Government response to the thirteenth report of the Royal Commission on Environmental Pollution : the release of genetically engineered organisms to the environment / Department of the Environment.

GOVERNMENT RESPONSE TO THE THIRTEENTH REPORT OF THE ROYAL COMMISSION ON ENVIRONMENTAL POLLUTION

THE RELEASE OF GENETICALLY ENGINEERED ORGANISMS TO THE ENVIRONMENT

Department of the Environment *June 1993*

GOVERNMENT RESPONSE TO THE THIRTEENTH REPORT OF THE ROYAL COMMISSION ON ENVIRONMENTAL POLLUTION

THE RELEASE OF GENETICALLY ENGINEERED ORGANISMS TO THE ENVIRONMENT

INTRODUCTION

1. The Government welcome The Royal Commission on Environmental Pollution's Thirteenth Report, "The Release of Genetically Engineered Organisms to the Environment", published in July 1989.

2. This response has been delayed so that it can reflect new legislation on the release of genetically modified organisms (GMOs) which came into force in February this year[1]. Part I outlines current and developing Government policy and Part II gives a detailed response to each of the Commission's recommendations.

PART I

3. The potential for trade in the products of genetic modification is considerable. Beneficial and profitable uses in agriculture, medicine and pollution control, as well as in other fields, are all feasible. The Government recognise the contribution this technology could make to wealth creation and wish to encourage and support its development.

4. A new and positive direction in the management of public resources supporting genetic modification research was announced in the recent White Paper, "Realising our Potential: A Strategy for Science, Engineering and Technology". Early in 1994, a Biotechnology and Biological Sciences Research Council (BBSRC) will be formed to replace the Agriculture and Food Research Council (AFRC). The Council will provide a focus for research priorities and the possibilities for wealth creation in this area.

5. The Government recognise that at the same time as encouraging industry to develop new applications of biotechnology, an important factor in its success is the building of confidence in its safety. The Government agree with the Commission's principal recommendation on the need for a risk-based and enforceable statutory consent system for GMO releases using expert advice and providing relevant information to the public.

6. The arrangements for deliberate release now in place reflect the Commission's recommendations in their Thirteenth Report very closely. All experimental releases of GMOs and proposals to market GMO products have, since 1 February 1993, been subject to the grant of a consent by the Secretary of State of the Environment (or the Secretary of State for Scotland or for Wales) agreed with the Health and Safety Executive (HSE). The Advisory Committee on Releases to the Environment (ACRE) give advice on applications for consent, on a statutory basis. There is a specific enforcement inspectorate and a public register of

---

[1] Part VI of the Environmental Protection Act 1990 and The Genetically Modified Organisms (Deliberate Release) Regulations 1992. This legislation implements EC directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms. Consistent with this legislation and widespread current usage, the terms "genetic modification" and "genetically modified organisms" (GMOs) are used in this response.

information about consents applied for and granted.

7. Gaining maximum benefit from genetic technology depends on the framework for its safety regulation being flexible as well as robust. The Government endorse the Commission's view that the regime for GMO releases should be adjusted with increasing experience, from an initial approach of treating all proposals at the same level of scrutiny to one, with experience, of concentrating more attention and resources on higher risk releases.

8. The Government consider that experience of certain experimental releases of GMOs is already sufficient to justify "fast track" procedures where the risk of damage to the environment has been shown to be low or effectively zero. As an initial step, streamlined procedures, foreshadowed in the Government's Second Year Report on "This Common Inheritance", have been introduced for releases of certain well-characterised GMOs or those which have been released before.

9. The Government are further developing this approach with our European Community partners in the context of Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms and hope soon to be able to agree simplified procedures for the clearance of experimental releases of GMOs which meet agreed safety criteria. In general, such procedures are likely to reduce the information requirements on applicants for consents to release GMOs without reducing protection against any risks.

10. A related objective is to encourage the development of "green" products. Such products would include, for example, pollution clean-up agents using GMOs where any environmental (or human health) risks are outweighed by the benefits of the contribution they make to a cleaner environment.

11. The Government consider that one way to encourage such products is to develop harmonised approaches to the risk assessment of GMO releases within the Community. To this end, the Government will host an EC workshop on risk assessment in London next October.

12. Also as an incentive to innovation, the Government support the objective of including in Community product legislation risk assessment provisions similar to those in directive 90/220/EEC. Provided suitable provisions can be agreed, the outcome will be to reduce industry burdens without compromising safety by ensuring that relevant products need only be cleared under the product law and not under both the product law and directive 90/220/EEC.

13. The Government consider that the value of traded GMO products will be increased if they are acceptable, in terms of safety, on the world market as well as within the European Community. International agreement on biotechnology safety could help to lower non-tariff trade barriers, to avoid the indiscriminate testing of living biotechnology products in developing countries, and to encourage industry to develop products applicable not only in developed but also in developing countries.

14. The Government have been active in seeking such agreement and played a central role in developing approaches to biotechnology safety at the United Nations Conference on

Environment and Development in 1992. The Government are seeking to take this work forward via the United Nations Environment Programme, incorporating the results of other related initiatives in which the UK is closely involved, such as work within the OECD to established mutually acceptable data sets for GMO releases.

15. The Government attach particular importance to having a regulatory system which can maximise the many benefits which GMOs have the potential to bring as soon as possible and with the least burden on industry consistent with safety and public confidence. In large part due to the Commission's sound advice in their Thirteenth report, we believe we now have a comprehensive and comprehensible system for GMO releases which, with increasing experience, can be readily adapted to meet both the needs of modern science and industry and the high standards of environmental protection which the public have a right to expect.

JOHN GUMMER
SECRETARY OF STATE FOR THE ENVIRONMENT

GOVERNMENT RESPONSE TO THE THIRTEENTH REPORT OF THE ROYAL COMMISSION ON ENVIRONMENTAL POLLUTION

THE RELEASE OF GENETICALLY ENGINEERED ORGANISMS TO THE ENVIRONMENT

PART II

The recommendations in italics refer to Chapter 12 of the Commission's Thirteenth Report. Where necessary, the recommendations have been grouped to make clearer the Government reponse.

12.1. Statutory control of releases of genetically engineered organisms (GEOs) to the environment must be put in place.

1. The Government agree. Since 1 February 1993, all new proposals to release or market GMOs have been subject to Part VI of the Environmental Protection Act 1990[2] and the Genetically Modified Organisms (Deliberate Release) Regulations 1992[3].

2. Part VI of the 1990 Act has effect "for the purpose of preventing or minimising any damage to the environment which may arise from the escape or release from control of genetically modified organisms"[4]. During Parliamentary consideration of the 1990 Act[5], the Government acknowledged their debt to the Commission's Thirteenth Report[6] in preparing this legislation.

3. The 1990 Act and the 1992 regulations implement in Great Britain Council Directive 90/220/EEC on the deliberate release of genetically modified organisms to the environment[7].

4. Separate but parallel legislation introduces provisions to protect the environment and will implement the deliberate release Directive in Northern Ireland[8].

12.2. Both the Secretary of State for the Environment and the Health and Safety Commission (HSC) (acting on behalf of the Secretary of State for Employment) should be involved in decisions on release.

12.3. The Secretary of State for the Environment should take primary responsibility for control with respect to the environmental consequences of such releases.

12.6. Any release licence should be granted by the Secretary of State for the Environment and the HSC (referred to as the licensing authorities) acting jointly. They should also have the power to revoke a release licence or to amend its terms if they had reason to believe that the continuation of the licence was inadvisable.

12.8 The new Genetic Manipulation Regulations should be revised to provide that the HSC's approval to release be given in the form of a licence.

---

2 Chapter 43
3 SI 1992/3280
4 1990 Act, Section 106(1)
5 Hansard, 15.01.90,Col. 42
6 Cmnd 720
7 OJ No.L117, 8.05.90,p.15
8 The Genetically Modified Organisms (NI) Order 1991 and regulations proposed in an April 1993 consultation paper.

5. All these recommendations have been accepted. The 1990 Act explicitly includes human health within its scope[9]. No decision to grant, revoke or vary a consent to release or market GMOs may be taken by the Secretary of State without the agreement of Health and Safety Executive (HSE) in so far as human health and safety are affected[10]. Specific provision is made for the revocation or variation, if necessary, of consents granted[11].

6. Formal responsibility for the regulation and control of environmental consequences of releases rests, under the 1990 Act, with the appropriate "environmental" minister: that is, the Secretary of State for the Environment and (where appropriate) the Minister for Agriculture, Fisheries and Food acting jointly[12], as respects England, the Secretary of State for Scotland, as respects Scotland, and the Secretary of State for Wales, as respects Wales.

7. In practice, environmental, as well as human health and safety, responsibilities are co-ordinated by the Department of Environment (DOE) under the terms of a memorandum of understanding agreed with the other interested departments.

12.4. The control of releases of genetically engineered organisms should be governed by a statute establishing controls in respect of environmental protection and providing a framework within which the Secretary of State would be empowered to make regulations including a system for licensing. The statute should, in addition, impose a duty of care obliging all those responsible for the release of a GEO, whether for experimental or commercial purposes, to take all reasonable steps for the protection not only of human health and safety but also of the environment.

8. Accepted. The Secretary of State is expressly enabled to prescribe the cases and circumstances in which his consent is required to release or market GMOs[13]. General conditions relating to the protection of the environment (including human health) are implied in every consent granted[14].

12.5. A licence, which we refer to as a release licence, should be required before the release of a genetically engineered organism may take place. It should be an offence, carrying a substantial penalty, to release a GEO without having first obtained a release licence or to fail to comply with any conditions attached to the licence.

9. Accepted. With the exception of "approved" products (that is, those cleared for the EC market), the release or marketing of all GMOs require the Secretary of State's consent[15]. The maximum penalty for failing to comply with the consent requirements is, on conviction on indictment, an unlimited fine or imprisonment for up to 5 years, or both[16].

12.7. Anyone proposing that a GEO be released into the environment should be required to notify the licensing authorities of his intention and to furnish them with details of the organism concerned and the method of release, including the results of an assessment of safety carried out by a local safety assessment

---

9 1990 Act, Sections 107(6) and 112 and The Environmental Protection Act 1990 (Modification of section 112) Regulations 1992, SI 1992/2617
10 1992 Regulations, 15(1), 15(5), 16(3) and 16(8)
11 1990 Act, Section 111(11)
12 1990 Act, Section 126
13 1990 Act, Section 111(1)
14 1990 Act, Section 112(5)-(7)
15 1990 Act, Section 111(1)(a) and 1992 Regulations, 5(1) and 10(1)
16 1990 Act, Section 118(3)

committee.

10. The thrust of this recommendation has been accepted. The requirements for information to be contained in applications to the Secretary of State for consent to release or market GMOs are detailed and specific[17]. The onus for risk assessment, a statement of the evaluation of which must be included with each application, is placed on the applicant[18]. The construction of GMOs prior to release is subject to The Genetically Modified Organisms (Contained Use) Regulations 1992, which requires all those making a risk assessment to establish a genetic modification safety committee[19]. Applicants are required to notify the relevant genetic modification safety committee of prescribed details of each GMO release consent application[20].

12.9. In the light of experience the licensing authorities may consider it to be safe to issue a release licence for a class or category of related GEOs. Persons or organisations wishing to make releases under such a licence should, however, be required to submit their proposals to the licensing authorities who would decide whether they fell within the scope of that licence. The authorities should have the power to require that any proposal with features which gave rise to concern should be the subject of an application for a specific release licence, even though it appeared to be covered by a licence for a category.

11. The Government accept the principle behind this recommendation. The 1990 Act makes provision for the development of the consent system on the lines suggested by the Commission, if justified by experience. Criteria for simplified clearance procedures for certain GMOs are being pursued with our EC partners. The October 1992, second anniversary, report[21] on the 1990 White Paper, "This Common Inheritance"[22], set as an objective the agreement of simplified procedures for "low" or "no" risk GMOs and for those conferring environmental benefits (for example, use in pollution clean-up).

12.10. Each stage of release in the development of a GEO should be the subject of a licence. The organism may then be proposed for use as or in a product. It should be assessed once more at that stage and be subject to licensing by the licensing authorities for sale, supply or use as or in a particular product. If no other product control applies to that product the licence should be issued directly by them.

12.11. Where other product controls apply, the product control authority should be required to inform the licensing authorities of any application for approval of a product which is or which contains a genetically engineered organism. They in response would inform the product control authority whether they were willing to issue a licence for the product. This applies both to products developed in this country and to those imported. Anyone applying for approval to the sale or supply of a GEO as or in a product should therefore be required to state in the application that it is genetically engineered.

12. The new statutory consent system reflects these recommendations. At the (experimental) release stage, consents may cover, within a specified period and for the same purpose, either one or more releases of the several GMOs on the same site or one or more releases of the same GMO on several sites[23]. Except where product clearance has been obtained via another EC country under the terms of the deliberate release Directive, a

---

17 1992 Regulations, 6 and 11 and Schedules 1 and 2
18 1992 Regulations, 6(1)(c) and 11(2)(b)
19 SI 1992/3217, Regulation 11
20 1992 Regulations, 8(1) and (3)(b)
21 Cmnd. 2068
22 Cmnd. 1200
23 1992 Regulations, 5(2)

separate consent is required from the Secretary of State for the marketing of any product consisting of or including GMOs and for each proposed new use of any product which has been marketed before[24]. This includes products imported from non-EC countries.

13. The deliberate release Directive provides a mechanism for the Community-wide clearance of products emanating from member states[25]. This is reflected in the 1992 regulations so far as the clearance of products first placed on the market in the UK is concerned[26]. The Directive also ensures that derogations from its requirements may only be agreed in relation to product legislation which makes provision for similar risk assessment of the GMO[27]. No such derogations have yet been made. However, because of their potential to reduce industry burdens, Government policy is to support derogations where they are justified on safety grounds.

12.12. The Secretary of State for the Environment should be given additional powers including the power to: set up advisory committees; draw up and publish codes of practice; maintain a register of people and organisations approved to carry out releases; make information available to the public and to other authorities; deal with emergencies and impose obligations on others to establish emergency arrangements; carry out or require others to carry out appropriate monitoring; require the provision of information about releases; require the proper disposal of waste products and, if necessary, cleaning up of release sites; inspect premises; and recover costs of regulation.

12.21. The Secretary of State for the Environment and the HSC, acting on advice from the Release Committee, should compile and maintain a register of persons authorised to release GEOs. It would be an offence for a person not so registered to be responsible for carrying out a trial release. A registered person would be held personally responsible by the registration authorities for the use of appropriately qualified and trained staff for every aspect of the release and for the issuing of adequate instructions for them. He or she should be required to record the names of all staff engaged in the release and to make the names available to the registration authorities if requested.

12.22. Appropriate arrangements should be made for the registration of companies or other organisations which carry out trial releases. Criteria for their entry to the register should include the employment of suitable qualified personnel, the provisions of appropriate training, designation of safety officers and the establishment of a local safety assessment committee. Registered organisations should be required to identify one or more registered persons who would be responsible for releases.

12.23. Registration, either of persons or organisations, could be made in respect of a single release, a specified series of releases or any release of a specified class or classes or organism. In addition to trial releases, it might occasionally be appropriate to require the registration of releasers of a licensed product; provisions for this should be made in the legislation.

14. The 1990 Act provides, either expressly or in effect[28], for most of the additional powers suggested by the Commission. However, the Government do not consider that the setting up of registers of authorised releasers of GMOs is justified.

15. The arguments for and against such registers were rehearsed during

---

24 1992 Regulations, 10

25 Directive 90/220/EEC, Articles 12 and 13

26 1992 Regulations, 16

27 Directive 90/220/EEC, Article 10

28 1990 Act, eg: Sections 124 (Advisory committee), 122 and 123 (public information, etc), 117 (power to deal with cause of imminent danger to the environment), 112 (general duty to keep informed of risks, etc), 112 (conditions attached to consents), 116 (obtaining of information from persons), 120 and 121 (powers to remedy harm and recover costs), 115 (rights of entry and inspection) and 113 (fees and charges).

Parliamentary consideration of the 1990 Act[29]. The Government's view is that such registers would be less effective than looking at each release case by case, in particular the qualifications of those responsible, which is one of the items of information required for each consent application[30].

12.13. The Government should consider whether the powers of the HSC need to be extended, in respect of the release of GEOs, to cover some or all of the powers listed in recommendation 12.12 which it does not already exercise.

16. All of the Secretary of State's powers under the 1990 Act are exercisable in relation to both human health and the wider environment, subject to HSE agreement where appropriate.

12.14. The first consideration in the proper control of releases of GEOs is a thorough, expert scrutiny of every proposed release. At this stage of the development of the technology we consider that each case needs to be scrutinised by a national committee of experts. Prior to such scrutiny a local committee based within the organisation developing the GEO should screen the proposal to ensure that only well thought out proposals come forward for national scrutiny.

17. The Government agree that proposed releases should be scrutinised by a national committee of experts. The Secretary of State has appointed the Advisory Committee on Releases to the Environment (ACRE) to advise him on all aspects of the consent system set up under the 1990 Act and the 1992 Regulations. ACRE was established in April 1990 and assumed its statutory responsibilities on the coming into force of the new legislation on 1 February 1993.

18. Responsibility for local scrutiny rests jointly with the applicant and the genetic modification safety committee (see paragraph 10).

12.15. The Secretary of State for the Environment and the HSC should refer each application for a release licence, or for product approval, in respect of a genetically engineered organism, to a committee of experts and should take account of its recommendations. The primary function of the committee should be the assessment of such proposals with regard to environmental protection and human health and safety.

19. The Government agree. ACRE advises the Secretary of State on each application for consent to release or market GMOs. The focus of their consideration is the risks of the proposed release or proposed marketing of a product, concentrating on whether the consent should be granted and, if so, on what limitations or conditions should attach to it.

12.16. The present Intentional Introduction Sub-Committee of the Advisory Committee on Genetic Manipulation (ACGM) should be constituted as a committee in its own right, distinct from the ACGM. It should be charged with giving advice to both the HSC and the Secretary of State for the Environment. We refer to it as the Release Committee.

12.20. The functions of the Department of Environment's Interim Advisory Committee on Introductions (IACI) should be taken on by the Release Committee, so that there will be no continuing need for IACI.

---

29 Hansard, Vol. 520, No. 112, Cols. 1998 - 2001

30 1992 Regulations, Schedule 1, paragraph 1

20. The appointment of ACRE meets these recommendations.

12.17. The Release Committee should have close links with the ACGM. This may be achieved through common membership and a joint secretariat.

21. Such links have been established. DOE provide the secretariat for ACRE and HSE the secretariat for ACGM. Appointments to ACRE are made by the Secretary of State and appointments to ACGM by the Health and Safety Commission (HSC). These arrangements are subject to consultations between interested departments and links are close, for example in relation to attendance by departmental assessors at committee meetings, and in the provision of some cross membership.

12.18. Members of the Release Committee should have expert knowledge of genetic techniques, microbiology, theoretical or field ecology or other relevant disciplines. They should be drawn from universities, other institutions, industry and workers' representatives. Persons engaged in the development and release of genetically engineered organisms should not be debarred from membership of the Committee but interests should be declared appropriately. Experts from the UK and from other countries should be invited to join the Committee on an ad hoc basis when needed for the assessment of particular proposals. There should also be representation from relevant Government departments and agencies and from local authority environmental health officers.

22. The membership and procedures of the ACRE reflect this recommendation.

12.19. In addition to advising on proposals for release, including any conditions which should be attached to licences, the Release Committee should have other functions including: development of codes of practice and guidance for applicants; advising on the scope for categorising releases; advising on the need for research especially on matters relating to release; reviewing the outcomes of releases; liaising with overseas organisations in relevant fields; and advising on possible needs for changes in legislation or procedures. The Committee should be asked to produce an annual report on its activities, on developments in the subject and on lessons learned. Adequate resources should be provided for its effective operation.

23. The Government agree that ACRE's remit should not be confined to advising on proposals for release. Their statutory role extends to advising the Secretary of State on any aspect relating to his functions under Part VI of the 1990 Act. The Committee will publish an annual report. DOE provides sufficient resources to enable it to perform its remit.

12.24. The new legislation should provide that any person, or the directors of any company or other organisation, responsible for carrying out the release of a genetically engineered organism without the necessary licence and registration, will be subject to strict liability for any damage arising. It should also provide that neither the licensing and registration authorities, nor members of the Committee on whose advice they or either of them acted in granting the licence or registration should be liable in respect of the consequences of the release.

24. The Government gave careful consideration to this recommendation during Parliamentary consideration of the 1990 Act, but decided that it would be not appropriate to pursue it solely in the context of GMOs[31]. Annex A of "This Common Inheritance" acknowledges the potential utility of strict liability as one of the economic instruments by which environmental objectives might be achieved. The issues are, however, very complicated and are better not pursued on an *ad hoc* basis. A number of international

---

[31] Hansard, Vol. 522, No. 137, Cols. 703 - 706

organisations, including the Council of Europe and the EC, are looking at the wider question and it is in the context of these international negotiations that the Government believe that policy on this subject is best considered.

25. So far as 1990 Act is concerned, the concept of "harm" to the environment is widely defined[32] and there is a wide range of offences and penalties for causing it[33]. In addition, an offender can be ordered by the court to remedy any harm caused or to repay the costs of any remedy effected by the Secretary of State[34].

12.25. The Secretary of State for the Environment should have the power to impose, in the release licence, a condition that the licence holder monitors the spread and fate of the organisms and of any introduced genes, the environmental impact of the release and any unexpected ecological event. The licence holder should be required to report the results of the monitoring to the licensing authorities, with immediate reporting of any significant untoward occurrence. There should be provision for monitoring to be required, on a temporary basis, in the case of licensed products where necessary.

26. The powers available to the Sectary of State under Section 112 of the 1990 Act to attach limitations and conditions to consents enable implementation of all these recommendations, where appropriate, in individual cases. The requirement to notify the Secretary of State of particular information about the release and its effects is one of the general conditions implied in all consents.

12.26. There should be a public register of applications for release licences and of licences granted. This should contain the names and addresses of the persons or organisations making the applications, particulars of the organisms, the purposes of the releases and the descriptions of the release sites. The register should be maintained nationally. Relevant sections of it should be kept in the localities of releases.

12.27. Information about releases of GEOs, concerning foreseeable effects and arrangements for monitoring and dealing with emergencies, should be made available by the DOE or HSE on request.

12.28. The national register should contain details of applications and licences granted for the sale or supply of GEOs as or in products. The register of authorised releasers should also be made public.

12.30. The legislation should empower the licensing authorities to allow public access to the information on the basis of which the Release Committee has made its recommendation. It should also enable them, if they considered it appropriate before allowing access, to invite the applicant to comment on the request for information and to take account of the applicant's views on commercial confidentiality.

12.64. We have recommended a degree of public access to information about releases which goes beyond the access allowed in respect of most products. Some of this information could be of value to other companies. A regime of intellectual property rights should be developed which provides sufficient protection to enable the release of adequate information to the public without undermining the commercial viability of the development and thereby damaging the incentive for innovation.

27. The Government agree on the importance of providing reasonable public access to information about GMO releases. A register of information in respect of consents applied for and granted has been set up under the new legislation[35]. The information placed on the register relates both to applications for consents and consents granted for a GMO

---

[32] 1990 Act, Section 107(6)
[33] 1990 Act, Section 118
[34] 1990 Act, Sections 120 and 121
[35] 1990 Act, Section 122 and 1992 Regulations, 17 and 18.

(experimental) release and for the marketing of a GMO product. There are local registers in the regional offices of HMIP covering England and Wales and, in Scotland, in the HSE area offices. Names and addresses of releasers are confined to the organisation responsible and do not refer to individuals.

28. Register entries comprise summary details of each application plus a complete copy of the associated risk assessment, subject to the exclusion of any information determined by Secretary of State to be confidential on grounds of commercial confidentiality, national security or the prevention of damage to the environment. Applicants have an express right to make representations about commercial confidentiality before any information is put on the register[36]. Information not placed on the register may be made available via the Environmental Information Regulations 1992[37], which provide a general right of reasonable access to any environmental information, subject to confidentiality limitations which are similar to those which apply to the placing of information on the register.

29. The deliberate release Directive makes specific provision for the protection of intellectual property rights[38]. During consultations on the Genetically Modified Organisms (Deliberate Release) Regulations 1992, the Government had discussions with patent interests to consider how this provision could be reflected in the regime for the protection of commercial confidentiality. As a result, the Genetically Modified Organisms (Deliberate Release) Regulations 1992 were framed to ensure that certain information which may affect intellectual property rights need only be placed on the public register of information after it has been published[39].

12.29. Persons or organisations applying for licences to carry out trial releases of GEOs should be required to place advertisements, in the local press serving the areas of intended release, announcing their proposals. Anyone applying for a licence for the sale or supply of a GEO as or in a product should be required to place a notice in the London Gazette and an advertisement in an appropriate national newspaper.

12.32. Members of the public should have the opportunity to make representations to the licensing authorities in respect of any application for a release licence within 30 days of the appearance of the local or national advertisement. The applicant, and anyone who has made such representations, should subsequently receive a copy of the recommendation made by the Release Committee and be given the opportunity to make representations about that recommendations before the decision of the licensing authorities is taken.

30. The Government agree that applications for consent for (experimental) releases of GMOs should be advertised[40]. Advertisements are not appropriate in the case of products since the clearance system is EC-wide and the registers of information in any case provide the relevant information.

31. Comments in response to information about consent applications placed on the register or in response to advertisements may be made at any time up to the point of the Secretary of State's decision on each application (up to a maximum of 90 days after its receipt). Each register entry comprises a cumulative record of the application's consideration

---

36 1990 Act, Section 123
37 SI 1992/3240
38 90/220/EEC, Article 19.1
39 1992 Regulations, 6(1)(d), 17(4) and 18(3)
40 1992 Regulations, 8(1) - (2)

from the point of receipt to the Secretary of State's final decision. Further information relating to risk that comes available after the application's receipt[41] is also entered, as is ACRE's advice[42]. Interested members of the public have the opportunity to make representations in response to any of this register information before the final decision is made.

12.31. The licensing authorities will need to be able to communicate information about release proposals to the European Commission and competent authorities in other EC member states and other countries; if a specific power is necessary for that, it should be given to them. The UK authorities should also, if necessary, be empowered to make information available to the OECD, UNEP and other international organisations, and should do so to the fullest extent possible.

12.42. It is clearly desirable that there should be international agreement on the information to be required of releasers and the procedures for assessment. We hope that the Government will use the final version of the ACGM's revised guidelines for information and risk assessment as a model in international discussions on this subject.

12.53. International exchanges of information between assessment bodies could provide valuable material to assist in assessing release proposals. The European Commission has proposed regular exchanges of information on this subject between member states. We support this initiative.

12.54. We recommend that the UK authorities should, in appropriate circumstances, notify proposed releases of GEOs to the competent authorities not only in other EC member states but also in other countries and should take full account of their views.

12.57. We support proposals by the European Commission for regular meetings of officials from member states to discuss and exchange information on release proposals, for an expanded research programme on biotechnology, in particular on risk assessment of releases, and for the creation of a database of releases.

32. The Government agree that there should be adequate provision for information exchange with other countries and that it is desirable to base approaches to the assessment of GMO releases on internationally accepted principles. The UK's obligations under the deliberate release Directive for information exchange with the European Commission and other EC member States are specifically implemented in the new legislation[43]. The Directive also expressly provides for more general information exchange arrangements between member states and for regular meetings of competent authorities[44].

33. The UK plays a full part in wider information exchange on GMO releases via the OECD, UNEP and other international organisations. ACGM's guidelines are one element in a developing body of UK principles on information and risk assessment. The new legislation is based in these respects on EC obligations, which were in turn a development of OECD work[45] which is under regular review. The UK, with the Netherlands, played a central role in the development of a secretariat paper[46] for Agenda 21 of the 1992 United Nations Conference on Environment and Development which the Government see as forming a basis for future international agreement on information exchange and risk assessment and

---

41 1992 Regulations, 17(6)

42 1992 Regulations, 17(3)(h)

43 1992 Regulations, Part III

44 90/220/EEC, Articles 18 and 22

45 "Recombinant DNA Safety Considerations", OECD, Paris, 1986

46 "Environmentally Sound Management of Biotechnology - Safety in Biotechnology: Assessment and Management of Risk", Research paper No.55, United Nations Conference on Environment and Development, February 1992

management in this area.

12.33. The powers over the release of genetically engineered organisms which are to be exercised by the Secretary of State for the Environment and the HSC should apply to the marine environment within UK territorial waters. They should exercise these powers in consultation with the Minister responsible for fisheries.

34. The 1990 Act applies to the territorial sea adjacent to Great Britain and to any area designated as applying to Great Britain under the Continental Shelf Act 1964[47]. All powers of the Secretary of State are exercised jointly with the Minister for Agriculture, Fisheries and Food, where appropriate[48].

12.34. There will need to be an extension of controls over contained work on genetically engineered organisms to minimise the risk of damage to the environment. These will include powers to require the proper disposal of waste products and to regulate storage, transport and import for continued use. The powers should be given to the Ministers already having responsibilities in each area.

12.35. The Secretary of State for the Environment should be given power in respect of waste disposal from contained work on genetically engineered organisms. In exercising his power, including the issue of advice by Her Majesty's Inspectorate of Pollution to the waste disposal authorities immediately responsible, he should receive advice from the ACGM and, as appropriate, from the Release Committee and elsewhere.

35. These recommendations are effected by The Genetically Modified (Contained Use) Regulations 1992[49], which in turn implement Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms[50]. Like the Directive, the regulations address the question of wastes from contained use facilities. HSE are the lead authority for these regulations. The Secretary of State's responsibilities for environmental matters to do with contained use notifications is exercised via a specific cooperation power which enables him to comment on such notifications and, if appropriate, request further information[51].

12.36. The Secretary of State for the Environment, together with agriculture and other Ministers, should conduct a review of issues arising over the selection and use of naturally occurring organisms. They should consider the possibility of enacting more comprehensive controls than those afforded by the Wildlife and Countryside Act and other present legislation.

36. The Government's first priority has been to secure a comprehensive control system for GMOs, in line with our Community obligations, and there are no proposals for wider review at present.

12.37. It is important that any definition of genetic engineering should be kept under review by experts and amended as necessary both to clarify if necessary the position of new techniques and to modify the coverage in the light of experience.

37. The Government agree that genetic modification techniques should be kept under review. The 1990 Act enables the Secretary of State to prescribe in regulations the artificial techniques of genetic modification which are regarded to result in GMOs[52]. The

---

47 1990 Act, Section 127(2)
48 1992 Act, Section 126
49 SI 1992/3217
50 OJ No. L117, 8.05.90,p.1
51 SI 1992/3217,Regulation 18
52 1990 Act, Section 106

currently prescribed techniques[53] derive from the deliberate release Directive[54]. They will be amended, if necessary, in the light of any discussions with the Commission of the European Communities and our EC partners.

12.38. International measures are called for in relation to commercial releases of plants. Viable samples of current commercially-used plant varieties should be conserved so that it will be possible to return to these in order to eliminate an undesirable trait if necessary. There should be lineage registers which record the history of plant varieties including information on any introduced genes. In addition, before organisms with introduced genes are released the introduced DNA sequence for the new genes should be characterised for future reference.

38. The Government actively support several initiatives to conserve both international and national plant genetic resources. In addition to being a signatory to the International Convention on Biodiversity, they provide funding for the International Board for Plant Genetic Resources (IBPGR) as well as a number of UK gene banks. Lineage histories of conventionally bred crop varieties are currently recorded as part of the National Listing trials that must be satisfied prior to the variety being approved for market. Parentage and breeding methods of transgenic crops will be recorded in the same manner. Relevant information about the sequences of DNA introduced into modified plants is covered by the requirements for release consent applications.

12.39. Research on selective, readily degradable chemical pesticides leaving no objectionable residues and which are non-toxic to humans should not be abandoned in the enthusiasm for biological control. The development of agricultural practices such as integrated pest management, which may help to reduce the scale of the problem with which pesticides are trying to deal, should also continue to receive attention.

39. The Ministry of Agriculture, Fisheries and Food (MAFF) actively support the whole concept of integrated pest management (IPM) and are committed to improving agricultural performance and reducing the use of pesticides and fertilisers. Within this framework, Government funded research is currently in progress to identify and utilise novel compounds, such as synthetic pheromones and insect anti-feedants that exhibit the properties listed in the recommendation.

12.40. Local safety assessment committees may not need the same range of expertise as the national committee but should contain ecologists as well as experts in genetic engineering. Other members with relevant local knowledge and expertise should be appointed where possible.

12.41. Local authority environmental health officers should be invited to serve on local safety assessment committees. In order to make an informed contribution on a subject which is somewhat outside the range of current EHO responsibilities, training and advice will be needed.

40. These recommendations are reflected in advice issued by HSE which is currently under review[55].

12.43. The progression from laboratory to widespread release should go through a series of stages gradually relaxing the degree of containment at each, for example from laboratory, to greenhouse, to single field trial, to wider trials, to full marketing.

---

53 1992 Regulations, 3

54 90/220/EEC, Article 2 and Annex I

55 ACGM/HSE/Notes 3, 10 and 11

12.45. There should be a step-by-step approach to innovation in the releases that take place so that the modifications made at each step do not introduce an unacceptable degree of uncertainty.

41. This "step by step" approach is endorsed by the deliberate release Directive and the new legislation. The size of each "step" will depend on the assessment of the risks, which is the basis for the regulatory controls.

12.44. As products move through stages of release, responsibility for scrutiny may fall progressively to various bodies. Close links are needed between these bodies together with arrangements for exchange of information about assessments and about the results of releases that have taken place.

42. The Government agree. Such links are provided by the memorandum of understanding (see paragraph 7) between official bodies with responsibilities in relation to GMO releases.

12.46. The use of debilitating mechanisms should always be considered when genetically engineered micro-organisms are proposed for release.

43. The Government agree that releasers should always consider the use of such mechanisms for the release of genetically modified micro-organisms but acknowledges that in many cases this is not a practical option.

12.47. The potential for clean-up and decontamination of a release site should always be considered but it would nevertheless be prudent to work on the assumption that, once released, it may not be possible totally to eradicate an organism, particularly a micro-organism, from the environment.

44. The possibility that GMOs could cause problems by persisting in the environment following release is fully taken into account by the consent system, both in terms of the risk assessment which must be carried out before release and the general conditions providing for continued protection of the environment following release which attach to each consent granted.

12.48. Releasers should be given clear advice by the Release Committee, both in general guidance on good practice and in specific comments on their releases, about the manner in which releases should be carried out, including arrangements for security, for monitoring, for clean-up and for dealing with contingencies. Compliance with these arrangements should be checked by appropriately trained inspectors with authority to take action where necessary.

12.49. At least until more knowledge is gained and confidence acquired about the behaviour of GEOs in the environment, releasers should be required to carry out monitoring. When assessing a proposal, the Release Committee should consider the extent, methods and arrangements for the monitoring that should be carried out.

12.50. The monitoring of the release of as GEO should normally continue after completion of the experiment for an appropriate period depending on the nature of the release, with agreed arrangements for reporting the outcome.

12.52. The Release Committee should carry out regular reviews of the information it has obtained about the outcome of releases. Consideration should be given to publishing the results of the reviews.

45. The consent system now in place takes account of these recommendations. ACRE are responsible, with the DOE and other interested departments, for issuing general

guidance on all aspects of the consent system. ACRE consider all the information in each particular application for consent. Such information includes, for example, relevant proposals for monitoring, control, waste treatment and emergency plans[56]. The Committee may either advise that the proposals contained in the application are adequate as they stand, or recommend that they should be varied as a condition of any consent granted. The consent granted covers the scope of the release described in the application, with any variations stipulated by the Secretary of State (including those based on ACRE's advice). Consent conditions are enforceable by the Secretary of State's inspectors[57], who are currently HSE inspectors acting under an agency agreement with the Secretary of State[58].

46. The general conditions attached to each consent require the holder to keep himself informed in relation to environmental risks following release, to use the best techniques not entailing excessive costs to prevent or minimise any risks identified, and to notify the Secretary of State of appropriate information in relation to risks, including, in each case, a report on the effects of the release for the assessment of future releases, particularly of any products that may be developed from an experimental release[59]. ACRE will be asked to advise on releasers' reports on the outcome of their releases. The general conclusions will be included in the Committee's annual report.

12.51. There is scope for co-ordinating the general monitoring of the environment to develop a systematic approach. The DOE should take the lead in promoting and funding this co-ordination work as part of its responsibilities for protection of the environment.

47. This recommendation is being effected as part of DOE's role as lead department on release. Specific guidance on monitoring has been developed with ACRE and other interested departments and will be published shortly.

12.55. The relationship between living organisms and their environment is such that proposed releases of GEOs must be considered in the appropriate environmental context. This aspect of the draft EC Directive on the release of GEOs needs further thought and should be the subject of careful discussion between the European Commission and member states.

48. This recommendation has been overtaken by events. The adopted text of the deliberate release Directive makes specific provision for the environmental context to be taken into account, both in relation to experimental releases and products, including, in the case of products, the type of environment and/or geographical area(s) of the Community for which the product is suited[60]. This is reflected in the 1992 regulations[61].

12.56. The list of exclusions from the product section of the draft EC Directive on the release of GEOs considerably weakens the value of the proposals. Where product controls exist, those responsible for them must, before they authorise release of a product which is or which contains a genetically engineered organism, receive expert advice on those features which differentiate it from, for example, a chemical product. For products which are subject to no control, it is essential that controls should be established in respect of those which are or which contain GEOs.

---

56 1992 Regulations, Schedule 1, paragraphs 74 - 89
57 1990 Act, Sections 114 - 117
58 1990 Act, Section 125
59 1990 Act, Section 112(1)-(2), (5) - (7), 1992 Regulations, 9
60 90/220/EEC, Article 5, 11, Annex II, Part III and Annex III, paragraph 3
61 1992 Regulations, 6(1), 11(2), Schedules 1, paragraphs 43 - 54 and Schedule 2, paragraph 3

49. The adopted text of the deliberate release Directive does not contain lists of excluded products. Product derogations may only be made as result of the procedure outlined in paragraph 13, that is only if the relevant product legislation provides for risk assessment similar to that contained in the deliberate release directive.

12.58. The ACGM, in consultation with the Release Committee, HSE, DOE and MAFF, should revise its containment guidelines to take into account potential harm to the environment from the escape of GEOs.

50. Such guidance will be provided in a revision of ACGM/HSE Note 7, "Guidelines for the risk assessment of operations involving the contained use of genetically modified micro-organisms", which will be published shortly.

12.59. The risk of accidents in the use or storage of commercially produced GEOs needs to be considered when proposals for products which are or which contain GEOs are put forward for assessment. Clear labelling, including instructions for storage, use, disposal and action to be taken in the event of an accident, should be considered where potential hazards exist.

51. Unless applicants for marketing consents are able to show that the product concerned does not present a risk to human health or the environment, a proposal for packaging and labelling must be specifically included in their consent application[62].

12.60. Well-designed protocols for procedures at the laboratory, field trial site and production process plant are very important in reducing the risk of accidents occurring. Staff should be appropriately trained so that they understand how to handle the GEOs and associated equipment safety. Response plans should be drawn up to deal with the consequences of an accident and staff should be trained to implement them.

52. The applicant must satisfy the Secretary of State that the staff conducting a release are appropriately qualified and that there are appropriate emergency response plans[63].

12.61. Her Majesty's Inspectorate of Pollution should consider the waste disposal issues raised by the development of genetic techniques and, in consultation with the appropriate authorities, issue advice on the selection of BPEOs for the disposal of the wastes.

12.63. Guidance for the disposal of GEOs in biological and biotechnological waste, and its enforcement, should be kept under review to ensure that it remains appropriate. The waste disposal procedures recommended for field trials should also be kept under review.

53. The Government will consider the development of guidance on wastes as part of ACRE's and ACGM's programmes of work.

12.62. When a proposed product which is or which contains a GEO is submitted for assessment, a licence should be granted only if any waste or residue can be disposed of safely and if appropriate advice on waste disposal appears on the product label.

54. Consent applicants must satisfy the Secretary of State, on a case by case basis, that any necessary waste treatment arrangements and, where appropriate, arrangements for the handling and labelling of products are adequate[64]. The arrangements authorised by the

---

[62] 1992 Regulations, 10(5) and Schedule 2, Part II.

[63] 1992 Regulations, Schedule 1, paragraphs 1 and 85 - 89.

[64] 1992 Regulations, Schedule 1, paragraphs 81 - 84 and Schedule 2, Part II

Secretary of State form part of the consent and are enforceable.

12.65. Knowledge of genetics and ecology should be included in the curriculum of schools. Students should be aware of the factors involved in judging the impact on the environment of a proposed release.

55. The National Curriculum for Science makes specific provision in relation to genetics and ecology[65].

12.66. There is a need for a substantially enhanced research base in the basic sciences underpinning the release of genetically engineered organisms to the environment. It should be located in the universities and research institutes and should receive adequate funding. Such research should be in three major areas: the molecular biology of organisms in the environment, interactions between organisms and the environment and basic studies on ecology and population biology.

56. The Research Councils already support important research programmes in the basic sciences underpinning the release of GMOs to the environment. A new impetus for such research will be provided by the setting up of a Biotechnology and Biological Sciences Research Council (BBSRC) to replace the Agriculture and Food Research Council (AFRC), as announced in the Government's May 1993 White Paper, "Realising our Potential: A Strategy for Science, Engineering and Technology"[66].

12.67. Basic research should supplemented by projects related to specific environmental issues commissioned by the relevant Government departments.

57. DOE funded research to the value of £1.3m in 1992/93 on identifying and assessing risks associated with the release of genetically modified organisms. Additional funding relating to the environmental safety of GMOs was provided by MAFF and the Department of Trade and Industry (respectively £361,000 and £760,000 over the same period).

---

[65] "Science and the National Curriculum", HMSO, 1991, Attainment Target 2

[66] Cmnd. 2250