This Statutory Instrument has been amended by S.I.1993/152 which is printed hereinas pages 19 and 20 and is being issued free of charge to all known recipients of S.I. 1992/3280.

STATUTORY INSTRUMENTS

1992 No. 3280

ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Deliberate Release) Regulations 1992

Made - - - -	*21st December 1992*
Laid before Parliament	*11th January 1993*
Coming into force - -	*1st February 1993*

The Secretary of State for the Environment and the Minister of Agriculture, Fisheries and Food, acting jointly, as respects England, the Secretary of State for Wales, as respects Wales, and the Secretary of State for Scotland, as respects Scotland, in exercise of the powers conferred on them by section 2(2) of the European Communities Act 1972(**1**), being the Ministers designated(**2**) 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(1), (4), (5), (7) and (11), 122(1) and (4) and 126(1) of the Environmental Protection Act 1990(**3**), and the Secretary of State for the Environment, 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 156 of the Environmental Protection Act 1990, hereby make the following Regulations:—

PART I

GENERAL

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Deli-berate Release) Regulations 1992 and shall come into force on 1st February 1993.

(**1**) 1972 c. 68.
(**2**) S.I. 1991/775.
(**3**) 1990 c. 43.

Interpretation

2. In these Regulations—

"the Act" means the Environmental Protection Act 1990;

"the Commission" means the Commission of the Communities;

"the Deliberate Release Directive" means Council Directive 90/220/EEC(**4**) on the deliberate release into the environment of genetically modified organisms;

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

"heritable genetic material" means genes or other genetic material, in any form, capable of being replicated or transferred by any means;

"local authority" means—

(a) in Greater London, a London borough council, the Common Council of the City of London and the Sub-Treasurer of the Inner Temple and the Under- Treasurer of the Middle Temple,

(b) outside Greater London, a district council and the Council of the Isles of Scilly, and

(c) in Scotland, an islands or district council;

"product" means a product consisting of or including genetically modified organisms, and "approved product" means a product marketed in pursuance of and in accordance with 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 purposes 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 hybridisation, 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.

(**4**) OJ No. L117, 8.5.90, p.15.

Capacity of organisms for causing harm

4.—(1) For the purposes of sections 110(1), 112(5)(**5**) 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) for causing harm of the description specified in paragraph (3), and

(b) harm, caused by genetically modified organisms of the description specified in paragraph (2), which is of the description specified in paragraph (3).

(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 and in accordance with—

(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 paragraphs (3) and (4), the cases and circumstances prescribed under section 111(1)(a) of the Act in relation to the release of any genetically modified organisms are any cases and circumstances other than the release of an approved product in accordance with the conditions and limitations to which the use of the product is subject.

(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 organisms on the same site for the same purpose 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(**6**), 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 2nd May 1993.

(4) Paragraph (1) shall not apply to a person who releases a product which was marketed in the United Kingdom before 1st February 1993 and is not an approved product.

(**5**) Section 112(5)is ammended by regulation 9 of these Regulations
(**6**) S.I. 1992/810

Information to be contained in application for consent to release

6.—(1) Subject to regulation 7 (Exemptions from regulation 6), the following is the information which 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 release of the organisms, or of organisms of the same description, which has 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 another competent authority of a 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,

(d) a statement whether the detailed description of the organisms and the details of the purpose for which the organisms will be released have been published, and the bibliographic reference for any information so published,

(e) a summary, in the format established by the Commission under Article 9(1) of the Deliberate Release Directive, of the information contained in the application.

(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 in accordance with paragraph (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) The application may in addition contain data or results from an application for consent to release genetically modified organisms previously made by some other person, provided that a copy of that person's agreement in writing is contained in the application.

Exemptions from regulation 6

7. An application for a consent to release 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 acknowledgement of receipt of that application is sent to him 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 general description of the organisms to be released,

(c) the location and general purpose of the release, and

(d) the foreseen dates of the release.

(2) Where the information on the location of the release which has been placed on the register kept by the Secretary of State under section 122 of the Act differs in its level of detail from that contained in the application for consent, the notice shall contain the level of detail regarding the location of the release which appears on the register.

(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 acknowledgement of receipt of that application is sent to him by the Secretary of State, give to the following persons notice that he has made the application and the information prescribed in paragraph (1)(a) to (d)—

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

(b) the local authority for the area of the proposed release,

(c) the Nature Conservancy Council for England, Scottish Natural Heritage or the Countryside Council for Wales, as appropriate, according to whether the release will be in England, Scotland or Wales,

(d) the Countryside Commission, if the release will be in England,

(e) the Forestry Commission,

(f) the National Rivers Authority or, if the release will be in Scotland, the river purification board or islands council for the area of the proposed release,

(g) the water undertaker for the area of the proposed release or, if the release will be in Scotland, the regional or islands council for the area of the proposed release,

(h) each member of the genetic modification safety committee established by the applicant under regulation 11 of the Genetically Modified Organisms (Con tained Use) Regulations 1992(**7**).

General condition on consents to release organisms

9. In section 112 of the Act (Consents: limitations and conditions) 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 risks there are of damage to the environment being so caused, and

(ii) the effects of any releases by him for the assessment of any risks there are of damage to the environment being so caused by such organisms being released or marketed;".

(**7**) S.I. 1992/

PART III

MARKETING ORGANISMS

Consent to market products

10.—(1) The cases and circumstances prescribed under section 111(1)(a) of the Act in relation to the marketing of any genetically modified organisms are any cases and circumstances other than the marketing of a product in accordance with a written consent given by another competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive.

(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) where the product has not previously been marketed in pursuance of and in accordance with 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, or

(b) where the product is intended for a use for which it has not previously been marketed in pursuance of and in accordance with 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.

Information to be contained in application for consent to market

11.—(1) The following is the information which 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 consent to release the organisms, or 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 another competent authority of a 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,

(d) a summary, in the format established by the Commission under Article 12(3) of the Deliberate Release Directive, of the information contained in the application.

(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 and in accordance with 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, 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) The application may in addition contain data or results from an application for consent to market genetically modified organisms previously made by some other person, provided that a copy of that person's agreement in writing is contained in the application.

Transitional provision for marketing

12. Regulation 10(1) shall not apply to a person who markets a product which—

(a) was marketed by him in the United Kingdom before 1st February 1993, and

(b) is not an approved product,

until 1st February 1995.

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

Duty of the applicant after applying for consent

13.—(1) In section 111 of the Act (Consents required by certain persons), after subsection (6) there shall be inserted the following subsection—

> "(6A) Where an applicant for consent for releasing or marketing genetically modified organisms becomes aware, before his application is either granted or rejected, of any new information with regard to any risks there are of damage to the environment being caused as a result of the organisms being released or marketed, he shall notify the Secretary of State of that new information forthwith."

(2) In section 118(1)(e) of the Act (Offences), after the words "section 108(5) or (6)" there shall be inserted the words "or section 111(6A)".

Duties of the Secretary of State on receiving applications for consent to release

14.—(1) The Secretary of State shall within 30 days of receiving an application for a consent to release genetically modified organisms forward to the Commission a summary of that application in the format established by the Commission under Article 9(1) of the Deliberate Release Directive.

(2) The Secretary of State shall—

(a) examine an application for a consent to release genetically modified organisms 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) where appropriate, take into account any comments made by the competent authority or authorities of member States following the circulation to them by the Commission of the summary referred to in paragraph (1) above, and

(e) record his conclusions in writing.

Decisions by the Secretary of State on applications for consent to release

15.—(1) The Secretary of State shall not grant a consent to release 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 to release genetically modified organisms to the applicant before the end of a period of 90 days beginning with the day on which the application was received.

(3) The period prescribed 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 received by the Secretary of State.

(4) The Secretary of State shall inform the competent authority or authorities of each member State and the Commission of his decision on each application for consent to release genetically modified organisms.

(5) The Secretary of State shall not revoke or vary a consent to release genetically modified organisms as it relates to the protection of human health without the agreement of the Health and Safety Executive.

Duties of the Secretary of State in relation to applications for consent to market

16.—(1) The Secretary of State shall examine an application for consent to market genetically modified organisms 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 for consent to market genetically modified organisms the Secretary of State shall either—

(a) forward to the Commission—

(i) the application,

(ii) a summary of the application in the format established by the Commission under Article 12(3) 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 require ments 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 requirements of the Act and of these Regulation and is rejected.

(3) The Secretary of State shall not forward his favourable opinion on the applicationas it relates to the protection of human health where the Health and Safety Executive has informed him that it does not fulfil the requirements of the Act and of these Regulations.

(4) The period prescribed 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 is required and ending with the day on which that information is received by the Secretary of State.

(5) The Secretary of State shall immediately inform the competent authority or authorities of each member State and the 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 a competent authority of a 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 the competent authority or authorities of the member States by the Commission, grant consent to market the genetically modified organisms and inform the competent authority or authorities of the member States and the Commission that he has done so.

(7) Where an objection has been raised by a competent authority of a member State and the Commission has taken a favourable decision under Article 13(3) of the Deliberate Release Directive, the Secretary of State shall grant consent to market the genetically modified organisms and inform the competent authority or authorities of the member States and the Commission that he has done so.

(8) The Secretary of State shall not revoke or vary a consent to market genetically modified organisms as it relates to the protection of human health without the agreement of the Health and Safety Executive, and shall immediately inform the competent authority or authorities of each member State and the Commission of any decision to revoke or vary a consent.

PART V

REGISTER OF INFORMATION

Information to be included in register

17.—(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 (7).

(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,

(d) the purpose for which the genetically modified organisms are proposed to be released or marketed,

(e) the reason for the service of the notice,

(f) any date specified in the notice as the date on which the prohibition is to take effect.

(3) Subject to paragraph (4), 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 general description of the genetically modified organisms in relation to which the application is being made,

(c) the location at which the genetically modified organisms are proposed to be released,

(d) the general purpose for which the genetically modified organisms are proposed to be released or marketed,

(e) the foreseen dates of the release,

(f) the methods and plans for monitoring the genetically modified organisms and for emergency response,

(g) the evaluation of the environmental impact of the genetically modified organisms, in particular any pathogenic and/or ecologically disruptive effects, and

(h) either—

(i) the conditions or limitations in accordance with which the committee appointed by the Secretary of State under section 124 of the Act has advised that the consent should be granted, or

(ii) a summary of the reasons why that committee has advised that the consent should not be granted.

(4) Where—

(a) the application is for a consent to market genetically modified organisms,

(b) an application for a consent to release genetically modified organisms contains a statement that a detailed description of the organisms and the details of the purpose for which the organisms will be released have been published, or

(c) the Secretary of State is notified, under the conditions of a consent to release genetically modified organisms which he granted in relation to an application, that a detailed description of the organisms and the details of the purpose for which the organisms will be released have been published,

the information prescribed under paragraph (3)(b) shall be the detailed description of the organisms in relation to which the application is made and the information prescribed under paragraph (3)(d) shall be the details of the purpose for which the organisms will be released.

(5) 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) any 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) the fact that the consent has been revoked or varied, and the contents of the notice by which the consent was revoked or varied.

(6) In relation to information furnished under section 111(6A)(**8**) or 112(5)(b)(i)(**9**) of the Act, any new information which becomes available with regard to any risks there are of damage to the environment, and in relation to information furnished under section 112(5)(b)(ii) of the Act, the effects of any releases for the assessment of any risks there are of damage to the environment.

(7) 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.

(**8**) Section 111(6A) is inserted by regulation 13 of these Regulations.
(**9**) Section 112(5)(b) is amended by regulation 9 of these Regulations.

Keeping of the register

18.—(1) The information prescribed in regulation 17(2) shall be placed on the register within fourteen days of the prohibition notice being served.

(2) Subject to paragraph (3), the information prescribed in regulation 17(3) shall be placed on the register within fourteen days of the receipt by the Secretary of State of the application for consent to release or market.

(3) Where regulation 17(4)(c) applies, the information prescribed in regulation and (d) shall be placed on the register within twenty-eight days of the Secretary of being notified, under the conditions of a consent to release genetically modified organisms which he granted in relation to an application, that a detailed description of organisms will be released have been published.

(4) The information prescribed in regulation 17(5)(a), (b) and (d) shall be placed on the register within fourteen days of the consent being granted, revoked or varied, as appropriate.

(5) The information prescribed in regulation 17(5)(c), (6) and (7) shall be placed on the register within fourteen days of its receipt by the Secretary of State.

Michael Howard
18th December 1992 — Secretary of State for the Environment

In witness whereof the Official Seal of the Ministry of Agriculture, Fisheries and Food is hereunto affixed on 21st December 1992.

L.S.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

David Hunt
17th December 1992 — Secretary of State for Wales

Hector Monro
Parliamentary Under Secretary of State, Scottish
18th December 1992 — 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 quantitative terms) and specificity of detection and identification techniques.

8. The description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, prey, parasites, competitors, symbionts and hosts.

9. The potential of the organisms 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 Communities 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 organisms and to make the introduced vector and insert function in those organisms.

16. The frequency of mobilisation, genetic transfer capabilities and/or methods of determina tion 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 organisms

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 organisms

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.

24. The structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organisms.

25. The stability of the organisms in terms of genetic traits.

26. The rate and level of expression of the new genetic material in the organisms, 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 quantitative terms), and specificity of detection and identification techniques.

30. The history of previous releases or uses of the organisms.

31. In relation to human health—

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

(b) the product hazards,

(c) the comparison of the organisms to the donor, recipient or (where appropriate) parental organisms regarding pathogenicity,

(d) the capacity of the organisms for colonisation, and

(e) if the organisms are 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) carcogenicity, 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 cultivation, 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 organisms 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 ORGANISMS 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, multiplica tion 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 organisms.

59. The studies on the behaviour and characteristics of the organisms and their 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 organisms.

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 organisms 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 organisms.

67. The identification and description of the target organisms.

68. The anticipated mechanism and result of interaction between the released organisms and the target organisms.

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, symbionts, predators, parasites and pathogens.

72. The known or predicted involvement of the organisms 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 the Community 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 Community 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 Community and the estimated level and amount of imports of the product into the Community.

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 ("the Act"), give effect to Council Directive 90/220/EEC (OJNo. 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 as to the application of the definitions of "artificial techniques" and "harm" in the Act.

Part II of the Regulations makes provision as to the circumstances in which 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 the circumstances in which 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 applicants and the Secretary of State following the making 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.