one year after the coming into force of the regulations. Such products may be used, or released for experimental or R&D purposes, without any additional restrictions (unless they were subject to further genetic modification, in which case the new regulations would apply). After one year, however, if the marketer wishes to continue to market, he can only do so with a consent; this consent would allow him, at the same time, to market throughout the Community without any further regulatory hurdles.

If products receive environmental safety clearance in some Member States before 23 October 1991, and were marketed by that date, they can continue being on the market of those Member States after October 23, but they will need to be approved by the Community procedures of Directive 90/220/EEC before they are marketed throughout the EC.

PART IV
DUTIES PLACED ON SECRETARY OF STATE

This Part explains the duties of the Secretary of State in processing applications for consent to release or market genetically modified organisms, including his duties in relation to the system of information exchange on R & D releases and for the clearance of products for marketing throughout the whole of the European Communities.

DUTIES ON RECEIVING APPLICATIONS FOR CONSENT TO RELEASE

The regulations in this part use the powers of the European Communities Act 1972.

Regulation 13:

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(1) The Secretary of State shall within 30 days of receiving an application for a consent under regulation 5 forward to the European Commission a summary of that application in the format established by the Commission in accordance with the procedure laid down in Article 21 of the Deliberate Release Directive.

This is a requirement under the Deliberate Release directive to allow the exchange of information between competent authorities in all the Member States. Authorities in countries other than the one where the release is taking place have the opportunity to make relevant observations within a 30-day period on the basis of the summary notification information format (SNIF) provided. These observations are not binding in any way. Applicants are requested to complete and submit the SNIF when making application for consent to release.

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(2) The Secretary of State shall -

(a) examine an application for a consent under regulation 5 for its conformity with the requirements of the Act and of these Regulations,

(b) evaluate the risks posed by the proposed release,

(c) if necessary, carry out such tests or inspections as may be necessary for control purposes,

(d) take into account any comments from Member States of the European Communities made following the circulation to them by the European Commission of the summary referred to in paragraph (1) above, and

(e) record his conclusions in writing.

Any application will be examined as soon as it is received to ensure that it contains all the necessary information and assessment. ACRE will be asked for their advice on the proposal and other interested Government departments will also have the opportunity to comment and give advice.

Other Member States may comment on SNIFs sent from the UK and the Secretary of State and the Health and Safety Executive will consider these, together with the views of ACRE and other Departments.

The final decision will be sent to the applicant, placed on the public register and sent to the European Commission.

DECISIONS ON APPLICATIONS FOR CONSENT TO RELEASE OR MARKET

Regulation 14:

The Secretary of State shall not grant a consent for the release of genetically modified organisms as it relates to the protection of human health without the agreement of the Health and Safety Executive.

This provisicn enables the Health and Safety Executive to determine the human health and safety side of all consents and associated conditions.

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(2) The Secretary of State shall communicate his decision an application for consent under regulation 5 before the end of a period of 90 days beginning with the day on which the application was made.

This regulation "starts the clock" by stating that Day 1 is the day of receipt of the application. A decision will then be made within 90 days, provided there is no need to "stop" the clock.

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(2) The period referred to in paragraph (2) shall not include any period beginning with the day on which the Secretary of State gives notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending with the day on which that information is given to the Secretary of State.

If DOE, on behalf of the Secretary of State, consider that the information provided in the application is inadequate, they may contact the applicant to request further information. During the time in which this information is being sought and provided, the clock stops i.e. this period is not included in the 90 day period for consideration of an application for a consent.

(3) The Secretary of State shall inform each member State and the European Commission of his decision on each application for the release of genetically modified organisms.

When the 90 day period has expired, the competent authorities approving the release must inform the authorities of other Member States and the Commission of their final decision. This again is for the purpose of information exchange between Member States.

DUTIES IN RELATION TO APPLICATIONS FOR CONSENT TO MARKET

Regulation 15:

(1) The Secretary of State shall examine an application for consent under regulation 10 for its conformity with the requirements of the Act and of these Regulations, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.

As for releases, any application will be examined as soon as it is received to ensure that it contains all the necessary information and assessment. ACRE will be asked for their advice on the proposal and other interested Government departments will also have the opportunity to comment and give advice.

(2) Before the end of a period of 90 days beginning with the day on which he receives an application under regulation 10 the Secretary of State shall either -

(a) forward to the European Commission -

(i) the application,

(ii) a summary of the application in the format established by the Commission in accordance with the procedure laid down in Article 21 of the Deliberate Release Directive,

(iii) a statement of the conditions under which he proposes to consent to the marketing of the product,

(iv) where acceded to by the Secretary of State, details of any proposal by the applicant under regulation 11(5) not to comply with any of the requirements of regulation 11(1)(c), and

(v) his favourable opinion on the application, or

(b) inform the applicant that the proposal does not fulfil

the conditions of the Act and these Regulations and is rejected.

This regulation "starts the clock" by stating that Day 1 is the day of receipt of the application. The Secretary of State will then give his opinion on the proposal to the European Commission within 90 days, provided there is no need to "stop" the clock to obtain further information during this period.

A consent to market a product means that approval has been given for a person to market throughout the European Community. For this reason, every competent authority is given the opportunity to examine the complete application, rather than only the summary, as in the case of R & D releases.

Other Member States will need to know, as part of their examination of the product application, why a proposer may be choosing not to comply with any of the requirements in Part II of Schedule 2, such as a proposal for packaging and labelling. This information will be forwarded to other Member States, via the Commission, by the competent authorities on behalf of the Secretary of State.

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(3) The Secretary of State shall not forward his favourable opinion on the application as it relates to the protection of human health where the Health and Safety Executive has informed him that it does fulfill the conditions of the Act and these Regulations.

This regulation ensures that any positive opinion on a marketing consent is not forwarded to the European Commission without the agreement of the Health and Safety Executive.

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(4) The period referred to in paragraph (2) shall not include any period beginning with the day on which the Secretary of State gave notice in writing under section 111(6) of the Act that further information in respect of the application was required and ending with the day on which that information was given to the Secretary of State.

If DOE, on behalf of the Secretary of State, consider that the information provided in the application is inadequate, they may contact the applicant to request further information. During the time in which this information is being sought and provided, the clock stops i.e. this period is not included in the 90 day period for consideration of an application for a consent.

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(5) The Secretary of State shall immediately inform the competent authority of each member State and the European Commission of any other information he receives from the

applicant before or after the granting of the consent.

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(6) Where no objection has been raised by the competent authority of another member State the Secretary of State shall, within a period of 60 days beginning with the day on which the documents referred to in paragraph (2)(a) were forwarded to those member States by the European Commission, give the applicant consent in writing to the application to market the product and inform those member States and the Commission that he has done so.

The Commission is responsible for ensuring that the Community-wide consultation procedure takes place effectively and efficiently. The consultation of the other Member States is made without a meeting, by simply circulating the dossier to the competent authorities, with the necessary confidentiality precautions. A consent valid for the whole Community is given to the applicant by the main authority dealing with the dossier, if within the period of 60 days no insurmountable difficulties or objections are raised.

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(7) Where an objection has been raised by the competent authority of another member State and the European Commission has taken a favourable decision under Article 13(3) of the Deliberate Release Directive, the Secretary of State shall give the applicant consent in writing to the application to market the product and inform those member States and the Commission that he has done so.

If a competent authority of a Member State indicates within the period of 60 days that it does not wish consent to be given to market that particular product, then a meeting of the Article 21 Committee will be called to vote on the matter shall be taken by the regulatory committee set up under the directive. This will be done as soon as possible, and no later than 3 months from the expiry of the period of the 60 day period for Member States' comments.

If the qualified majority vote in the committee is favourable, the consent will be issued to the applicant by the competent authority. The consent may mention specific conditions, but it is likely that many products will receive a consent for marketing without any conditions attached.

PART VII
REGISTER OF INFORMATION

Sections 122 and 123 of EPA require the Secretary of State to set up a public register:

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(1) The Secretary of State shall maintain a register ("the register") containing prescribed particulars of or relating to -

.....

(c) prohibition notices;
(d) applications for consents (and any further information furnished in connection with them) and any advice given by the committee appointed under section 124 below in relation to such applications;
(e) consents granted by the Secretary of State and any information furnished to him in pursuance of consent conditions;
(f) any other information obtained or furnished under any provision of this Part;
(g) conviction for such offences under section 118 above as may be prescribed;
(h) such other matters relating to this Part as may be prescribed;

but that duty is subject to section 123 below.

(2) It shall be the duty of the Secretary of State-

(a) to secure that the register is open to inspection by members of the public free of charge at all reasonable hours; and
(b) to afford to members of the public facilities for obtaining copies of entries, on payment of reasonable charges.

(3) The register may be kept in any form.

(4) The Secretary of State may make regulations with respect to the keeping of the register; and in this section "prescribed" means prescribed in regulations made by the Secretary of State.

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(1) No information shall be included in the register under section 122 above if and so long as, in the opinion of the Secretary of State, the inclusion of the information would be contrary to the interests of national security.

(2) No information shall be included in the register if and so long as, in the opinion of the Secretary of State, it ought to be excluded on the ground that its inclusion might result in damage to the environment.

(3) No information relating to the affairs of any individual or business shall be included in the register without the consent of that individual or the person for the time being carrying on that business, if the Secretary of State has determined that the

information-

(a) is, in relation to him, commercially confidential; and

(b) is not information of a description to which subsection (7) below applies;

unless the Secretary of State is of the opinion that the information is no longer commercially confidential in relation to him.

(4) Nothing in subsection (3) above requires the Secretary of State to determine whether any information is or is not commercially confidential except where the person furnishing the information applies to have it excluded on the ground that it is (in relation to himself or another person) commercially confidential.

(5) Where an application has been made for information to be excluded under subsection (3) above, the Secretary of State shall make a determination and inform the applicant of it as soon as is practicable.

(6) Where it appears to the Secretary of State that any information (other than information furnished by the person to whom it relates) which has been obtained under or by virtue of any provision of this Part might be commercially confidential, the Secretary of State shall-

(a) give to the person to whom or to whose business it relates notice that the information is required to be included in the register unless excluded under subsection (3) above; and

(b) give him a reasonable opportunity-

(i) of objection to the inclusion of the information on the ground that it is commercially confidential; and

(ii) of making representations to the Secretary of State for the purpose of justifying any such objection;

and the Secretary of State shall take any representations into account before determining whether the information is or is not commercially confidential.

(7) The prescribed particulars of or relating to the matters mentioned in section 122 .. (d) and (e) above shall be included in the register notwithstanding that they may be commercially confidential if and so far as they are of any of the following descriptions, namely-

(a) the name and address of the person giving the notice or furnishing the information;

(b) the description of any genetically modified organisms to which the notice or other information relates;

(c) the location at any time of those organisms;

(d) the purpose for which the organisms are being .... released or marketed (according to whichever of those acts the

notice or other information relates);

(e) results of any assessment of the risks of damage to the environment being caused by the doing of any of those acts;

(f) notices under section 112 (3,) (4), (5) or (7) above;

and the Secretary of State may by regulations prescribe any other description of information as information which the public interest requires to be included in the register notwithstanding that it may be commercially confidential.

(8) Information excluded from the register under subsection (3) above shall be treated as ceasing to be commercially confidential for the purposes of that subsection at the expiry of a period of four years beginning with the date of the determination by virtue of which it was excluded; but the person who furnished it or to whom or to whose business it relates may apply to the Secretary of State for the information to remain excluded on the ground that it is still commercially confidential.

(9) The Secretary of State may by order substitute for the period for the time being specified in subsection (8) above such other period as he considers appropriate.

An additional feature of the new control regime is the provision, on a statutory basis, of information to the public about GMO work. This is in line with general UK and EC policy on public access to such kinds of information. Information will be made available on public registers kept at specified offices of DOE and HSE. The information included on the registers will include, for example, particulars about applications for consents and consents issued.

The Secretary of State will not include information which, in his view, prejudices national security or whose disclosure could itself lead to environmental damage. Nor will the Secretary of State include on the register information which he determines to be commercially confidential.

Certain information, however, may not be excluded from the register on grounds of commercial confidentiality where it relates to notifications, or to applications for consents, or to consents granted by the Secretary of State.

There is clearly an intention to make environmental information accessible to the public. The provisions of the EPA and the regulations serve to implement an EC directive (90/313/EEC; OJ L 158/56) on the freedom of access to information on the environment. The categories of restriction on putting entries on to the register i.e. commercial confidentiality, potential of causing damage to the environment and national security, are the specific categories which, under the directive, need not be disclosed. Nonetheless, commercially sensitive information must be protected, and only that information will be placed on the register that will not prejudice the patentability of the GMO.

The details of the information to be placed on the register are set out in the regulations:

Regulation 16:

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(1) The register kept by the Secretary of State under section 122 of the Act shall contain the particulars set out in paragraphs (2) to (6).

(2) In relation to a prohibition notice served under section 110 of the Act -

(a) the name and address of the person on whom the notice is served,
(b) the description of the genetically modified organisms in relation to which the notice is served,
(c) the location at which the genetically modified organisms are proposed to be released or marketed, and the purpose for which they are being released or marketed,
(d) the reason the notice is served,
(e) the day specified in the notice as the day on which the prohibition is to take effect.

(3) In relation to an application for a consent under section 111(1) of the Act -

(a) the name and address of the applicant,
(b) the description of the genetically modified organisms in relation to which the application is being made,
(c) the location at which, and the purpose for which, the genetically modified organisms will be released,
(d) the foreseen dates of the release,
(e) the methods and plans for monitoring the genetically modified organisms and for emergency response,
(f) the evaluation of the environmental impact of the genetically modified organisms, in particular any pathogenic and/or ecologically disruptive effects,
(g) the conditions or limitations in accordance with which the Committee has advised that the consent should be granted,
(h) a summary of the reasons why the Committee has advised that the consent should not be granted.

(4) In relation to consents granted under section 111(1) of the Act -

(a) the fact that the consent has been granted, and a reference to the application in respect of which it was granted,
(b) the conditions or limitations to which the consent is subject,
(c) any information supplied to the Secretary of State in accordance with those conditions or limitations,
(d) any variation or revocation.

(5) In relation to information furnished under section 112(3)(b), (4)(b) or (5)(b) of the Act, the description of the risks which

are considered to be more serious than was apparent when the consent was granted.

(6) In relation to convictions for any offence under section 118 of the Act -

(a) the name and address of the person convicted,
(b) the description of any genetically modified organisms in relation to which the conviction was obtained,
(c) the offence which was committed,
(d) the penalty imposed and any order made by the court under section 120 of the Act.

It should be noted that information included on the register is based on information submitted in an applications sent to the Secretary of State, the consideration of that information by the Secretary of State and ACRE, and consents granted by the Secretary of State.

For these purposes, an "application" is one made in the format set out is Section 2 of this guidance and accompanied by the appropriate fee. At the time of submitting their application, applicants should make clear which information they regard as being commercially confidential for the purposes of the register. This information will then be excluded from the register when the application is received by the Secretary of State.

Section 123 of the EPA provides, however, that the final decision about information to be included on the register rests with the Secretary of State. If the Secretary of State determines that information which an applicant has declared to be commercially confidential should nevertheless be included on the register, he will inform the applicant. This will give the applicant the opportunity of either withdrawing his application or proceeding with it. If he withdraws his application, no further information will go on the register and his original assessment of commercial confidentiality will be protected. If he decides to proceed with the application, the information which the Secretary of State regards as not being commercially confidential will be placed on the register.

In practice, this process will in most cases take the form of a dialogue between the applicant and officials. Applicants are encouraged, where appropriate, to discuss release proposals with officials informally before submitting a formal application to the Secretary of State. Such discussions will be in confidence and will help to avoid the withdrawal of applications because of commercial considerations relating to information which is formally required to be entered on the register.

The information placed on the register will follow, in principle, the agreement of the competent authorities of all the EC Member States on the interpretation of the information that cannot be kept confidential:

i. Description of the GMO

The following points may provide a description of the GMO, but in cases where patents have not yet been applied for (this may apply particularly to release applications), only that information will be made available that will not prejudice the patentability:

For releases: Identity of the GMO, including the trait; the complete name of the recipient or of each parental organism; information relating to the method of genetic modification; for modifications where base substitution occurs, description of the original function of the gene in which the base substitution occurred and the function of the modified gene.

For marketing: Identity of each GMO contained in the product;introduced/modified traits and genes responsible for these traits; complete name of the recipient or of each parental organism; complete name of the organism from which the insert is derived; information relating to the genetic modification; function of each inserted DNA or RNA sequence or of deleted sequences; for modifications where base substitution occurs, description of the original function of the gene in which the base substitution occurred and the function of the modified gene.

ii. Name and address of applicant

The name and official address of the research institute/company/manufacturer/importer etc is meant here. Names of individual persons can be kept confidential.

iii. Purpose

For releases: Objectives of release, and parameters tested

For marketing: Use of product and type of users

iv. Location of the release

Depending on the type of release, this might be the village or town, or, if it is a field release in the countryside, the nearest village or town. An indication of the size of the release site or area and an indication of the expected spread of the organism may be relevant. In some cases , the "wider site" might be given

v. Methods and plans for monitoring the GMOs

In principle, this is likely to be all the information submitted in the application.

vi. Methods and plans for emergency response

Again, this is likely to be all the information submitted in the application.

vii. Evaluation of environmental impact

The register will contain the evaluation of the environmental impact in the form of the risk assessment supplied with the application, although a summary, which will be readily understandable, will also be given.

Advice given to the Secretary of State and HSE by ACRE and ACGM on notifications and consent applications will be among the matters included on the register. To enable the Secretary of State and HSE to consider representations on consent applications, there will be a period allowed to elapse between the placing of advice from either committee on the register and their taking a decision on the application. This period cannot be fixed since the date of receipt of applications in relation to meetings of the advisory committee is not known. Applicants will be encouraged to file applications several weeks in advance of a meeting in order to allow adequate time for scrutiny, but the final decision will have to be taken within a 90 day period.

[Examples of register entry to be prepared.]

KEEPING OF THE REGISTER

Regulation 17:

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(1) The information prescribed in regulation 16(2) shall be placed on the register within fourteen days of the prohibition notice being served.

(2) The information prescribed in regulation 16(3), (5) and (6) shall be placed on the register within fourteen days of its receipt by the Secretary of State.

(3) The information prescribed in regulation 16(4) shall be placed on the register within fourteen days of the granting of the consent.

(4) The register is to be kept at the following offices of Her Majesty's Inspectorate of Pollution:
[Romney House, 43 Marsham Street, London SW1P 3PY]
[addresses of divisional offices]
and at [Scottish equivalent].

Like Integrated Pollution Control registers, registers of information about GMOs will be kept at local and central offices of HMIP and DOE, the addresses of which are available on request. In Scotland, the register will be kept at HSE offices. Inspection of the registers will be free of charge, but there will be a fee charged for copies of entries. People who do not live in the locality of any of these offices may apply for a copy of an extract of the register by writing to any one of the offices.

GUIDANCE TO INFORMATION REQUIRED FOR CONSENTS TO RELEASE OR MARKET GMOS AS PRESCRIBED IN SCHEDULES 1 & 2 AND GUIDANCE TO ENVIRONMENTAL RISK ASSESSMENT

CONSENT TO RELEASE OR MARKET

PART I

GENERAL INFORMATION

1. The name and address of the applicant, and the name, qualifications and training of the responsible scientist and of every other person who will be responsible for planning and carrying out the release of the organisms, for carrying out the release and for the supervision, monitoring and safety of the release.

This part requests general information on the applicant and persons (including a genetic modification safety committee) involved in the release. The name of the applicant will normally be that of a body corporate eg. company, university, institute etc. Details of qualifications and training need be no more than a very short precis of direct experience with GMOs.

For consents to market GMOs, only information relating to the applicant(s) need be provided.

PART II

INFORMATION RELATING TO THE ORGANISMS

Characteristics of donor, parental and recipient organisms

The following section should provide information both on the biology of the recipient or parental organism(s) prior to genetic modification, and on the donor organism(s) from which the genetic material used in the modification was derived. Two sets of data are thus required for each of the points described below with the appropriate level of emphasis and detail at each stage. In most cases, information on recipient (or parental) organisms will be much more relevant to the Secretary of State's consideration of a release than information about donors. Extensive data sets will usually not be required for any one point. The meaning of the terms is set out below:

Recipient: an organism which undergoes a genetic modification, for example, by the introduction of a foreign gene transferred from a second, donor, organism.

Parental: organisms used in cell fusion experiments where the genome of the fusion product is a hybrid of the entire genomes of the two original cells (organisms), neither of which can therefore be considered to be the recipient or donor.

2. Scientific name and taxonomy.
3. Usual strain, cultivar or other name.

For Points 2 and 3, give sufficient information accurately to describe the organism. The common name of the organism should be provided for plants and animals.

Animals: provide details of the order and higher taxon;

Plants: provide the family, genus, species, (sub-species), cultivar;

Microorganisms: provide the genus, species, pathovar and strain.

If it is not possible to classify organisms to these levels, provide as much taxonomic information as possible, including such characteristics as may be useful in placing them in an appropriate taxonomic hierarchy. Appropriate reference to taxonomic literature may also be useful.

4. Phenotypic and genetic markers.

Give details of any recognisable phenotypic characteristics of the organisms. Genetic markers such as antibiotic resistance or heavy metal resistance markers will usually be those used in microorganisms. Markers (phenotypic and genotypic) which can be used to distinguish organisms from natural relatives will be particularly important.

Other relevant information may include genetic and/or restriction maps or lists of restriction sites and other traits such as allozyme patterns. This level of detail is only likely to be required if no simple markers are available and is most appropriate in the case of microorganisms.

5. The degree of relatedness between the donor and recipient organisms or between the parental organisms.

The level of information supplied here should be of the same order as the taxonomic data asked for at 3 above.

6. The description of identification and detection techniques.
7. The sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.

In response to Points 6 and 7, give information on standard methodologies employed or test kits available for identification/detection of the organisms. This information will be particularly useful in the case of microorganisms and will in general not be relevant for vertebrates.

8. The description of the geographic distribution and of the natural habitat of the organism including information on natural predators, prey, parasites, competitors, symbionts and hosts.

Give details of the countries/climatic regions where the organism can be found, either in natural ecosystems or in culture. In the case of plants or animals, provide information on the source of origin and where they are normally found. State whether the organism is usually found in a terrestrial, freshwater, estuarine, coastal, marine or other ecosystem. Expand on the niche the organisms occupy within the identified ecosystem and provide information on known or presumed natural predators, prey, parasites, competitors, symbionts and hosts. Detailed information on natural habitats may be limited, particularly for microorganisms.

9. The potential of the organism for genetic transfer and exchange with other organisms.

Describe whether the organism is able to transfer or exchange genetic information with other organisms and vice versa, e.g. conjugation, cross pollination, cross-fertilisation or other forms of genetic transfer.

10. Verification of the genetic stability of the organisms and factors affecting that stability.

Provide evidence for the stability of the organism and, in particular, provide information on any history of genetic instability such as high mutation rates. Comment on any external environmental factors (eg, UV, $[O_2]$) which could affect the genetic stability of the organism.

11. The following pathological, ecological and physiological traits:

(a) the classification of hazard according to [existing Community rules] concerning the protection of the environment;

This refers to classifications of organisms as hazardous to human, animal or plant health (these classifications reflect "pathological traits"). The relevant classifications are contained in the following Community legislation:

- Directive 90/679/EEC on the protection of workers from risks related to exposure of biological agents at work;
- Directive 77/93/EEC on the protective measures against introduction into Member States of organisms harmful to plants or plant products, as amended until now.
- Directives 64/432/EEC, 64/433/EEC, 71/118/EEC, 72/462/EEC, 82/894/EEC, 90/424/EEC, 90/426/EEC, 91/67/EEC, 91/68/EEC & 91/69/EEC on animal health.

(b) the generation time in natural ecosystems, and sexual and asexual reproductive cycle;

This will be fairly simple to quantify for many multicellular organisms, but nearly impossible for some microorganisms. If no such information is available or easily obtainable for micro-organisms, data on generation times from laboratory studies or

microcosms should be given.

State how the organism usually reproduces and, if by more than one mode, indicate the relative frequency and ecological importance. Any relevant factors affecting the mode and rate of reproduction should be indicated.

(c) survivability, including seasonability and the ability to form survival structures, including seeds, spores and sclerotia;

State known survival forms of the organism, the order of their longevity (e.g. 10-20 years for Fusarium conidiospores, 60 minutes for Nicotiana pollen) and any relevant factors which might affect longevity.

(d) pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses), and ability to colonise other organisms;

State whether the organism is known to be pathogenic to any other organism: if so, provide information on its infectivity, virulence, host range, and ability to colonise other organisms.

Indicate if the organism is a vector of a pathogen or can activate latent viruses. This latter point will be particularly important for organisms which have a wide host range.

(e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

State whether the organism carries antibiotic resistance genes and whether these could be expressed in the final GMO. If so, indicate whether the antibiotic concerned is used for therapeutic purposes for humans or animals.

(f) involvement in environmental processes, including primary production, nutrient turnover, decomposition of organic matter and respiration.

This point is particularly relevant to microorganisms and should be addressed in relation to biogeochemical processes (see Point 72).

12. The sequence, frequency of mobilisation and specificity of indigenous vectors, and the presence in those vectors of genes which confer resistance to environmental stresses.

This point is likely to be relevant only for recipient (or parental) organisms. List known indigenous vectors and indicate whether any of these contain sequences which code for antibiotic resistance, heavy metal resistance or resistance to other environmental stresses.

13. The history of genetic modification and of any application of additional techniques to the organism.

This information is only required if the donor, recipient or parental organism is already a GMO. A precis will suffice if this is the case.

Characteristics of the vector

The following are interpretations of key terms:

Vectors may be RNA or DNA sequences used for introducing the insert into the recipient or parental organism.

Insert means all the sequences donated by a parental or donor organism, together with those of the vector, which remain in the genome of the modified organism. In the case of plasmids or plasmid-derived vectors, the insert comprises sequences from the donor organisms(s) and those sequences from the vector which are useful or necessary for that particular genetic modification.

Although "construct" is not used in the text of schedules 1 & 2, it is equivalent to the term "insert" described above.

Points 14-17 refer to vector-mediated transformations of recipients and need not be answered for other sorts of modification.

14. The nature and source of the vector.

State whether the vector is a plasmid, bacteriophage, virus, cosmid, phagemid, transposable element etc. Give the usual designation (eg, pBR322, M13mp8) and the organism(s) from which it was derived. Details of the sequence of the functional insert present in the GMO should be provided in response to Point 22 below.

15. The sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organism and to make the introduced vector and insert function in that organism.

Provide a genetic map and/or restriction map of the vector, transposons and other non-coding segments used to construct the GMO. This is not the same as the information required at Point 22.

16. The frequency of mobilisation, genetic transfer capabilities and/or methods of determination of the inserted vector.

Give a brief account of the genetic transfer capabilities (eg host range, conditions for transfer) and a best estimate of the frequency of mobilisation. Include a brief description of the methods used to determine that the vector is present/ inserted in host. Reference to published sources of information may avoid an unnecessarily lengthy answer.

17. The degree to which the vector is limited to the DNA required to perform the intended function.

Reference to the information provided in response to Point 15 should help here. Estimate the amount of the vector which is "unnecessary" to the modification (eg no. of base pairs, percentage of base pairs).

Characteristics of the Modified Organism

18. The methods used for the modification.

Precis the methods used referring, where possible, to "standard techniques" or published methods. For example, state whether an Agrobacterium-mediated or other vector-mediated system was used, or whether bioballistics, micro-injection etc. Detail need only be given if steps are novel and relevant to the risk assessment consideration.

19. The methods used -

(a) to construct inserts and to introduce them into the recipient organism

State the organisms from which each constituent part of the insert used in the modification was derived.

Describe the methods by which the insert(s) was constructed: in most circumstances the inserted nucleic acid will consist of promoter sequences, coding regions and non-translated regions. The coding regions could include genes responsible for the production of proteins, which may serve either as selectable markers or scorable markers, and genes coding for the required characteristic (eg herbicide resistance/ insect resistance/toxin production/drug production).

If a vector system was used, the response to Point 15 should have already provided all relevant information.

(b) to delete a sequence;

If the method of modification involves the deletion of sequences, details of the deletion(s) should be given.

20. The description of any insert and/or vector construction.

Any relevant information not contained in Points 14, 17, 21 & 22, should be given here.

21. The purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function.

State whether the insert is limited to sequences which carry out the required function. If not, indicate the size of the

additional sequences, their position in the insert and, if known, their likely function.

22. The sequence, functional identity and location of the altered, inserted or deleted nucleic acid segments in question, and in particular any known harmful sequence.

Provide a genetic map of the insert, or deleted sequence, in the modified organism. Identify the location(s) and copy numbers of the insert in the host, and state whether these are functional and whether they are chromosomally integrated or not. State the function of each part of the insert and draw attention to any sequence which is known to be harmful.

<u>Characteristics of the genetically modified organism</u>

NOTE: In the case of products containing more than one GMO, points 23 to 30 will need to be answered for each GMO contained in the product.

23. The description of the genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

This should focus on the differences (if any) between the recipient organism and the GMO.

Concentrate on major traits which might affect ecological factors such as: disease resistance, host range, survivability, dispersal, loss or gain of significant metabolic activity.

24. The structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organism.

Which sequences have remained in the GMO following modification and what is their function? Give an indication of whether they code for products or whether the sequences are redundant. If details have already been given in Point 22, refer to those.

25. The stability of the organism in terms of genetic traits.

Indicate how stable the GMO is, in particular in comparison to the recipient/ parental, and especially for the introduced trait. If evidence exists for loss of trait(s), quote this (preferably in terms of numbers of generations). If GMOs appear stable, indicate the number of generations over which stability has been measured. Reference to phenotypic expression of traits will be useful but, where possible, this should be backed up with molecular evidence. Reference to the response to Point 10 above may help.

26. The rate and level of expression of the new genetic material in the organism, and the method and sensitivity of measurement of that rate and level.

Give data on the rate and level of expression of the gene(s) inserted. Brief details of the methods used to determine the level of expression will suffice. Reference to standard methodologies by name is preferable to detailed descriptions.

27. The activity of the gene product.

Give results of standard assay procedures, if these exist. Otherwise compare expression to that normally seen in the source organism.

28. The description of identification and detection techniques, including techniques for the identification and detection of the inserted sequence and vector.

State available techniques for identifying and detecting the modified organism in the environment. If specific techniques are needed, give the name of the technique and appropriate detail. For some organisms, eg some plants and animals, detection may simply be by visual monitoring.

State how the presence of the insert is detected. Include simple techniques (eg detection of selectable markers) and molecular techniques, eg. Southern blots, PCR, RNA dot blots, immunoblotting etc.

29. The sensitivity, reliability (in quantitative terms), and specificity of detection and identification techniques.

Supply this information, where possible, for all techniques described in response to Point 28. If quantitative data are not available, respond with comparative qualitative data.

30. The history of previous releases or uses of the organism.

State whether the GMO has ever been released before and, if so, for what purpose (reference to previously submitted applications for consent will be useful here and will avoid the inclusion of unnecessary detail in this response). If the GMO has been used in contained facilities in the past, refer briefly to the use.

31.In relation to human health -

[Guidance to be developed]

(a) the toxic or allergenic effects of the non-viable organism and/or its metabolic products,

(b) the product hazards,

(c) the comparison of the organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity,

(d) the capacity of the organism for colonisation, and

(e) if the organism is pathogenic to humans who are

immunocompetent -

(i) diseases caused and mechanisms of pathogenicity including invasiveness and virulence,

(ii) communicability,

(iii) infective dose,

(iv) host range and possibility of alteration,

(v) possibility of survival outside of human host,

(vi) presence of vectors or means of dissemination,

(vii) biological stability,

(viii) antibiotic-resistance patterns,

(ix) allergenicity, and

(x) availability of appropriate therapies.

PART III
CONDITIONS OF RELEASE

<u>The release</u>

The information supplied in response to Points 32-40 should describe the experiment itself. The level of detail of information required here will depend to a large extent on the degree of complexity of the release experiment. If the application for consent relates to a programme of work, as much information as possible should be supplied at the beginning of the programme. However, plans may change as a programme evolves. For example, it may not be possible to state unequivocally which individual field sites will be used over the duration of the programme at the onset of work. As much accurate information as possible should be given, and further detail supplied to the Secretary of State as it becomes available. The supply of such detail would be made a condition of the consent. Information supplied later could mean that the terms of the consent would require variation. Nevertheless, it should be borne in mind that the risk assessment for the work must be sufficiently detailed to allow a decision on the consent to be made.

32. The description of the proposed deliberate release, including the purpose or purposes of the release and the foreseen products of the release.

Provide a brief statement outlining the aims and objective of the release. State whether final products are expected. If so, describe their intended utility. If the application covers a programme of work, the broad objectives should be described here. Detail is more appropriately supplied in response to Point 33.

33. The foreseen dates of the release and time planning of the experiment including frequency and duration of releases.

This will be particularly important for programmes of work. A list of milestones, or a Gantt chart are preferred alternatives for presentation of the time plan. These should include start times, durations and completion dates for each part of the programme. Where practicable, this information should be provided for each individual release of the GMO(s) on each site throughout the programme. Detail in response to Point 32 for programmes should be integrated into these milestones.

34. The preparation of the site before the release.

Examples of release site pre-treatments include ploughing, application of pesticides, selective removal of organisms, erection of barriers or traps etc. Indicate whether any aspect of site preparation is likely to affect the survival, persistence or dispersal of the released GMO.

35. The size of the site.

State the dimensions of the field site where the release is to take place and of the wider release area which will include any control and/or buffer zones. If a number of sites are to be used, supply this information for each of these.

36. The methods to be used for the release.

Give a summary of the protocol to be used in releasing the GMO. For example, if the release involves plants, state whether they will be planted out as seeds or seedlings, by hand or direct drill etc. Alternatively, if the release involves a rhizosphere microorganism, state how it will be applied: this might be as a seed coating or root dip, by low-volume sprayer, by distribution of dry pellets etc.

37. The quantity of organisms to be released.

Where possible, this should be an actual number. Otherwise, a best estimate should be made. For example: if 30 transgenic poplar trees were to be planted out, an actual number could be provided. However, if a pseudomonad were to be released for bioremediation, a better estimate might be 200l of culture containing approximately 3.4×10^8 cells l^{-1}.

38. The disturbance of the site, including the type and method of cultivation, and mining, irrigation, or other activities.

Summarise any foreseeable sources of disturbance to the site. Further examples of disturbance are, inter alia, ploughing of cultivated land, recent history of subsidence, activities of burrowing mammals and browsing ruminants.

39. The worker protection measures taken during the release.
[Guidance to be developed]

40. The post-release treatment of the site.

Describe any procedures to which the site may be subject following the completion of the release experiment. These should include any planned subsequent experimental activities or standard (eg agricultural) practices to be carried out post release. In some cases, the release will not "finish". For example, after harvest of a genetically modified plant, the site may be treated with herbicide but then monitored for regrowth; microbial releases are likely to require continued monitoring for survival and spread. In such cases, considerations of post release treatments are more appropriately addressed in response to points on monitoring plans.

41. The techniques foreseen for elimination or inactivation of the organisms at the end of the experiment or other purpose of the release.

State how the GMO will be eliminated or inactivated. Techniques could include, for example, hand-harvesting of crop plants followed by a stated number of herbicide applications or sterilisation of soil over a stated period. State known efficacy of techniques if relevant/available.

42. Information on results of previous releases of those organisms, or of organisms of the same type as those which are to be released, and in particular releases on a different scale or into different ecosystems.

If information of this nature is available, provide a brief precis of the relevant details. Source material should be adequately referenced and appropriate attention paid to relevant issues of intellectual property rights.

<u>The environment (both on the site and in the wider environment)</u>

43. The geographical location and national grid reference of the site onto which the release will be made, or the foreseen areas of use of the product.

This point is to elicit information solely on the geographical location of releases, and detail on ecosystems into which the GMO is to be introduced is not appropriate here. If the application is for a consent to release a product, "areas of use of the product" will mean countries or regions where the product is likely to be used.

44. The physical or biological proximity of the site of the organisms to humans and other significant biota.

Physical proximity should be indicated by stating distances of the release site from sites of human habitation or other significant biota where other significant biota will usually mean any species under human control for the purpose of agricultural, industrial or recreational benefit and related wild species.

Biological proximity should be estimated from the likelihood of successful spread/dispersal of the GMO or inserted gene to humans etc.

45. The proximity to significant biotopes or protected areas.

Internationally recognised biotypes or protected areas include those specified by Directive 79/409/EC on the protection of birds, the RAMSAR Convention and RAMSAR Directory of Wetlands, the World Heritage Convention and the Man and Biosphere Programme of the United Nations. They also include national parks, areas of outstanding natural beauty, sites of special scientific interest etc.

46. The size of the local human population.

State the proximity of the release site to local centres (eg, farms, hamlets, villages, towns, cities) of human population. If these are very small, indicate the population size. This need only be stated for areas within the locality of the release: "locality" should take account of the biological proximity of the site to humans as estimated in response to Point 44.

47. The local economic activities which are based on the natural resources of the area.

Briefly state whether the natural resources of the area support economic activity: for example, forestry, hydro-electric power, fisheries, arable agriculture (natural resources here is taken to mean <u>any</u> natural resource and not just those indigenous to the region).

48. The distance to the nearest drinking water supply zone and/or areas protected for environmental purposes.

Examples of protected areas are provided in guidance to Point 45. Microbial releases are likely to be of most concern here as microbes could seep into water sources and eventually into groundwater. Consideration should also be given to gene "products" which might be toxic, or to toxin-producing microorganisms when the toxin could leach from soil into groundwater.

49. The climatic characteristics of the region or regions likely to be affected.

Relevant information here could include average temperatures, rainfall, winds etc. If such data is quoted, indicate the degree of variability. This is likely to be particularly relevant to organisms dispersed by wind or rain splash and to those adapted to a narrow range of climatic conditions.

50. The geographical, geological and pedological characteristics.

Use standard terms to describe sites: for example, chalk

grassland, eutrophic peat bog or estuarine.

51. The flora and fauna, including crops, livestock and migratory species.

Provide a general description of the flora and fauna in the vicinity of the site. State whether the flora and fauna is typical of any particular habitat, for example, that typically found in grassland, heathland, forest, agricultural or wetland areas. If possible, include estimates of the abundance of each major species (eg. hectarage, population size etc.). State whether any of the species are rare or protected under UK law.

52. The description of the target and non-target ecosystems likely to be affected.

Target ecosystems will be those in the immediate vicinity of the release and those targeted for the product. As a consequence of the release, non-target, adjoining ecosystems could be affected. "Run-off" of microbial applications into rivers or lakes could also affect non-target ecosystems.

53. The comparison of the natural habitat of the recipient organism with the proposed site or sites of release.

Describe the site of release eg terrestrial, freshwater, estuarine, coastal, marine or other. Is this the same as the natural habitat of the unmodified recipient/parental organism (see Point 8)? Indicate any differences in the habitat of the proposed release site that would affect growth, performance or survivability of the GMO when compared to the natural habitat eg improved soil conditions, absence of competitors or natural enemies etc.

54. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

Particularly relevant are any planned changes that would increase the spread or persistence of the GMO. For example, the movements of large amounts of earth for landscaping purposes may transport soil borne GMOs or propagules of other GMOs resident in the soil (spores, rhizomes, seeds, eggs etc) into other areas away from the original site of release. Agricultural land may be sold for other uses, construction,recreational etc. In this case, the holder of a consent would need to apply to the Secretary of State for a variation in his consent.

PART IV
THE ORGANISM AND THE ENVIRONMENT

Characteristics affecting survival etc.

55. The biological features which affect survival, multiplication and dispersal.

Describe any features of the organism that would enhance survivability such as the ability of microbes to form specialist structures, eg spores, sclerotia and cysts. State if the organism is able to reproduce itself rapidly, particularly by asexual means. Where applicable, include specific details of generation times, number of generations per year, clonal or vegetative growth, pathogenicity and the formation of seed banks.

56. The known or predicted environmental conditions which may affect survival, multiplication and dissemination, including wind, water, soil, temperature and pH.

Identify the environmental conditions that would initiate the adoption of survival measures and the formation of survival structures. How is the reproductive process affected by environmental constraints, such as temperature, photoperiod, rainfall etc.

57. The sensitivity to specific agents.

Specific agents will include antibiotics, heavy metals, pesticides etc.

Interactions with the environment

58. The predicted habitat of the organism.

Describe the ecological niche the modified organism will be expected to occupy. State if this is likely to be wider than the niche that would be occupied by the unmodified recipient/parental organism or unmodified organism of the same species.

59. The studies on the behaviour and characteristics of the organism and its ecological impact carried out in simulated natural environments, such as microcosms, growth rooms and greenhouses.

Indicate if any of the studies performed in a simulated environment suggest that changes in the characteristics of the organism as a result of genetic modification are likely to have significant ecological impacts when compared to unmodified organisms of the same species.

60. The capability of post release transfer of genetic material

(a) from the genetically modified organisms into organisms in affected ecosystems,

State the probability of the exchange of genetic material with other organisms. In particular, provide information on:

- conjugation, transduction and transformation between micro-organisms;

- transfer of genetic material by viral vectors;

- transfer of genetic material by insect vectors;

- cross pollination between plants.

(b) from indigenous organisms to the genetically modified organisms.

Are any of the processes described above likely to result in the transfer of genetic material from indigenous organisms to the introduced GMO?

61. The likelihood of post release selection leading to the expression of unexpected or undesirable traits in the genetically modified organism.

Is there a possibility that the modification will be linked to other genes that are responsible for the expression of undesirable trait(s)? If post-release selection were to occur in favour of the modification, will the undesirable trait(s) be expressed also?

62. The measures employed to ensure and to verify genetic stability, the description of genetic traits which may prevent or minimise dispersal of genetic material, and methods to verify genetic stability.

Suicide vectors in microorganisms may be used to limit survival, and modifications may be made to plants to produce sterile lines in which case no gene transfer is possible.

For the verification of genetic stability give the frequency of detectable genotypic or phenotypic changes per generation. Where possible, provide numerical data on the stability of the GMO during successive subcultures.

63. The routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact and burrowing.

Is any stage in the life-cycle of the modified organism capable of movement and dispersal unassisted such as in larvae and adults of some species of insects and fish? State any abiotic or biotic constraints that may limit dispersal. For example:

- micro-organisms or their survival structures may be transported by birds or other animals;

- seeds from plants may be transported by insects, birds or animals.

If possible, for each of the main routes of dispersal, provide some quantification of the numbers of modified organisms that would be involved and the distance the organism is likely to be transferred.

State if dispersal mechanisms are unknown.

64. The description of ecosystems to which the organism could be disseminated.

Is the organism likely to be limited to a particular ecosystem? If not, please describe in general terms the type of ecosystem(s) into which the organism is likely to be dispersed eg marine, coastal, freshwater, heath, forest, agricultural etc. Indicate if the ecosystem(s) contains target or any other organisms which may be affected.

Potential environmental impact

65. The potential for excessive population increase of the organisms in the environment.

If the modification is likely to result in the organism having a competitive advantage, what other factors are likely to be important in preventing excessive population growth?
These will include mortality factors that are independent of population size (density-independent population regulation) and mortality factors that increase with population size (density-dependent population regulation).

66. The competitive advantage of the organisms in relation to the unmodified recipient or parental organism.

Is the genetic modification designed to improve the performance of the organism? These will include modifications that promote growth, increase the tolerance to harsh environmental conditions such as high temperature or pH, broaden the host range etc. What is the probability that the modifications will also confer a significant competitive advantage over recipient or parental organisms?

67. The identification and description of the target organisms.

If the target organism is a microbe, include details of the method of detection and the sensitivity of the technique. If identification of higher organisms is not straightforward then also provide details of any special procedures used. This might include molecular probing, use of specific keys, comparison with reference collections etc.

68. The anticipated mechanism and result of interaction between the released organisms and the target organism.

For modified biological control agents, explain exactly how the target organism will be affected and the cause of mortality. If the modified organism is designed to improve the performance of another organism, for example root nodulating bacteria intended for plant growth promotion, explain how the process will occur.

69. The identification and description of non-target organisms which may be affected.

This may be of particular relevance to biological control agents. Identification should be carried out in a similar way as that described for target organisms (Point 67).

70. The likelihood of post release shifts in biological interactions or in the host range.

Describe the original host range of the non-modified organism. Is there any evidence of the modified organism switching to another food source or to another host in times of stress? Has the biological host range been broadened or narrowed by the genetic modification either intentionally or unintentionally? Will the selection pressures following release be likely to change the host range in any way?

71. The known or predicted effects on plants and animals and non-target organisms in the environment, impact on population levels of competitors, prey, hosts, symbiont, predators, parasites and pathogens.

Describe how non-target organisms within an ecosystem to which the modified organism has disseminated are likely to be *directly* affected. What effect is this likely to have on population dynamics and species composition?

For example:

- If the GMO is a biological control agent does its host range extend beyond the target organism?

- are plants or animals modified to be toxic to certain insects likely to have an effect on non-target or beneficial insects?

Which other non-target organisms are likely to be *indirectly* affected? Is the modification likely to confer an advantage that will alter the competitive or natural balance between species within the community of introduction? For example:

- a GMO released as a biological control agent may create a vacant niche for the potential invasion by a similar organism that would otherwise have been previously suppressed by the target organism

- the target organism may be involved in a complex food web, the removal of which would result in the loss of species at several levels

- a crop plant modified for insecticide resistance may become invasive of habitats from which it was previously excluded as a result of an increase in competitive ability

- modified root nodulating bacteria may promote extensive growth also resulting in a crop plant becoming invasive due to an increase in competitive ability

Consider any effects of a successful invasion into non-target

habitats.

72. The known or predicted involvement of the organism in biogeochemical processes.

State whether the recipient or parental organisms play a key role in any of the major cycles, for example, carbon, nitrogen and sulphur. Is the modification likely to change the status the organism plays within a cycle and what is the overall predicted result? Examples include organisms that are modified to fix atmospheric gases such as nitrogen.

73. Any other potentially significant interactions of the organisms with the environment.

Include any interaction considered to be of importance that is not adequately covered elsewhere.

PART V
MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY PLANS

Monitoring techniques

74. Methods for tracing the organisms, and for monitoring their effects.

In the case of microorganisms provide details of any molecular techniques that are envisaged for detection. Describe how differences between the parental/recipient and modified plants and animals will be determined if there are no obvious phenotypic differences. Will molecular or other techniques be adopted?

How will unconstrained modified animals, such as genetically modified fish or insects, be monitored? Which sampling methods will be adopted? Consideration should also be given to the likely effects of the release, and how these effects might be followed.

75. Specificity (to identify the organisms, and to distinguish them from the donor, recipient or the parental organisms), sensitivity and reliability of the monitoring techniques.

What are the detection limits using molecular techniques? Are the performance and accuracy of the detection methods likely to change with the use of actual environmental samples? How efficient are the sampling processes for monitoring animals such as fish or insects?

76. Techniques for detecting transfer of the donated genetic material to other organisms.

Describe any molecular or other techniques envisaged to detect transferred genetic material in other organisms, indicating the expected limits of detection.

77. Duration and frequency of the monitoring.

If the same GMO is to be released at several sites or a number of different GMOs to be released at one site, the frequency and duration of monitoring may usefully be summarised in a table.

Control of the release

78. Methods and procedures to avoid and/or minimise the spread of the organisms beyond the site of release or the designated area for use.

If the GMO is likely to persist in the environment, list any natural constraints that would limit the spread from the point of introduction eg altitude, temperature, rainfall.

Describe the other measures that will be taken to contain the GMO to the site of release, taking into account, for example, fencing, trenching, netting or ditching to enclose the released organisms or exclude their vectors; removal of any escapes from the site of release by physical, chemical or other methods.

79. Methods and procedures to protect the site from intrusion by unauthorised individuals.

Please state if the site of release or the surrounding area is either public or private. If private, are the public normally allowed access? Are there any plans for extra security measures such as the erection of fences, use of specialist security staff or regular security patrols, use of close circuit TV.

80. Methods and procedures to prevent other organisms from entering the site.

This should cover any measures not already specified in Point 78.

Waste treatment

81. Type of waste generated.

Indicate whether, for example, the waste material is plant material, whether it is liquid or solid waste and whether it contains live GMOs with or without products.

82. Expected amount of waste.

State the expected amount of total waste at each release site

83. Possible risks.

Describe the toxicity of the waste and indicate the capacity of the waste for causing harm.

84. Description of treatment envisaged.

Provide information on the fate of the waste. For example, it might be:

- disposed of in a landfill site
- flushed out to sea
- autoclaved
- incinerated
- fed to cattle

Describe the efficiency and safety of the disposal process.

Emergency response plans

85. Methods and procedures for controlling the organisms in case of unexpected spread.

Provide details of any physical and chemical methods that are envisaged to isolate and render the GMO inactive. State the efficiency of these methods.

86. Methods, such as eradication of the organisms, for decontamination of the areas affected.

Is decontamination of the site likely to be immediate or take place over an extended period of time? State the probability of success of restoring the site to its pre-release state.

87. Methods for disposal or sanitation of plants, animals, soils, and any other thing exposed during or after the spread.

Will contaminated material be disposed of in a manner described in Point 84? If sanitation of exposed organisms is possible how long will this take? Is quarantine proposed for higher animals?

88. Methods for the isolation of the area affected by the spread.

Outline plans to evacuate any livestock and other fauna that might be adversely affected and to prevent any further entry.

89. Plans for protecting the environment in case of the occurrence of an undesirable effect.

Describe any other procedures that will be adopted to prevent environmental damage if unexpected events occur.

SCHEDULE 2

CONSENT TO MARKET

PART I
GENERAL INFORMATION

1. The name of the product and the name of the genetically modified organisms in the product.

Provide the commercial name and any other name by which the product is known. Give the name and nature of each type of GMO contained in the product but include only the name of the

recipient or parental organism(s) with an indication of the modified genetic function(s) provided by the donor organism(s).

For each type of GMO included in the product, indicate the type of biological entity (viroid, RNA virus, DNA virus, bacterium, fungus, plant, animal etc).

2. The name and address in one of the member States of the manufacturer or distributor of the product.

3. The specificity of the product and the exact conditions of use including, where appropriate, the type of environment and/or the geographical areas within the member States for which the product is suited.

Give details of the particular properties of the product concerning its use (e.g. toxic action on a particular group of insects). For the conditions of use, the frequency and method of application, dosage, measures to protect the user, organisms on which the product is used, and restrictions on use (e.g.not to be used in the summer months, in drought, in rainy season, etc) might be entered.

A general description of the environment/geographical area(s) should be provided, for example, agricultural land, forestry, horticultural land, contaminated land, mines,industrial fermenters, laboratories, parts of buildings, animal farms, fisheries, marine environment, recreational areas, medical and veterinary practise, food for general use, others. Where more detail is appropriate, it should be provided.

4. The type of expected use of the product and the description of the persons who are expected to use the product.

Indicate whether the product is a vaccine, pesticide, crop plant, ornamental plant, bioremediation agent, diagnostic reagent, food, food ingredient etc

Also indicate whether the product will be used in industry, agriculture, skilled trades, contained use facilities, state agencies or by consumers, etc. If there are multiple users this should be stated.

PART II
ADDITIONAL RELEVANT INFORMATION

5. The measures to be taken in the event of the escape of the organisms in the product or misuse of the product.

This question should be answered by those proposing to market GMO products intended for use in contained use facilities as well as products to be used in the environment. Relevant points to consider would be procedures needed in cases of:

-microbial escapes (products such as diagnostic kits, vaccines,

biopesticides and bioremediation agents etc.

- plants growing in areas not recommended which could result in environmental damage.

- animals escaping into areas where their use/presence is not recommended (escapes from containment, eg biocontrol agents being used in glasshouses

If the product was misused, what action would be taken to protect both the environment and human health and safety?

6. Specific instructions or recommendations for storage and handling of the product.

7. The estimated level and amount of production of the product within the member States of the Communities and the estimated level and amount of imports of the product into those member States.

8. Information regarding the proposed packaging for the product and its appropriateness so as to avoid the escape of genetically modified organisms during storage or at a later stage.

The information given here should be appropriate so as to avoid unintended release of GMOs during storage or at a later stage

9. Information regarding proposed labelling including the proposals for stating, in full or summarised form, the information prescribed in paragraphs 1 to 3, 5 and 6 above.

ENVIRONMENTAL RISK ASSESSMENT:

RELEASE OF GENETICALLY MODIFIED ORGANISMS

GENERAL CONSIDERATIONS AND APPROACH

1. An environmental risk assessment for the release of GMOs is in essence no different from any other type of risk assessment i.e. firstly an identification of the hazards and then an evaluation of the likelihood that specific hazardous events will be realised; this is the risk.

2. **A hazard is a characteristic (biological, chemical or physical) which if manifested would cause harm to the environment. It thus reflects the potential for harm.**

3. Hazardous characteristics, with regard to organisms, are intrinsic properties of organisms that could cause environmental damage. An example of this is pathogenicity or the potential for harmful exchange of genetic material with related species. **Hazards are independent of the characteristics of a release.**

4. **The risk is the likelihood that the hazard will be realised, ie the likelihood that a specified undesired event will occur within a specified period or in specified circumstances.**

5. For example, the likelihood that oil seed rape modified to express an insect toxin will transfer genetic material to non-modified rape planted immediately adjacent to it is high; therefore the risk of harmful gene transfer is high. Similarly, because it is unlikely that a storm force wind would occur in June, the risk of increased pollination distances by this means is low. **The risk is dependent upon the characteristics of the release and the receiving environment since these determine which, and to what extent, potential hazards will be realised.**

6. The Genetically Modified (Deliberate Release) Regulations 7(1)(c) and 12(2)(b) require an applicant for a consent to release or market to submit a statement evaluating the impacts and risks posed to the environment by the release or marketing of the organisms.

7. In accordance with the step-by-step principle, the assessment of hazards and risks associated with the final GMO could be based on the results of previous biological and ecological studies, if these are available and appropriate.

INDIVIDUAL STAGES IN RISK ASSESSMENT PROCESS

8. There are a number of stages in estimating the overall risk of a release of a GMO (Figure 4). At each stage, brief reasons for any assessment should be given. The key assessments are:

I. HAZARD IDENTIFICATION

9. Firstly, all the potential hazards associated with a GMO are identified. In most cases, it will be useful to consider 5 key areas in order to identify the hazards. These areas are:

i. Potential for transfer of genetic material between the GMO and other organisms

ii. Phenotypic and genetic stability

iii. Pathogenicity

iv. Potential for survival, establishment and dissemination

v. Other negative effects on organisms (target and non-target effects).

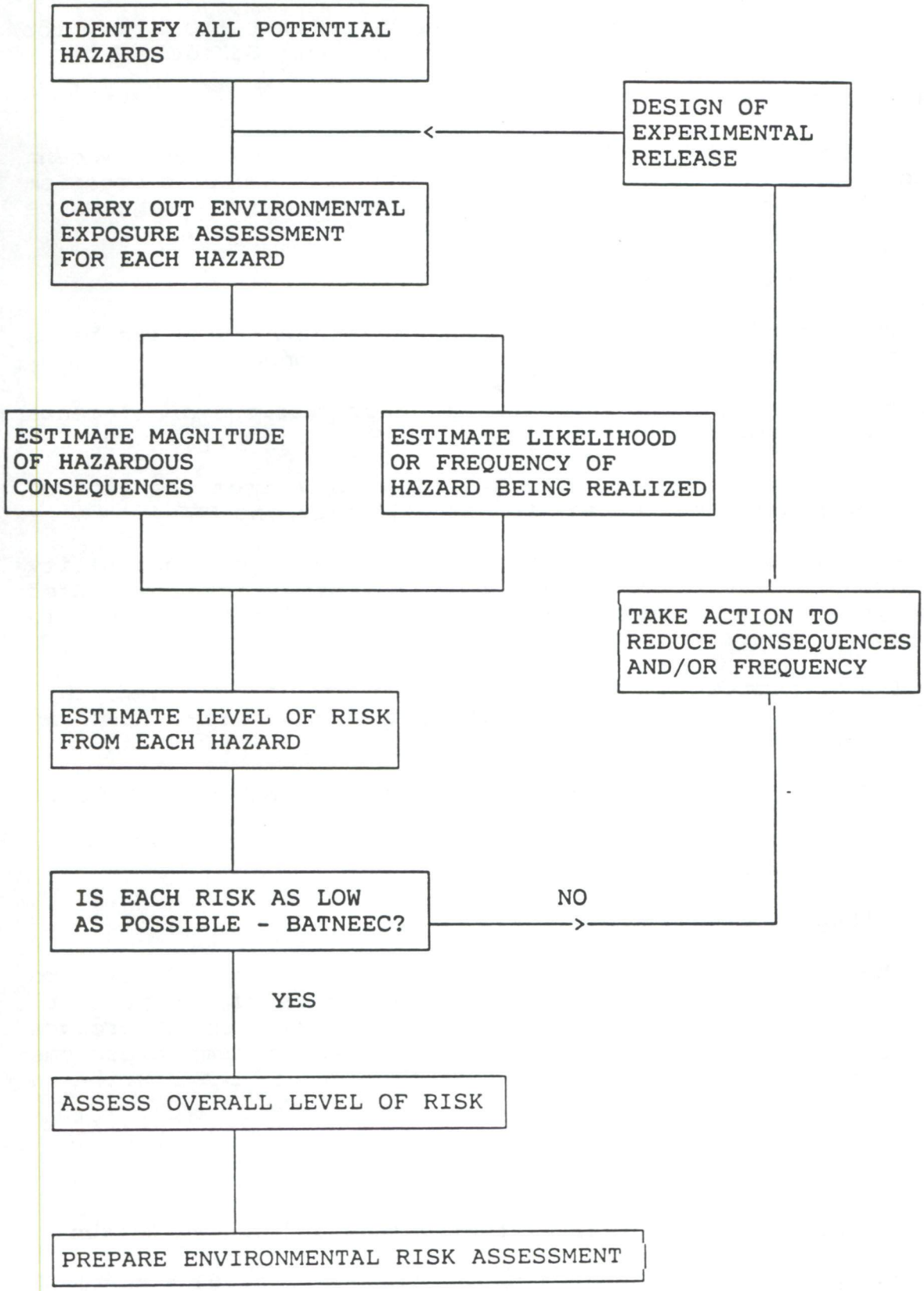
10. For each hazard identified, the characteristics of the organism which are relevant to the hazard should be considered. As a rule, it will be appropriate to consider the characteristics of both the parental or recipient organism, and the final GMO. If, for example, the recipient organism exhibits pathogenic or invasive attributes, or is genetically unstable prior to the modification, the final GMO is likely in most cases to exhibit the same characteristics or hazards.

11. There are likely to be particular points which should be considered for each of the above hazard areas. These are outlined below, together with the information provided under Schedule 1 which is likely to be relevant. The specific points are indicative rather than definitive, however. Examples have been chosen to reflect particular hazards related to the types of modifications and releases currently being undertaken.

i. Potential for transfer of genetic material between the GMO and other organisms

12. Those characteristics of the parental organism and the GMO which could lead to the undesirable spread and establishment of the inserted genetic material in other organisms should be identified. For example, if insect resistance genes are inserted into a crop plant, their transfer to wild relatives could increase their potential for invasiveness; such gene transfer would therefore be harmful and thus, present a hazard. However, in some cases, the transfer of certain marker genes, such as GUS, to other species might not be considered to be harmful. Such gene transfer would not constitute a hazard.

FIGURE 4 : STAGES IN RISK ASSESSMENT



13. It might also be relevant to consider whether the method of modification is likely to increase the potential for genetic exchange between the GMO and other organisms. [Example]

14. The hazard(s) might be assessed on the basis of the following points of information required under Schedule 1:

9, 12 and 16.

15. However, there might not be any hazard related to gene transfer, such as in the case of a genetically modified organism which is sterile with an inserted vector that can not be transferred.

ii. Phenotypic and genetic instability

16. The hazards in this area should be identified on the basis on consideration of the following types of concern:

- genes inserted into the GMO on extrachromosomal elements might be lost or inactivated

- the inserted genetic material might move from the site of insertion and thereby affect the stability of the GMO

- genetic instability might lead to phenotypic instability with adverse environmental effects (potential for unexpected phenotypes and genotypes in the modified organism or in subsequent generations)

- the inserted genetic material might be inserted into different parts of the genome producing variability in expression.

17. The relevant points of information from Schedule 1 to be considered in assessing the hazard(s) are:

10, 25, 26 and 27.

iii. Pathogenicity

18. The characteristics of the GMO which are relevant to pathogenicity are due to those characteristics of the parental or recipient organism and the final GMO that could produce disease in either plants or animals. [List of some organisms classified as pathogens.] The relevant points of information in Schedule 1 are:

8, 11a, and 11d.

iv. Potential for survival, establishment and dissemination

19. Hazards can be identified by focusing on particular survival forms of the parental organism and the GMO, and characteristics of the GMO that are important for its establishment and

dissemination. The relevant points from Schedule 1 are likely to be:

Parental organism: 8, 11b, 11c, 11d, 11f

GMO: 23, 26, 55, 58, 63, 66, 72, 73

20. For a genetically modified plant, the viability of pollen, seeds, and any vegetative structures would need to be considered.

v. Other negative effects on organisms (target and non-target effects).

21. Consideration should be given to the trait expressed and its effect on other organisms. GMOs such as microorganisms used as agricultural inoculants may be modified to express compounds which are not known to be toxins, but which could have an effect in the environment.

22. The ability of the parental and GMO to exert a significant negative effect on indigenous organisms and any contribution of the gene product(s) to this should be considered. This might be the desired effect of the modification. The relevant points of information in Schedule 1 are:

11a, 11d, 26, 27

Examples:

Gene expressing known toxic compounds or compounds which may have an effect on exposed flora and fauna

The concerns in this case are that:

- the gene product (or intermediates of the gene product) could reduce the population of a pest species to a level which may have a negative effect on ecosystems by, for example, removing a food source for other organisms

- the gene product could kill and reduce populations of native flora and fauna which are not targets of the GMO or of its product(s)

- the GMO or its products could affect the reproduction of native flora and fauna

- consumption of the GMO or its products by flora and fauna could impair their health.

Gene expressing viral coat proteins

In this case, it is necessary to identify the characteristics of the GMO that could underlie:
- the possible evolution of new viral pathogens by

recombination events

- the possible transmission and replication of viruses in other plants as a result of transencapsidation.

II. ENVIRONMENTAL EXPOSURE ASSESSMENT

23. This stage consists of considering the characteristics of the receiving environment that are likely to play a role in causing the hazards to be realised. Climatic, geographical and pedological conditions, and the types of flora and fauna in the receiving environment are examples of important factors. Thus, using the example in paragraph 21 of genes which express toxic compounds which affect certain flora and fauna, the identification of the particular flora and fauna at and surrounding the proposed site of release will be important. In most cases, both the release site and the wider environment (the environment to which the GMO or its survival forms could be disseminated) should be considered.

24. For example, the presence of weed beet in an area adjacent to a release site of genetically modified sugar beet will affect the extent of successful gene transfer. Similarly, the presence in the area near the release site of, say, oil seed rape, of a large number of pollinators provided by beehives may contribute significantly to the extent of gene transfer. Any potential effects on soil, water or air quality should also be considered.

25. For any one release, the environmental assessment is likely to be very similar for each of the five hazards. The basic information required for this assessment will, in most cases, be covered by consideration of the information provided under specific points in Schedule 1, viz:

Points 33, 34, 35, 36, 37, 40, 41, 43, 44, 45, 48, 49, 50, 51, 53, 56 and 64.

26. In addition, when considering the risk from realisation of the harmful transfer of genetic material, the potential for genes to be transferred from indigenous relatives into the GMO, thereby affecting the expression of the insert and/or stability of the GMO might need to be considered.

27. When considering pathogenicity, the presence in the receiving environment of any host organisms will be of particular importance.

Example

For the environmental exposure assessment, the relevant considerations for gene transfer from a genetically modified plant to related species will be how much pollen is produced, and whether:

- there are potential recipients of pollen from the genetically modified plant in the vicinity of the release

- the recipients flower at the same time and may therefore receive pollen

- cross pollination between these plants is known to occur

- the necessary vectors involved in pollen transfer are present

- fertile hybrids are likely to be produced as a result

- there are any other methods of gene transfer, such as between the genetically modified plant and microorganisms

III. ESTIMATING MAGNITUDE OF HAZARDOUS CONSEQUENCES AND ESTIMATING RISK

28. There are two elements to this stage of the risk assessment:

i) estimating the extent or seriousness of the consequences of the hazards if they are realised

ii) estimating the likelihood or frequency with which the hazards will occur.

29. For each hazard, the factors to be taken into account will include the characteristics of the GMO, the numbers of GMOs to be released, the frequency of the release(s), and the period of exposure of the environment to the GMOs i.e. the scale and purpose of the release.

30. For example, some events, such as the transfer to and subsequent expression in grasses of a gene expressing an alkaloid highly toxic to ruminants, would be of high consequence. However, if that gene were located in a bacterial species applied to the soil, the probability of the transfer actually occurring would be exceedingly low. Consequently, the risk of grass producing the alkaloid would be "low". This event could be said to be of high consequence but low probability. Other events might be of low consequence and high probability. When considering the release to the environment of GMOs, many events are likely to be of low consequence and low probability.

31. When GMOs are released for small scale R & D purposes, the environment will often be exposed to these organisms for only a limited period, and therefore the frequency with which a particular hazard occurs is likely to be relatively low. The effect on the environment, i.e. the consequences, may be immediate or delayed, short-lived or persistent. However, as R & D releases are usually terminated within a defined period of time, the probability of persistent or delayed effects will often also be low. Nonetheless, if the frequency with which a hazard is realized is low, any increase in scale will mean an increase in risk, even though the overall risk may still be low.

32. On the other hand, GMOs marketed for release may have a prolonged environmental effect as their use will, in most cases, not be limited. However, the magnitude of any realisation of the hazards (i.e. the consequence) is likely to be low for the majority of products which have undergone appropriate trials. But the likelihood of widespread and regular applications should be considered in estimating the frequency of realisation.

33. For products intended for contained use applications, the frequency estimation will need to include any incidental release of organisms and to take into account an assessment of the implications of any failure of the containment i.e. accidental release, when large numbers of organisms might be released to the environment.

IV. ESTIMATION OF LEVEL OF RISK

34. The level of risk for each hazard is derived from the two estimates of consequence and probability. It should be expressed as high, medium, low or effectively zero.

35. If any individual risk proves not to be "low" or "effectively zero", it should be reexamined to see how other management practices might be used to reduce the level of the risk. This can be achieved either by reducing the magnitude of the consequences, and/or by reducing the probability or frequency.

36. Consider, for example, an R & D release of genetically modified sugar beet with a gene which is believed to increase plant vigour and seed set. Transfer of this gene to natural beet populations might render these plants more invasive than hitherto. The consequence of this event could therefore be high. In an early R & D trial evaluation of the phenotypic effect of this gene would have to go hand in hand with safeguards to prevent such gene transfer. These safeguards might include locating the release at a sufficient distance from natural populations, or prevention of flowering of the trial plants. The first of these safeguards would result in a low risk whereas the second in effectively zero risk. Reexamination of the design of the experiment should allow the frequency of the hazard being realised to be reduced, thereby reducing the level of the risk.

37. Such considerations need to be borne in mind when estimating the level of risk and judging whether, using the best available techniques not entailing excessive cost (BATNEEC), the risk of causing damage to the environment has been prevented. If not, modification of the experimental design or protocol will be required to reduce them further. It will then be profitable to take into account the sensitivity of certain parameters; adjustment to these will have a proportionately large effect on the level of risk. The risk assessment should then be performed again, until the risks are indeed as low as is consistent with BATNEEC and preventing any damage to the environment. Thus, the process is iterative.

38. Again, as an example, the risk for survival and establishment for a release of spring flowering oil seed rape might be high, because of the intention to allow full flowering, and because of the presence of winter flowering rape within 100 m of the release site. By using more extensive guard rows, however, biological containment might be increased, and more extensive monitoring for and removal of volunteers might reduce the extent of establishment. However, the simplest approach would be to ensure that the release took place sufficiently late to ensure that there was no overlap in flowering. This would lower the frequency of formation of fertile hybrids and therefore lower the risk of survival and establishment.

V. OVERALL RISK ASSESSMENT

39. After reiteration, the probability that each hazard will be realised is assessed as a "high", "medium", "low" or "zero" risk. The overall risk is a compound of the individual components of risk.

40. The final stage of the risk assessment is to consider the risks arising from each hazard, and then to evaluate the risk overall of the release causing damage to the environment. The type and magnitude of the overall risk should be assessed as it will constitute a major part of the Secretary of State considerations in making his decision on the consent.

41. If the levels of risk for each of the following hazards were:

1.	Harmful transfer of genetic material	:medium
2.	Phenotypic and genetic stability	:effectively zero
3.	Pathogenicity	:low
4.	Survival and establishment	:medium
5.	Other effects on organisms	:low

there would clearly be a tendency towards low risk. If the procedure outlined above had been followed, these would be the lowest practicable levels of risk consistent with BATNEEC and prevention of damage to the environment. In the overall statement therefore, it would then be necessary to evaluate these components: if the inserted gene conferred resistance to insects but the total number of flowering plants was to be small, the final assessment might be that the overall risk of damage to the environment would be low.

42. The full risk assessment will be placed on the public registers established under regulation 17. It should therefore include a summary of the risks written, as far as possible, in non- technical terms.

EXAMPLES OF RISK ASSESSMENT

The two examples set out below are both of low risk releases. However, the first of these is intrinsically low risk, whereas the second is low risk because of appropriate management startegies.

Worked Example 1

The following worked example is for guidance only and is not presented in the level of detail which might be required for a genuine release. The intent is to guide proposers through the *process* of a risk assessment, not to provide a blueprint.

Scenario:

A proposer wishes to release a rhizosphere-colonising *Pseudomonas spp.* strain, modified for production of chitinase, which confers a degree of protection to the plant against infection by root-infecting fungi. In particular, the take-all fungus, *Gaeunomannomyces graminis* var *tritici*, is a prime target.

The *Pseudomonas spp.* in question is a poor competitor for soluble sugars, so tends usually to be found in senescing tissues where there is a short-term abundance of nutrients. This makes it a particularly common resident in the rhizosphere of cereals and grasses (where root senescence is common-place) but less so in most other species, although it does occasionally occur at meristematically active zones.

The modification involves a construct which is stably integrated into the *Pseudomonas spp.* chromosome as a single copy and consists of a chitinase gene with its origin in a *Pythium spp.* together with promoter and terminator sequences from *E.coli*.

Detection of the organism is *via* selection on a chitin-based medium, simple chitinase assay or direct probing of unique shoulder sequences between the *E.coli* promoter and the *Pythium spp.* functional gene.

RISK ASSESSMENT

STAGE 1: HAZARD ASSESSMENT

All potential hazards should be identified in this stage (although this exercise will pick on only a few of the possible hazards). Each of the five key areas identified in the main text (para 9) should be considered in turn.

(i) Potential for gene transfer

(See my answer to point 9 in Schedule 1)

There is no reason to suspect that the GMO is different in this respect from the recipient *Pseudomonas spp.*.

Possible occurrences are:

(a) transfer of chitinase gene to other pseudomonads

(b) transfer of chitinase gene to other microorganisms

(c) transfer of chitinase gene to plant

(d) transfer of other introduced microbial genes to any of the above.

(ii) Phenotypic and genetic stability

(see my answer to point 10 in schedule 1)

There is no reason to suspect that the GMO is different in this respect from the recipient *Pseudomonas spp.*.

(a) expression of the chitinase gene increases

(b) expression of the chitinase gene decreases

(c) expression of the chitinase gene fluctuates

(d) part of the construct is deleted resulting in the production of a new gene product

(e) the entire construct is repeated in the genome resulting in multiple copies leading to (a) above.

(iii) Pathogenicity

The recipient *Pseudomonas spp.* is not listed or considered to be a pathogen of plants or of any other organism. The donor *Pythium spp.* is often found associated with diseased plants, although there is no convincing evidence that it is a pathogen of these. However, there is some evidence that it can act as a mycoparasite and the production of chitinase is implicated in this ability.

Possible hazards:

(a) expression of the chitinase gene makes the introduced *Pseudomonas spp.* pathogenic to the take-all fungus

(b) expression of the chitinase gene makes the introduced *Pseudomonas spp.* pathogenic to other fungi, in particular to "beneficial" fungi such as VA mycorrhizal fungi

(c) expression of the chitinase gene makes the GMO pathogenic to the plant

(d) expression of the chitinase gene makes the GMO pathogenic to another organism

(e) insertion of the construct causes a genotypic change which results in non-intended pathogenicity to an organism

(f) the recipient *Pseudomonas spp.* is unexpectedly pathogenic despite its absence from lists of pathogens, as is the GMO.

iv. Potential for survival, establishment and dissemination

Populations of the recipient *Pseudomonas spp.* are found commonly in the rhizosphere of wheat, and in lesser numbers in bulk soil under wheat, but do not persist for long in soils following rotations. Little information is available about the longevity of individuals. However, in laboratory tests the introduced organism disappears quickly (10 days) in soil which is isolated from plant roots.

The donor *Pythium spp.* is a common member of the soil flora, and forms characteristic resting structures in soil which may survive for some years. However, chitinase activity is not thought to play any role in the formation of the resting spores or of survival. It may, however, increase the ability of the organism to colonise new sites by virtue of its implicated role in mycoparasitism.

Possible hazards associated with the GMO:

(a) the introduced *Pseudomonas spp.* survives longer in its vegetative state by virtue of an improved ability to compete with other soil bacteria due to chitinase activity;

(b) The introduced *Pseudomonas spp.* is better able to spread into new soil habitats due to its improved competitive ability (and perhaps pathogenicity);

v. Other negative effects on organisms

Possible hazards might be:

(a) production of a new toxic intermediary metabolite associated with the expression or activity of chitinase in the recipient organism;

(b) unexpected negative effects arising as a consequence of possible changes to the normal rhizosphere microflora of wheat.

STAGE II. ENVIRONMENTAL EXPOSURE ASSESSMENT

Having identified all possible hazards associated with the release of the GMO, the next stage is to assess whether the conditions of the release (eg location, climate, management practices etc.) might influence the likelihood of the hazard being manifested. For example, if the GMO in this example were to be released in water rather than an agricultural soil, the organisms to which it would be exposed would be significantly different.

i. Transfer of Genetic Material

The release environment envisaged would present no limitations to the manifestation of the hazards indicated.

ii. Stability

The environment is not thought likely to affect the likelihood of the manifestation of any of the indicated hazards.

iii. Pathogenicity

The GMO will be exposed to a large variety of soil fungi (including the target species and VA mycorrhizal fungi) and bacteria and to plants. Thus, the environment into which the GMO will be released will provide almost unlimited access to the possible host species identified in the hazard assessment.

iv. Potential for survival etc.

The organism is likely to be introduced as a seed coating, so there is only very limited scope for transfer of the GMO by tillage prior to harvest. There is, however, some scope for spread of the organism as a consequence of normal farm management procedures - eg nitrogen dressing etc.

v. Other negative effects

No environmental influence foreseen.

STAGE III. ESTIMATING MAGNITUDE OF HAZARD AND RISK

i. Transfer of Genetic Material

Exchange of genetic material between *Pseudomonas spp.* is well documented (Bloggs, 1982; Johnson & Johnson, 1987; Heinz, 1992). However, the vast majority of gene transfer observed is associated with plasmid transfer, and there is little evidence for high frequency mobilisation of chromosome integrated genes, although this can occur. Heinz (1992) estimated a frequency of 10^{-12} for transfer of a 1kB sequence. The total construct is 75kB and the gene for chitinase production is 43kB. Consequently, the probability of complete transfer of a functional gene is vanishingly small.

Transfer of functional genetic material (any of a, b, c or d) is thus a LOW risk.

The consequence of the successful transfer of the chitinase gene is unknown. However, a number of soil-inhabiting fungi produce chitinase as do some bacteria. None of these organisms is regarded as being particularly successful or to be a particularly aggressive parasite. Chitinase production in the modified *Pseudomonas spp.* is thought to give a small selective advantage only because of the close association between the bacterium, the target pathogen and just senescing host root cells. Thus the

consequence of successful transfer of chitinase activity to another organisms (micro-organism or plant) is likely to be LOW.

ii. Stability

There is no reason to expect inherent instability in the expression of the chitinase gene. *In vitro* tests have demonstrated that the integrated construct is as stable in the GMO as are other chromosomal genes (Heinz, 1992b). The most likely consequence of altered expression of the gene would be a change in phytoprotective capability of the GMO: it is considered more likely that expression levels would drop rather than increase (given that the strain used in the experiment is the best of 215 tested using a chitinase assay), so the worst outcome would be that the GMO would give no more protection than the recipient, unmodified strain. Thus, both probability and consequence are deemed to be LOW. We would use a similar argument to estimate a LOW probability/ consequence of multiple inserts occurring.

Our chitinase gene is approximately 43kB, and it is theoretically possible that a partial deletion could result in the production of a new gene product (the closest sequence homology we can detect of random fragments is less than a 85% match to any known product). However, the probability of this occurring and maintaining functional promoter and terminator sequences must be extremely LOW indeed (we make a guesstimate of less than 10^{-12}). Furthermore, since the theoretical new product is not identified, the consequence of its theoretical production can not be assessed.

iii. Pathogenicity.

We consider probability and consequence for each of the identified hazards:

(a) this is the intention of the introduction.

(b) chitin is a common component of fungal cell walls, in particular the Zygomycetes. Consequently, it is unlikely that chitinase will be very specific in the rhizosphere. Furthermore, VA mycorrhizal (VAM) fungi may use nutrients from senescing cells to boost their inoculum potential for infection of roots and are often found in close association with the GMO. In glasshouse trials, infection of young wheat roots by VAM fungi was reduced by 30% when the GMO was present; however, this had negligible effect on the growth of the host plant. Thus, the likelihood of the GMO reducing the population of VAM fungi is HIGH, but the consequence of this is LOW.

(c) there is no evidence that this occurs: wheat root cells do not have detectable amounts of chitin in their walls. Likelihood is thus extremely LOW.

(d) chitinase activity could only be expected to have activity against organisms containing chitin. These include fungi and many arthropods. Any of these organisms could (theoretically) be non-target hosts. However, the GMO produces no more chitinase than many common saprophytic soil fungi and are fairly restricted in their ecological niche on roots. Any additional effect on populations of non-target hosts as a consequence of the expression of chitinase by the GMO is thus expected to be LOW. The likelihood of a very small effect is probably MEDIUM.

(e) the GMO has been screened according to recommendations for tier 1 toxicity testing in the Control of Pesticide Regulations (1986) and has no new activity compared to the non-GMO. It is possible that pathogenic activity occurs which was not detected in these tests, but the likelihood of this is extremely LOW.

(f) similar comments as for (e) hold here.

iv. Survival etc.

(a) in glasshouse tests, the modified organism on shows population dynamics on wheat roots indistinguishable from the non-modified organism. There is thus no reason to suppose that it is better able to survive in a vegetative state. The likelihood of this is thus LOW.

(b) numbers of viable organisms isolated from rhizosphere and bulk soil are the same for the modified and non-modified strains: the *Pseudomonas spp.* survives very poorly in bulk soil and does not seem to colonise substrata *de novo* in this environment. The likelihood of better spread in the soil is thus LOW.

v. Other negative effects

(a) no toxic activity was seen in the tier 1 pesticide tests.

(b) no evidence exists for this in the scientific literature, and the predicted changes in rhizosphere microflora are expected to have positive rather than negative effects.

For each of these, the likelihood is LOW.

STAGE IV: ESTIMATE OF RISK

For almost all the above, the estimate of risk (likelihood x consequence) is LOW x LOW = LOW.

However, in one case (iii b), risk is LOW (consequence) x HIGH (likelihood), and another (iii d) is LOW (consequence) x MEDIUM (likelihood).

STAGE V: OVERALL ESTIMATE OF RISK

The introduction of this GMO poses almost no identifiable risk. In the two cases noted above, it is likely that events of low consequence will occur. However, we feel that the likely **environmental impact** of these events is extremely low. Consequently, our risk assessment indicates an overall **LOW** risk for the release of our GM *Pseudomonas Spp.*.

Worked example 2

HYPOTHETICAL RELEASE

Summary:

Organism: Potatoes - Solanum tuberosum

Modifications: - marker for kanamycin resistance - bacterial donor
plus a bacterial gene coding for a protein toxic to a Coleopteran pest which attacks the tuber. A plant promoter is being used to ensure that the gene is expressed in the tuber only.

Release: - small scale release, 1,000 transgenic plants to be released on one site in Cambridgeshire. Four metre guard row of un-modified potatoes to surround the transgenic plants.
Termination - harvested mechanically, 1st year fallow, 2nd and third years sown to grass. Standard agricultural practices followed with regard to herbicide treatment.

I HAZARD ASSESSMENT

Recipient organism - Solanum tuberosum is grown in the UK as an agricultural crop. The crop is managed within the agricultural environment an does not present a hazard. This crop plant is considered to be a weed within the agricultural environment as it frequently 'carries over' into subsequent crops grown at the site. It is not known to be invasive or establish in natural environments.

Donor organisms - The bacterial donor species are not pathogenic and therefore no known pathogenic sequences will be present in the gm potato.

GMO potato - The marker gene will not give a selective advantage to the plant and should not result in the GM potato behaving differently from the recipient. The insect resistance gene will give protection to the plant from attack by an insect pest and is expected to give an advantage to the gm plant as compared to the non-modified plant. This may result in a greater carry over at the site as insect damage will be limited. It is possible that the gene, via pollen, could be transferred to other potato plants which could form seeds containing this gene. There are weed species related to S. tuberosum to which the gene may transfer. It is also possible that the protein produced by the plant could affect other invertebrates visiting the potato tuber.

Perceived hazards of release of the GM potato

Potential for survival, establishment and dissemination

- Making the plant into a weed

- Making a plant which will invade natural habitats

Potential for transfer of genetic material between the gmo and other organisms

- Transfer of the genes to other potatoes
- Transfer of the genes to other related species which may become weedy or invasive
- Transfer of the genes to microorganisms

Pathogenicity

- incomplete disarming of the Agrobacterium vector used in the modification

Negative effects on organisms (target and non target effects)

- target organisms affected
- non-target organisms may be affected

Phenotypic/genetic stability

- any changes

II ENVIRONMENTAL EXPOSURE ASSESSMENT

This is a small scale field trial in which gm potatoes will be grown using standard agricultural practices within an agricultural environment. The test plants will be monitored for resistance to damage. The trial will be terminated and any volunteer potatoes appearing in the year following the trial will be destroyed. The plants will produce pollen and there are other potato crops within 10m of the trial which may receive pollen. There are also related species in the area of the release which could also receive pollen. The scale and type of trial is expected to have negligible environmental impact and any effects will be short term.

From the location and type of release, there will be no effects on water, soil or air and hazards related to these can be discounted.

RISK ASSESSMENT

1. Potential for transfer of genetic material between the gmo and other organisms

Transfer by pollen - low
Transfer by other means - not known but expected to be 0 (microbe/plant interactions)

Justification for the assessment:

Potato plants produce pollen which can be transferred to other potatoes or related species in the vicinity of the release. Pollination is by wind and insects.
Percentage out-crossing data shows that between 0 to 3m, the percentage outcrossing with other potato species is 2%; this falls to 0,017% at 10m. There is a 4m guard row of un-modified potato plants (refs). The chance of cross pollination beyond this distance is low.
The transgenic potatoes may receive pollen from other potatoes in the vicinity but the rate of cross pollination will be low.

Solanaceous weeds which may be in the vicinity of the release in the UK are S. nigrum and S. dulcamara (refs). Pollen may reach these plants but the likelihood of this is low. Even if pollen reached these species there is no evidence that cross pollination can occur resulting in fertile hybrids. There is little or no evidence to date of sexual compatibility with commonly occurring Solanum species in temperate regions (refs).

There is no documented evidence to show that gene transfer from the crop plant to a microorganism will occur.

2. Phenotypic and genetic stability

Phenotypic and genetic stability - medium

Justification for the assessment:

During tissue culture somaclonal variation can occur. Regenerated plants with abnormal numbers of chromosomes are produced. The rates of production of abnormal variants can be calculated from observations made in the laboratory. In this case the rate is low and the clones to be planted out in the trial have been tested cytologically to show a normal chromosome compliment. Evidence in the literature (refs) from studies with transgenic plants show that introduced DNA is often stable. It is not possible to predict accurately the stability of these clones but instability should not pose a risk to the environment. Abnormal plants may be distinguished morphologically and can be removed from the trial.

3. Pathogenicity

Pathogenicity - effectively zero

Justification for the assessment:

The organism is not pathogenic to humans or other species which may come into contact with it. No pathogenic sequences are involved in the modification. The donor organisms are not pathogenic. The Agrobacterium vector used in the modification has been disarmed by removal of all genes involved in gall formation.

4. Potential for survival, establishment and dissemination

Potential for survival - medium
Potential for dissemination - low
Potential for establishment - low

Justification for the assessment:
Survival is by the formation of true seeds and by vegetative structures (tubers).

The number of seeds formed will depend on the weather conditions. This particular variety forms low numbers of seeds per plant, approximately 400 seeds/berry (approximately 20 berries per plant gives a total of approximately 8 million transgenic seeds). There is a likelihood that a proportion of these seeds will remain on the site following harvest. These may remain dormant for months or years depending on the environmental conditions.

Tubers may also be left behind on the site after harvest and result in potato plants the following year. Volunteer potatoes are a problem in agriculture and are controlled by standard agricultural management practices.

Termination/ harvest and post-harvest procedures will minimise the spread of seeds from berries formed and recover as many tubers as possible. The site will be treated with herbicide if volunteer potatoes appear. These activities will minimise the spread and establishment of the modified potatoes both within and beyond the agricultural environment.

The genes inserted into the potato are unlikely to make the potato more persistent in the agricultural environment or increase invasiveness beyond the site of release. The modification will not confer an advantage to the potato to allow true seeds or groundkeeper tubers to create a greater weed problem.

5. Other effects on organisms (target/non target organisms)

Effect on target organisms - high

Effect on non-target organisms - low

Justification for the assessment:

Tests have been carried out on local invertebrate fauna which may consume the tuber material. The results of the tests showed no adverse effects on these non-target organisms. The gm tuber material has been tested in feed trials with mice, with no adverse effects as the protein is easily degraded in the gut. The likelihood of non-target effects of the material on local fauna (vertebrate and invertebrate) is low.

Tests with the target Coleopteran show the level of toxicity of the tuber material. Other members of this family of Coleopterans have been tested, and are affected by the tuber material. However, these beetles are not normally found on potato plants and would be expected to move to the non-modified tubers to feed.

The toxic protein is not expressed in the aerial parts of the plant nor in the pollen and therefore there will be no effect on fauna visiting or consuming these parts of the plant.

OVERALL RISK ASSESSMENT

Transfer by pollen	**- low**
Transfer by other means	**- not known but expected to be 0 (microbe/plant interactions)**
Phenotypic and genetic stability	**- medium**
Pathogenicity	**- effectively zero**
Potential for survival	**- medium**
Potential for dissemination	**- low**
Potential for establishment	**- low**
Effect on target organisms	**- high**
Effect on non-target organisms	**- low**

The genetically modified potato plants are not expected to behave differently from the non-modified parental apart from being able to resist attack from the pest beetle. The potatoes are not pathogenic nor are they expected to invade or persist in natural habitats. Gene transfer from the genetically modified crop plant is expected to be low. The gene will only spread after pollen transfer to other potato plants whose seeds will carry the gene. This transfer will not have a negative affect in the environment. Standard management practices will be employed during and post-trial to control the presence of volunteers and limit any possible spread of potatoes from the site of release.

Therefore the overall risk of damage to the environment is low.

GLOSSARY

Environment: is land, air or water or any combination of these.

Receiving environment: is the environment at the release site and the surrounding area which might be affected by the release.

Damage to the environment: is caused by GMOs which are capable of causing harm being present in the environment after they have escaped or been released from a person's control.

Harm: is harm to humans or other organisms or interference with their ecosystems.

Parental organisms: are used in cell fusion experiments in which the genome of the fusion product is a hybrid of the entire genome of the two original cells (organisms), neither of which can be considered as the recipient or donor.

Recipient organism: is one which undergoes genetic modification by, for example, the introduction of a foreign gene from a second, **donor**, organism.

Genetic modification techniques: are those set out in Regulation 4. When considering the GMO in the risk assessment, all relevant aspects should be considered i.e. the donor organism, the nature and source of the vector (if used) and the method of modification.

Hazard: is a characteristic (biological, chemical or physical) which if manifested would cause harm to the environment.

Risk is the likelihood that the hazard will be realised, ie the likelihood that a specified undesired event will occur within a specified period or in specified circumstances.

Overall risk: is the compound of the individual components of risk arising from the five major hazard areas.