STATUTORY RULES OF NORTHERN IRELAND

2003 No. 167

EUROPEAN COMMUNITIES

ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003

Made - - - - - 12th March 2003

Coming into operation 15th April 2003

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The Department of the Environment, being a Department designated(**a**) for the purposes of section 2(2) of the European Communities Act 1972(**b**) in relation to measures relating to the control and regulation of genetically modified organisms, in exercise of the powers conferred by that section and Articles 3(4) and (5), 8(1), (4), (5), (7) and (11), 19(1) and (4) and 20(7) of the Genetically Modified Organisms (Northern Ireland) Order 1991(**c**), having consulted the Food Standards Agency in accordance with Article 22(5) of that Order, and of all other powers enabling it in that behalf, hereby makes the following Regulations:

PART I

GENERAL

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003 and shall come into operation on 15th April 2003.

Interpretation

2.—(1) In these regulations –

"the Advisory Committee on Releases to the Environment" means the Committee appointed by the Department under Article 22A of the Order;

"antibiotic resistance markers" means genes employed in the modification of an organism to make that organism express resistance to a particular antibiotic or antibiotics;

"application for consent to release" shall include any notification made under the First Simplified Procedure (crop plants) Decision;

"approved product" means a product permitted to be marketed by a consent granted under Article 8(1) of the Order or in accordance with Article 15(3), 17(6) or 18(2) of the Deliberate Release Directive or Article 13(2) or (4) of the 1990 Directive;

"the Commission" means the European Commission;

"the Contained Use Directive" means Council Directive 90/219/EEC(**d**) on the contained use of genetically modified micro-organisms as amended by Commission Directive 1994/51/EC and Directive 98/81/EC;

"the Deliberate Release Directive" means Council Directive 2001/18/EC(**e**) on the deliberate release into the environment of genetically modified organisms;

"electronic communication" means the same as in the Electronic Communications (Northern Ireland) Act 2001(**f**);

"environmental risk assessment" means the environmental risk assessment required to be contained in an application for consent to release or market genetically modified organisms by regulation 11(1)(c) and regulation 16(2)(c);

(**a**) S.I. 1991/755
(**b**) 1972 c. 68
(**c**) S.I. 1991/1714 (N.I. 19). *See* Article 2(2) for the definition of "the Department". *See* Article 8(11) for the definition of "prescribed" in that Article
(**d**) O.J. No. L117, 8.5.1990, p. 1
(**e**) O.J. No. L106, 17.4.2001, p. 1
(**f**) 2001 c. 9

"the Executive" means the Health and Safety Executive for Northern Ireland;

"the First Simplified Procedure (crop plants) Decision" means Commission Decision 94//730/EC(**a**);

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

"higher plant" means a plant belonging to the taxonomic group *Spermatophytae* (*Gymnospermae* or *Angiospermae*);

"monitoring plan" means the plan required by regulation 16(2)(g);

"the Order" means the Genetically Modified Organisms (Northern Ireland) Order 1991;

"the register" means the public register kept by the Department under Article 19 of the Order;

"the 1990 Directive" means Council Directive 1990/220/EEC(**b**) on the deliberate release into the environment of genetically modified organisms as amended by Commission Directive 1994/15/EC(**c**) and Commission Directive 1997/35/EC(**d**);

"the 1994 Regulations" means the Genetically Modified Organisms (Deliberate Release) Regulations (NI) 1994(**e**);

(2) The Interpretation Act (Northern Ireland) 1954(**f**) shall apply to these regulations as it applies to an Act of the Northern Ireland Assembly.

Purpose of the Order and meaning of expressions used

3.—(1) Article 3 of the Order (purpose of Order and meaning of "genetically modified organisms" and related expressions) is amended as follows.

(2) For paragraph (1) there shall be substituted –

"(1) This Order has effect for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment which may arise from the escape or release from human control of genetically modified organisms.".

(3) In paragraph (4) (definition of organism which is genetically modified) for sub-paragraph (a) (modification of prescribed artificial technique) there shall be substituted –

"(a) have been artificially modified, or".

(4) After paragraph (4) insert –

"(4A) Genes or other genetic material in an organism are "artificially modified" for the purposes of paragraph (4) if they are altered otherwise than by a process which occurs naturally in mating or natural recombination.

This paragraph is subject to paragraphs (4B) and (4C).

(4B) For the purposes of paragraph (4) –

(a) genes or other genetic material shall be taken to be artificially modified if they are altered using such techniques as may be prescribed for the purposes of this sub-paragraph;

(b) genes or other genetic material shall not be regarded as artificially modified by reason only of being altered by the use of such techniques as may be prescribed for the purposes of this sub-paragraph.

(**a**) O.J. No. L292, 12.11.1994, p. 31
(**b**) O.J. No. L1117, 8.5.1990, p. 15
(**c**) O.J. No. L103, 22.4.1994, p. 20
(**d**) O.J. No. L169, 27.6.1997, p. 72
(**e**) S.R. 1994 No. 144 as amended by the Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations (Northern Ireland) 1995 (S.R. 1995 No. 413), the Genetically Modified Organisms (Deliberate Release and Risk Assessment) (Amendment) Regulations (Northern Ireland) 1997 (S.R. 1997 No. 534) and the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001 (S.R. 2001 No. 295)
(**f**) 1954 c. 33 (N.I.)

(4C) An organism shall be taken not to be a genetically modified organism for the purposes of this Order if it is an organism of a prescribed description.

(4D) In paragraphs (4B) and (4C) "prescribed" means prescribed by regulations made by the Department.".

(5) Paragraphs (5) and (6) are omitted.

Meaning of "damage to the environment" etc

4.—(1) Article 4 of the Order (meaning of "damage to the environment" etc) is amended as follows.

(2) For paragraph (2) (meaning of "environment") substitute –

"(2) The "environment" includes land, air and water and living organisms supported by any of those media.".

(3) In paragraph (3) (meaning of "damage to the environment") omit "to the living organisms supported by the environment".

(4) For paragraph (6) (meaning of "harm") substitute –

"(6) "Harm" means any adverse effects as regards the health of humans or the environment.".

(5) For paragraph (9) (meaning of organism being under a person's "control") substitute –

"(9) Organisms of any description are under the "control" of a person where he keeps them contained by measures designed to limit their contact with humans and the environment and to prevent or minimise the risk of harm.".

(6) For paragraph (11) (meaning of organism being "marketed") substitute –

"(11) Genetically modified organisms of any description are "marketed" by a person when products consisting of or including such organisms are placed on the market by being made available to other persons, whether or not for consideration.".

Techniques of genetic modification

5.—(1) Until the coming into operation of the first regulations under Article 3(4B)(a)(**a**) of the Order, genes or other genetic material shall be taken, for the purposes of paragraph (4) of that Article to be artificially modified if they are altered using any of the following techniques:

(a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

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

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

(2) Until the coming into operation of the first regulations under Article 3(4B)(b) of the Order, genes or other genetic material shall not be regarded, for the purposes of paragraph (4) of that Article, as artificially modified by reason only of being altered by the use of any of the following techniques: –

(a) in vitro fertilisation,

(b) natural processes such as conjugation, transduction and transformation,

(c) polyploidy induction.

(**a**) Article 3(4) is amended by regulation 3(3) and Article 3(4A) to 4(4D) is inserted by regulation 3(4)

provided that such techniques do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques or methods other than –

(i) mutagenesis;

(ii) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

(3) Until the coming into operation of the first regulations under Article 4(4C) of the Order, an organism shall be taken, for the purposes of the Order, not to be a genetically modified organism if it is yielded from the techniques or methods listed in paragraph (2)(i) or (ii) provided that those techniques or methods did not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those made by techniques or methods listed in that paragraph.

Environmental risk assessment

6.—(1) An environmental risk assessment contained in an application for consent to release or market genetically modified organisms shall –

(a) identify and evaluate the potential damage to the environment, whether direct or indirect, immediate or delayed, which may arise from the release or marketing of genetically modified organisms,

(b) be carried out in accordance with Annex II of the Deliberate Release Directive and contain the conclusions required in section D of that Annex,

(c) include any bibliographic reference and indications of the methods used where applicable.

(2) Where the genetically modified organisms contain antibiotic resistance markers, the environmental risk assessment shall include an examination of the particular risks of damage to the environment which may be posed by the deliberate release or marketing of those genetically modified organisms.

Communication with applicant for consent

7.—(1) Wherever an applicant for consent or renewal of a consent to which these Regulations apply or a holder of such consent is required under these Regulations to submit any document in writing, he is required to submit that document in both a paper and in a commonly used electronic form.

(2) Wherever these Regulations require any communication from the Department to the applicant for a consent or renewal of a consent to be in writing, "writing" shall include an electronic communication.

(3) Any documents required by these Regulations to be in writing which do not fall within the provisions of paragraph (1) or (2) must be in paper form.

PART II

RELEASING ORGANISMS FOR ANY OTHER PURPOSE THAN MARKETING

Requirement for consent to release

8. The cases and circumstances prescribed for the purposes of Article 8(1)(a) of the Order in relation to the release of any genetically modified organisms are all cases and circumstances in which genetically modified organisms are intended to be released.

Exempt activities

9. The cases and circumstances prescribed for the purposes of Article 8(7) of the Order in which persons are exempt from the requirements of Article 8(1)(a) of the Order, insofar as those requirements apply to the release of genetically modified organisms, are all cases and

circumstances in which the release is in accordance with a consent to market genetically modified organisms under Article 8(1)(a) of the Order or in which an approved product is released in accordance with the conditions and limitations to which the use of the product is subject.

Applications for consent to release genetically modified organisms – general provisions

10.—(1) An application for a consent to release genetically modified organisms must be made in writing to the Department.

(2) Proposed releases of the same genetically modified organism or of a combination of genetically modified organisms on the same site or on different sites for the same purpose and within a defined period may be notified in a single application.

(3) Where an application for a consent to release genetically modified organisms is expressed to rely on the First Simplified Procedure (crop plants) Decision, in the event of any inconsistency in the requirements as to information to be provided under that Decision and the requirements as to information to be provided under these Regulations, the provisions of that Decision shall prevail.

Information to be contained in applications for consent to release

11.—(1) An application for a consent to release genetically modified organisms must contain –

(a) the information prescribed in –

(i) Schedule 1, where the application is for consent to release any genetically modified higher plant, or

(ii) Schedule 2 in any other case,

to the extent and at the level of detail that such information is appropriate to the nature and scale of the release or application;

(b) information on data or results from any previous release of the organisms, or of the same combination of organisms, which has been carried out by the applicant, and information from any previous application for the release of the organisms, or of the same combination of organisms, which the applicant has made to the Department pursuant to the Order or to another competent authority in accordance with Article 6 of the Deliberate Release Directive;

(c) an environmental risk assessment prepared in accordance with regulation 6;

(d) a summary, in the format established by the Commission under Article 11(1) of the Deliberate Release Directive, of the information contained in the application.

(2) The application may contain –

(a) 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; and

(b) any other information which the applicant considers is relevant.

Advertisement of applications for consent to release

12.—(1) Subject to paragraphs (2) and (3), a person who makes an application for a consent to release genetically modified organisms shall, not more than ten days after he sends that application to the Department, cause to be published in at least three newspapers to be specified by the Department 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 purpose of the release,

(d) the intended date or dates of the release,

(e) a statement that information about the application will be placed on the register by the Department within twelve days of its receipt of the application,

(f) the means by which that register can be inspected,

(g) a statement that the Department will consider any representations made to it relating to risks of damage to the environment posed by the release of the genetically modified organisms within a period which it shall specify in accordance with these Regulations

and shall immediately send copies of the newspapers containing the advertisement to the Department.

(2) A notice published under paragraph (1) need not contain the information referred to in sub-paragraphs (c) and (d) of that paragraph insofar as the First Simplified Procedure (crop plants) Decision does not require that information to be submitted with the application and that information is not submitted with the application.

(3) An applicant for consent shall ascertain from the Department the level of detail on the location of the release which will be placed on the register and shall include the same level of detail in the notice to be published under paragraph (1).

(4) A person who makes an application for a consent to release genetically modified organisms shall, not more than ten days after he sends that application to the Department, give to the following persons notice in writing that he has made the application and shall include in such notice the information prescribed in paragraph (1)(a) to (g), save in so far as paragraph (2) permits such information to be excluded from the notice referred to in paragraph (1) –

(a) the district council for the area or areas of each proposed release,

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

(c) each member of the genetic modification safety committee established by the applicant under regulation 16 of the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001(**a**),

(d) the Department of Agriculture and Rural Development,

and shall immediately send to the Department copies of the notices.

Transitional provisions for release

13. Where the Department has received an application for consent to release genetically modified organisms before 15th April 2003 pursuant to the 1994 Regulations and has not yet determined the application –

(a) the application shall be subject to the provisions of these Regulations,

(b) the applicant shall submit to the Department such further information, additional to that already provided in connection with the application, as is necessary in order to comply with the requirements of these Regulations by 17th July 2003,

(c) the application shall be treated as having been sent to the Department for the purposes of regulations 12(1) and (4) and as having been received by the Department for the purpose of regulation 20 on submission of the information required by paragraph (b), and

(d) if the information required by paragraph (b) has not been submitted by 17th July 2003, the Department may refuse to proceed with the application.

PART III

MARKETING ORGANISMS

Requirement for consent to market

14. The cases and circumstances prescribed for the purposes of Article 8(1)(a) of the Order in relation to marketing genetically modified organisms are all cases and circumstances in relation to the marketing of genetically modified organisms.

(**a**) S.R. 2001 No. 295

Exempt activities

15. The cases and circumstances prescribed for the purposes of Article 5(7) and Article 8(7) of the Order in which persons are exempt from the requirements of Article 5(1)(a) of the Order (to carry out a risk assessment) and of Article 8(1)(a) of the Order (to obtain consent), insofar as they relate to marketing genetically modified organisms, are all cases and circumstances in which –

(a) an approved product is marketed for a use for which it has approval;

(b) genetically modified micro-organisms are made available for activities regulated under the Contained Use Directive;

(c) genetically modified organisms other than micro-organisms falling within paragraph (b) are made available to be used exclusively for activities where appropriate stringent containment measures based on the same principles of containment as laid down in the Contained Use Directive are used to limit their contact with and to provide a high level of safety for the general population and the environment;

(d) genetically modified organisms are made available to be used exclusively for deliberate releases complying with the requirements laid down in Part II;

(e) a genetically modified organism authorised under Council Regulation (EEC) No. 2309/93(**a**), as amended by Commission Regulation EC No 649/98(**b**), is marketed; or

(f) a novel food or novel food ingredient within the scope of Regulation EC No. 258/97 of the European Parliament and of the Council(**c**) is marketed.

Applications for consent to market

16.—(1) An application for a consent to market genetically modified organisms under Article 8(1) of the Order must be made in writing to the Department.

(2) An application for a consent to market genetically modified organisms which is not an application for renewal of a consent must contain the following information –

(a) the information prescribed in –

(i) Schedule 1 where the application is for consent to market any genetically modified higher plant, or

(ii) Schedule 2 in any other case,

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 the same combination of organisms, which has been carried out by the applicant either inside or outside the European Community, and information from any previous application for consent to release the organisms, or the same combination of organisms, which the applicant has made to the Department in accordance with the Order and these Regulations or to another competent authority in accordance with Article 6 of the Deliberate Release Directive,

(c) an environmental risk assessment prepared in accordance with regulation 6,

(d) the information prescribed in Schedule 3,

(e) the proposed conditions for the marketing of the product, including specific conditions of use and handling,

(f) a proposed period for the consent which shall not exceed ten years,

(g) a monitoring plan prepared in accordance with Annex VII of the Deliberate Release Directive which shall include a proposal for the time period of the plan which may differ from the proposed period for the consent,

(h) a proposal for labelling which shall comply with the requirements laid down in Schedule 3,

(i) a proposal for packaging,

(**a**) O.J. No. L214, 24.8.1993, p. 1
(**b**) O.J. No. L88, 24.3.1998, p. 7
(**c**) O.J. No. L43, 14.2.1977, p. 1

(j) a summary of the application in the format established by the Commission under Article 13(2)(h) of the Deliberate Release Directive.

(3) The application may in addition contain –

(a) 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, and

(b) any other information which the applicant considers relevant.

(4) The information provided in accordance with sub-paragraphs (2)(a) and (d) shall take into account the diversity of sites of use of the genetically modified organisms and shall include information on any results obtained from research and developmental releases concerning the impact of the release on human health and the environment.

(5) Where the applicant can demonstrate in his application to the satisfaction of the Department, that, on the basis of the results of any release in pursuance of and in accordance with a consent under Article 8(1) of the Order or under Part B of either the Deliberate Release Directive or the 1990 Directive, or on other substantive, reasoned scientific grounds, the marketing and use of the product do not pose a risk of damage to the environment, he may omit from the application part or all of the information prescribed in Part II of Schedule 3.

Transitional provision of marketing

17. Where the Department has received an application for consent to market genetically modified organisms before 15th April 2003 pursuant to the 1994 Regulations and has not yet determined that application, or, in a case where the Commission is required to take a decision in accordance with Article 13(3) of the 1990 Directive, that decision has not yet been taken –

(a) the application shall be subject to the provisions of these Regulations;

(b) the applicant shall submit to the Department such further information, additional to that already provided in connection with the application, as is necessary in order to comply with the requirements of these Regulations by 17th July 2003;

(c) the application shall be treated as having been received by the Department for the purposes of regulation 23 on submission of the information required by paragraph (b);

(d) if, by 15th April 2003, the Department has forwarded to the Commission the information required by regulation 16(2) of the 1994 Regulations, it shall supplement it and, if it considers it to be necessary, revise it on receipt of the further information required by paragraph (b) in the light of its obligations under these Regulations, and

(e) if the information required by paragraph (b) has not been submitted by 17th July 2003, the Department may refuse to proceed with the application.

Applications for renewal of consent to market

18.—(1) Where the Department has granted a consent to market genetically modified organisms under Article 8(1) of the Order, any application to renew that consent shall be made in writing to the Department –

(a) before 17th October 2006 where the consent was granted before 15th April 2003; and

(b) no later than nine months before the expiry of the consent in all other cases.

(2) The application shall contain –

(a) a copy of the consent to market the genetically modified organisms;

(b) where applicable, a report on the results of the monitoring carried out in accordance with the requirements of regulation 28(f);

(c) any other new information which has become available with regard to the risks of the product causing damage to the environment;

(d) as appropriate, a proposal for amending or adding to the conditions of the existing consent, including the conditions concerning future monitoring, and a proposal for the time limitation of the new consent.

(3) Any consent to market genetically modified organisms granted by the Department under Article 8(1) of the Order before 15th April 2003 for which no application for renewal under

paragraph (1) has been received before 17th October 2006 shall be treated as having expired on that date.

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

Duty of the applicant after applying for consent to release or to market

19.—(1) In Article 8 of the Order (consents required by certain persons) in paragraph (6) (power of Department to require further information) insert as a second sentence –

"A notice under this paragraph must state the reasons for requiring the further information specified in the notice.".

(2) An applicant for a consent to release or to market genetically modified organisms who notifies the Department of any information in accordance with Article 8(6A) of the Order (requirement for applicant to notify new information regarding risks of damage to the environment) shall submit in writing to the Department a revised version of the original application for consent amended to take account of the new information.

Duties of the Department in relation to applications for consent to release

20. Following receipt of an application for consent to release genetically modified organisms the Department shall –

(a) inform the applicant in writing of the date of receipt of the application;

(b) invite any person by means of a request placed on the register, to make representations to it relating to any risks of damage being caused to the environment by the release before the end of a period to be specified which shall not be less than sixty days from the date the application was received by it;

(c) within 30 days of the date the application was received by it forward to the Commission a summary of that application in the format established by the Commission under Article 11(1) of the Deliberate Release Directive;

(d) examine the application for its conformity with the requirements of the Order and of these Regulations;

(e) evaluate the risks of damage being caused to the environment by the proposed release having regard to the environmental risk assessment; and

(f) take into account any representations relating to risks of damage being caused to the environment by the release made to it before the end of the period specified in accordance with paragraph (b) and any comments made by a competent authority or authorities of other Member States following the circulation to them by the Commission of the summary referred to in paragraph (c).

Decisions by the Department on applications for consent to release

21.—(1) The Department shall not grant a consent to release genetically modified organisms under Article 8(1) of the Order as it relates to the protection of human health without the agreement of the Executive.

(2) The Department shall not grant or refuse consent to release genetically modified organisms before the end of a period of 60 days beginning on the day on which the application for consent was received.

(3) The Department shall communicate its decision on an application for a consent to release genetically modified organisms to the applicant and to the Commission before the end of a period of 90 days beginning with the day on which the application was received and shall include in any refusal of consent the reasons for the decision.

(4) The period prescribed in paragraph (3) shall not include –

(a) any period beginning with the day on which the Department gives notice in writing under Article 8(6) of the Order that further information in respect of the application is required and ending on the day on which that information is received by the Department; or

(b) any period of time during which the Department is considering representations submitted by any persons in accordance with regulation 20(b), provided that this consideration shall not prolong the 90 day period referred to in paragraph (3) by more than 30 days.

(5) A consent to release genetically modified organisms shall require the applicant to send any information which might be relevant to assessing the risk of damage being caused to the environment, with, where appropriate, particular reference to any product which it is intended to market in the future, to the Department as soon as reasonably practicable after completion of the release and thereafter, at such intervals as the Department shall consider appropriate on the basis of the results of the environmental risk assessment.

(6) The Department shall send to the Commission the information submitted to it in accordance with paragraph (5).

Variation or revocation of a consent to release genetically modified organisms

22.—(1) The Department shall only vary or revoke a consent to release genetically modified organisms under Article 8(10) of the Order without the agreement of the holder of the consent where new information has become available to it which it considers would affect the assessment of the risk of damage being caused to the environment by the release.

(2) The Department shall not revoke or vary a consent to release genetically modified organisms under Article 8(10) of the Order as it relates to the protection of human health without the agreement of the Executive.

Duties of the Department in relation to applications for consent to market

23.—(1) Following receipt of an application for a consent to market genetically modified organisms the Department shall –

(a) inform the applicant in writing of the date of receipt of the application;

(b) forward to the Commission and to the competent authorities of the other Member States a summary of that application in the format established by the Commission under Article 13(2)(h) of the Deliberate Release Directive;

(c) examine the application for its conformity with the requirements of the Order and of these Regulations and, if necessary, request the applicant to supply additional information;

(d) before the end of a period of 90 days beginning with the day on which it received the application either –

(i) send to the applicant an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should be permitted to be marketed and under which conditions, or

(ii) refuse the application, stating reasons for its decision, supported by an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should not be marketed, and

(e) once it is satisfied it conforms to the requirements prescribed in regulation 16, and no later than when it sends its assessment report in accordance with paragraph (d), forward a copy of the application to the Commission.

(2) The Department shall forward to the Commission –

(i) its assessment report,

(ii) any further information it has received from the applicant pursuant to the service of a notice under Article 8(6) of the Order,

(iii) any additional information on which it has based its assessment report,

in the circumstances described in paragraph (1)(d)(i), before the end of a period of 90 days beginning with the day on which it received the application and, in the circumstances described in paragraph (1)(d)(ii), no sooner than 15 days from the date it sent the assessment report to the applicant and no later than 105 days from the date it received the application.

(3) The 90 day periods prescribed in paragraphs (1) and (2) shall not include any period beginning with the day on which the Department gives notice in writing under Article 8(6) of the Order that further information in respect of the application is required and ending on the day on which that information is received by the Department.

(4) Where the Department intends to submit to the Commission an assessment report which indicates that the genetically modified organisms to which an application relates should be permitted to be marketed, it shall first consult the Executive and shall not forward its favourable opinion on the application as it relates to the protection of human health where the Executive has informed it that it does not fulfil the requirements of the Order and of these Regulations.

Decisions by the Department on applications for consents to market genetically modified organisms

24.—(1) The Department may grant an application for consent to market genetically modified organisms only where it has prepared an assessment report which indicates that the genetically modified organisms should be marketed and –

(a) no objection has been raised by a Member State or by the Commission during a 60 day period beginning on the day the Commission circulated the assessment report, or

(b) an objection or objections have been raised by either a Member State or by the Commission but outstanding issues have been resolved in accordance with Article 15(l) of the Deliberate Release Directive within a 105 day period beginning on the day the Commission circulated the assessment report; or

(c) an objection has been raised by a Member State or the Commission and the Commission has adopted a decision in accordance with Article 18(l) of the Deliberate Release Directive in favour of granting consent.

(2) The Department shall inform the competent authority or authorities of each Member State and the Commission of its decision to grant consent to market genetically modified organisms within thirty days of its grant.

(3) For the purpose of calculating the final 45 day period of 105 days in paragraph (1)(b) no period during which further information is awaited from the applicant shall be taken into account.

(4) Subject to paragraphs (5) and (6), a consent to market genetically modified organisms shall be given for a maximum period of ten years beginning with the day on which the consent is issued.

(5) For the purpose of granting consent to market a genetically modified organism or any progeny of that genetically modified organism contained in a plant variety where that plant variety is intended only for the marketing of its seeds under the relevant Community provisions the period of the first consent shall end at the latest ten years after the date of the first inclusion of the first plant variety containing the genetically modified organism on an official national catalogue of plant varieties in accordance with Directives 2002/53/EC(**a**) and 2002/55/EC(**b**).

(6) For the purpose of granting consent to market a genetically modified organism contained in forest reproductive material, the period of any first consent shall end at the latest ten years after the date of the first inclusion of basic material containing the genetically modified organism on an official national register of basic material in accordance with Council Directive 1999/105/EC(**c**).

(**a**) O.J. No. L193, 20.7.2002, p. 1
(**b**) O.J. No. 193, 20.7.2002, p. 33
(**c**) Council Directive 1999/105/EC on the marketing of forest reproductive material (O.J. No. L11 15.1.2000, p. 17)

Duties of the Department on receiving applications for renewal of consent to market

25.—(1) On receipt of an application for renewal of consent to market genetically modified organisms the Department shall –

(a) inform the applicant in writing of the date of receipt of the application;

(b) examine the application for its conformity with the requirements of the Order and of these regulations and, if necessary, request the applicant to supply additional information;

(c) either –

(i) send to the applicant an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should continue to be permitted to be marketed and under which conditions, or

(ii) refuse the application, stating reasons for its decision, supported by an assessment report which indicates that the genetically modified organisms should not continue to be marketed,

(d) forward to the Commission a copy of the application and its assessment report.

(2) Where the Department intends to submit to the Commission an assessment report which indicates that the genetically modified organisms to which an application relates should be permitted to be marketed, it shall first consult the Executive and shall not forward its favourable opinion on the application as it relates to the protection of human health where the Executive has informed it that it does not fulfil the requirements of the Order and of these Regulations.

Decisions by the Department on applications for renewal of consent to market genetically modified organisms

26.—(1) The Department may grant an application to renew a consent to market genetically modified organisms only where it has prepared an assessment report which indicates that the genetically modified organisms should continue to be permitted to be marketed and –

(a) no objection has been raised by a Member State or by the Commission during a 60 day period beginning on the day the Commission circulated the assessment report; or

(b) an objection or objections have been raised by either a Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 17(8) of the Deliberate Release Directive within a 75 day period beginning on the day the Commission circulated the assessment report; or

(c) an objection has been raised by a Member State or the Commission and the Commission has adopted a decision in accordance with Article 18(l) of the Deliberate Release Directive in favour of granting consent.

(2) The Department shall inform the competent authority or authorities of each Member State and the Commission of its decision to renew consent to market genetically modified organisms within 30 days of its renewal.

(3) The consent to market genetically modified organisms shall be given for a period of ten years unless the Department considers that a shorter or longer period is justified, in which case it shall give its reasons in writing.

(4) The applicant may continue to market the genetically modified organisms under the conditions specified in the original consent until a final decision has been taken on the application.

Genetically modified organisms containing antibiotic resistance markers

27.—(1) The Department shall not grant a consent to an application for the release or marketing of genetically modified organisms containing antibiotic resistance markers which may have adverse effects on human health and the environment after –

(i) 31st December 2004 in the case of placing on the market; and

(ii) 31st December 2008 in the case of release.

(2) Where prior to 31st December 2004 in the case of placing on the market and 31st December 2008 in the case of release, an application is made for consent to release or place on

the market genetically modified organisms containing antibiotic resistance markers, the Department shall evaluate the information in the environmental risk assessment accompanying the application, taking into particular consideration those antibiotic resistance markers in use for medical or veterinary treatment, with a view to identifying and phasing out the release or placing on the market of the genetically modified organisms referred to in paragraph (1) within the time limits specified in that paragraph.

PART V

GENERAL PROVISION FOR CONSENTS TO MARKET

General provisions of consents to market genetically modified organisms

28. A consent to market genetically modified organisms granted by the Department under Article 8(1) of the Order shall specify –

(a) the scope of the consent, including the identity of the genetically modified organisms to be placed on the market, and their unique identifier;

(b) the period of validity of the consent;

(c) the conditions for the placing on the market the product, including any specific conditions of use, handling and packaging of the genetically modified organisms, and conditions for the protection of particular ecosystems or environments or geographical areas as applicable;

(d) that the applicant shall make control samples available to the Department on request;

(e) the labelling requirements, in accordance with paragraph 8 of Schedule 3, which shall include a requirement to notify the Department of any new commercial name of the product after consent has been given; and

(f) monitoring requirements which shall be in accordance with the monitoring plan, and shall include the time period of the monitoring plan, an obligation that the applicant shall submit the reports of monitoring to the Commission and the competent authorities of the Member States and, where appropriate, any obligations on any person selling the product or any user, which may include an obligation to provide the information at an appropriate level on the location of the genetically modified organisms that are grown.

General conditions in consents to release or market genetically modified organisms

29.—(1) Article 9 of the Order (consents: limitations and conditions) is amended as follows.

(2) In paragraph (1) (power of Department to impose limitations and conditions) after the words “as he may think fit” insert “for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment which may arise from the activity permitted by the consent.”.

(3) In paragraph (5) (implied condition when releasing or marketing) –

(a) in sub-paragraph (b) (obligation to notify Department of new information etc) –

(i) after “Department” insert “forthwith”,

(ii) omit head (ii), and

(iii) after that head insert –

“(iii) any unforeseen event, occurring in connection with a release by him, which might affect the risks there are of damage to the environment being caused as a result of their being released.”,

(b) for sub-paragraph (c) (duty as regards preventing damage to environment) substitute –

“(c) take such measures as are necessary to prevent any damage to the environment being caused as a result of the release or, as the case may be, the placing on the market of the organisms;”, and

(c) after that sub-paragraph insert –

"(d) notify the Department of the measures (if any) taken as a result of new information becoming available or an unforeseen event occurring as described in sub-paragraph (b)(iii); and

(e) in a case where new information becomes available or an unforeseen event so occurs, revise the information contained in his application for a consent accordingly and supply the revised information to the Department.".

Proof of compliance with consent condition

30. In Article 16 of the Order (onus of proof as regards techniques and evidence) in paragraph (1) (accused to prove use of best available techniques) after "the accused to prove" insert "the matters described in paragraph (1A).

(1A) The matters referred to in paragraph (1) are –

(a) in the case of an offence under Article 15(1)(c) consisting in a failure to comply with the general condition implied by Article 9(5)(c) –

(i) that no measures, other than the measures taken by him, were necessary to prevent damage being caused to the environment from the release or, as the case may be, placing on the market of the organisms, or

(ii) in a case where he took no measures, that no measures were necessary; and

(b) in any other case,".

New information on risks of damage from marketing genetically modified organisms

31.—(1) The Department shall immediately forward to the Commission and the competent authority or authorities of each Member State any new information which becomes available to it which it considers could affect the assessment of the risk of the damage being caused to the environment by releasing or placing on the market genetically modified organisms.

(2) Where an application for consent or for renewal of consent to place on the market genetically modified organisms has been made and the information referred to in paragraph (1) becomes available to the Department before the consent has been granted or renewed, the Department may seek to reach agreement with the Commission and other Member States pursuant to Articles 15(1) or 17(7) of the Deliberate Release Directive as applicable.

(3) Where an application for consent or for renewal of consent to place on the market genetically modified organisms has been made and the information referred to in paragraph (1) becomes available to the Department after the consent has been granted or renewed, it shall within 60 days after receipt of the new information, forward to the Commission an assessment report indicating whether the conditions of the consent should be varied, and, if so, how, or whether the consent should be revoked.

(4) The Department shall not forward an assessment report indicating that the consent to place on the market genetically modified organisms as it relates to the protection of human health should be varied without the agreement of the Executive.

(5) Where the Department has indicated that the consent should be varied and either –

(a) no objection has been raised by a Member State or by the Commission during a 60 day period beginning on the day the Commission circulated the assessment report, or

(b) an objection or objections have been raised by a Member State or by the Commission but outstanding issues have been resolved in accordance with Article 20(3) of the Deliberate Release Directive;

it shall vary the consent as proposed and inform the applicant, the competent authority or authorities of each Member State and the Commission that it has done so within 30 days thereof.

(6) The Department shall only vary or revoke a consent to market genetically modified organisms under Article 8(10) of the Order –

(a) where the information referred to in paragraph (1) has become available to it, and the procedure referred to in paragraphs (3) and (5) has been complied with, or

(b) in accordance with a decision by the Commission under Article 18(1) or Article 23(2) of the Deliberate Release Directive.

PART VI

SAFEGUARD

Safeguard

32.—(1) The Department may serve a prohibition notice under Article 7 of the Order to prohibit an act which is authorised by the consent granted by it under Article 8(1) of the Order or by a consent granted in respect of an approved product only if its opinion that doing such an act would involve a risk of causing damage to the environment is based on detailed grounds as a result of either –

(a) new or additional information made available since the date of the consent which affects the environmental risk assessment in respect of that product; or

(b) a reassessment of existing information in respect of that product on the basis of new or additional scientific information.

(2) Where, in the circumstances described in paragraph (1), the Department considers that the risk of damage being caused to the environment is severe it shall serve a prohibition notice requiring such measures to be taken as it may consider appropriate and once any work required by the notice has been carried out it shall enter details of it on the register.

(3) In cases to which paragraphs (1) and (2) apply, the Department shall immediately inform the Commission and the other Member States of its actions and shall at the same time provide them with –

(a) its reasons for taking such actions;

(b) the results of its review of the environmental risk assessment;

(c) its opinion as to whether the conditions of the consent should be varied, and if so, how, or whether the consent should be revoked; and

(d) where appropriate, the new or additional information on which its decision to take action was based.

(4) A prohibition notice served under Article 7 of the Order in accordance with this regulation shall be subject to any decision adopted by the Commission in accordance with Article 23(2) of the Deliberate Release Directive.

(5) Upon receipt of notification of a decision by the Commission to which paragraph (4) refers the Department shall send a copy of it to the holder of the consent to which the decision relates and shall at the same time withdraw any prohibition notice which is inconsistent with that decision.

(6) References in this regulation to the Department exercising a function under Article 7 of the Order shall, in any case to which Article 22(3) of the Order applies, be treated as references to the Department and the Food Standards Agency(**a**) acting jointly.

(**a**) *See* section 1 of the Food Standards Act 1999 (c. 28)

PART VII

CONFIDENTIALITY

Confidentiality

33.—(1) For the purposes of Article 20(7) of the Order, the following descriptions of information are also information which the public interest requires to be included in the register notwithstanding that it may be commercially confidential –

(a) the location of the release of the genetically modified organisms to which the information relates;

(b) the intended use of the genetically modified organisms to which the information relates;

(c) the environmental risk assessment;

(d) the methods and plans for monitoring and for responding to an emergency in relation to the genetically modified organisms to which the information relates;

(e) the name and address of the holder of a consent to which a prohibition notice or other information relates.

(2) In Article 20 of the Order (exclusion from register of certain information) in paragraph (7) (particulars included even if commercially confidential) –

(a) after "Article 19(1)(a)," insert "(c)",

(b) in sub-paragraph (b) for "the description" substitute "the general description", and

(c) sub-paragraphs (c) and (e) are omitted.

PART VIII

REGISTER OF INFORMATION

Information to be included in the register

34.—(1) The register shall contain the particulars set out in paragraphs (2) to (10).

(2) In relation to a prohibition notice served by the Department under Article 7 of the Order –

(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 placed on the market,

(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 Article 8(1) of the Order –

(a) the name and address of the applicant,

(b) a 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, to the extent that this information is notified to the Department,

(d) the purpose for which the genetically modified organisms are proposed to be released (including any future use to which they are intended to be put) or, in relation to a consent to place on the market, the purpose for which they will be marketed,

(e) the intended dates of the release,

(f) the environmental risk assessment,

(g) the methods and plans for monitoring the genetically modified organisms and for responding to an emergency, and

(h) a summary of any advice the Department has received from the Advisory Committee on Releases to the Environment as to whether an application for release of genetically modified organisms should be granted or rejected, and either –

(i) the conditions or limitations in accordance with which that committee 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 the Department is or becomes aware that information regarding the genetically modified organisms or the purpose for which they will be released or marketed has been published which is more detailed than that which would satisfy the requirements of paragraph (3), it shall enter so much of that more detailed information on the register as it shall consider appropriate.

(5) In relation to consents granted under Article 8(1) of the Order –

(a) a copy of the consent, and a reference to the application in respect of which it was granted,

(b) any information supplied to the Department in accordance with conditions imposed on the consent,

(c) the fact that the consent has been varied or revoked, the contents of the notice by which the consent was varied or revoked, and a copy of the varied consent,

(d) a summary of any advice the Department has received from the Advisory Committee on Releases to the Environment as to whether a consent to release genetically modified organisms should be varied or revoked.

(6) The following information concerning genetically modified organisms released or grown pursuant to a consent –

(a) any information provided to the Department in accordance with Article 8(6A) or Article 9(5)(b)(i) of the Order,

(b) any information relating to an unforeseen event occurring in connection with a release of a genetically modified organism which might affect the risks there are of damage being caused to the environment notified to the Department in accordance with Article 9(5)(b)(ii) of the Order.

(7) A copy of any consent to market genetically modified organisms granted by a competent authority of another Member State.

(8) The location of any genetically modified organisms grown in Northern Ireland pursuant to a consent to market insofar as that information is supplied to the Department in accordance with the monitoring requirements imposed on the consent.

(9) Any decision adopted by the Commission in accordance with Article 18 of the Deliberate Release Directive.

(10) In relation to convictions for any offence under Article 15 of the Order –

(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 Article 17 of the Order.

Keeping the register

35.—(1) The information prescribed in regulation 34(2) shall be placed on the register within 12 days of the prohibition notice being served.

(2) The information prescribed in paragraphs (a) to (g) of regulation 34(3) shall be placed on the register within 12 days of the receipt by the Department of the application for consent to release or to place on the market.

(3) The information prescribed in regulation 34(3)(h) shall be placed on the register within 12 days of the consent being granted or refused.

(4) The information prescribed in regulation 34(5)(a) shall be placed on the register within 12 days of the consent being granted.

(5) The information prescribed in regulation 34(5)(b) and (d) shall be placed on the register within 12 days of its receipt by the Department.

(6) The information prescribed in regulation 34(5)(c) shall be placed on the register within 14 days of the consent being revoked or varied.

(7) The information prescribed in regulations 34(6) and 34(10) shall be placed on the register within 14 days of its receipt by the Department.

(8) The information prescribed in regulation 34(7) shall be placed on the register within 14 days of its receipt by the Department.

(9) The information prescribed in regulation 34(8) shall be placed on the register within 14 days of its receipt by the Department.

(10) The information prescribed in regulation 34(9) shall be placed on the register within 14 days of the decision having been notified to the Department.

Publication of representations

36.—(1) The Department shall, within a period of 28 days after granting consent to or rejecting an application for the release of genetically modified organisms, make available to the public by whatever means it shall consider appropriate, details of where and when paper copies of representations received may be inspected.

(2) Paragraph (1) shall not require copies of representations to be made publicly available where they contain confidential information and the person making the representations has asked the Department to treat that information as confidential.

PART IX

MISCELLANEOUS

Advisory Committee for the purposes of the Order

37. After Article 22 of the Order there shall be inserted –

"Advisory Committee

22.—(1) The Department shall appoint a Committee to provide it with advice –

(a) on the exercise of its powers under Articles 8, 9 and 10;

(b) on the exercise of any power under this Order to make regulations,

and on such other matters concerning the Department's functions under this Order as the Department may from time to time direct.

(2) The Department shall pay to the members of the Committee such remuneration (if any) and such allowances as it may determine.".

(3) The "Committee" means the Committee appointed by the Secretary of State under section 124 of the Environmental Protection Act 1990(**a**).".

(**a**) 1990 c. 43

Revocations

38. The Regulations set out in Schedule 5 are revoked to the extent set out in that Schedule.

Sealed with the Official Seal of the Department of the Environment on 12th March 2003.

(L.S.) *Judena Goldring*
A senior officer of the Department of the Environment

SCHEDULE 1 regulations 11 and 16

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR CONSENT TO RELEASE OR MARKET GENETICALLY MODIFIED HIGHER PLANTS

PART I

GENERAL INFORMATION

1. The name and address of the applicant, and the name, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the release of the organisms, and for the supervision, monitoring and safety of the release.

2. The title of the project.

PART II

INFORMATION RELATING TO THE PARENTAL OR RECIPIENT PLANT

3. The full name of the plant –
(a) family name,
(b) genus,
(c) species,
(d) subspecies,
(e) cultivar/breeding line,
(f) common name.

4. Information concerning –
(a) the reproduction of the plant:
  (i) the mode or modes of reproduction,
  (ii) any specific factors affecting reproduction,
  (iii) generation time; and
(b) the sexual compatibility of the plant with other cultivated or wild plant species, including the distribution in Europe of the compatible species.

5. Information concerning the survivability of the plant:
(a) its ability to form structures for survival or dormancy,
(b) any specific factors affecting survivability.

6. Information concerning the dissemination of the plant:
(a) the means and extent (such as an estimation of how viable pollen and/or seeds declines with distance where applicable) of dissemination; and
(b) any specific factors affecting dissemination.

7. The geographical distribution of the plant.

8. Where the application relates to a plant species which is not normally grown in the United Kingdom, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

9. Any other potential interactions, relevant to the genetically modified organism, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

PART III

INFORMATION RELATING TO GENETIC MODIFICATION

10. A description of the methods used for the genetic modification.

11. The nature and source of the vector used.

12. The size, intended function and name of the donor organism or organisms of each constituent fragment of the region intended for insertion.

PART IV

INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

13. A description of the trait or traits and characteristics of the genetically modified plant which have been introduced or modified.

14. The following information on the sequences actually inserted or deleted –

(a) the size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced into the genetically modified plant or any carrier or foreign DNA remaining in the genetically modified plant,

(b) the size and function of the deleted region or regions,

(c) the copy number of the insert, and

(d) the location of the insert or inserts in the plant cells (whether it is integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form) and the methods for its determination.

15. The following information on the expression of the insert –

(a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation,

(b) the parts of the plant where the insert is expressed, such as roots, stem or pollen.

16. Information on how the genetically modified plant differs from the parental or recipient plant in the following respects –

(a) mode or modes and/or the rate of reproduction,

(b) dissemination,

(c) survivability.

17. The genetic stability of the insert and phenotypic stability of the genetically modified plant.

18. Any change to the ability of the genetically modified plant to transfer genetic material to other organisms.

19. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.

20. Information on the safety of the genetically modified plant to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the genetically modified plant is intended to be used in animal feedstuffs.

21. The mechanism of interaction between the genetically modified plant and target organisms, if applicable.

22. The potential changes in the interactions of the genetically modified plant with non-target organisms resulting from the genetic modification.

23. The potential interactions with the abiotic environment.

24. A description of detection and identification techniques for the genetically modified plant.

25. Information about previous releases of the genetically modified plant, if applicable.

PART V

INFORMATION RELATING TO THE SITE OF RELEASE

(Applications for consent to release only)

26. The location and size of the release site or sites.

27. A description of the release site ecosystem, including climate, flora and fauna.

28. Details of any sexually compatible wild relatives or cultivated plant species present at the release sites.

29. The proximity of the release sites to officially recognised biotopes or protected areas which may be affected.

PART VI

INFORMATION RELATING TO THE RELEASE

(Applications for consent to release only)

30. The purpose of the release of the genetically modified plant, including its initial use and any intention to use it as or in a product in the future.

31. The foreseen date or dates and duration of the release.

32. The method by which the genetically modified plants will be released.

33. The method for preparing and managing the release site, prior to, during and after the release, including cultivation practices and harvesting methods.

34. The approximate number of genetically modified plants (or plants per square metre) to be released.

PART VII

INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE TREATMENT PLANS

(Applications for consent to release only)

35. A description of any precautions to –

(a) maintain the genetically modified plant at a distance from sexually compatible plant species, both wild relatives and crops,

(b) any measures to minimise or prevent dispersal of any reproductive organ of the genetically modified plant (such as pollen, seeds, tuber).

36. A description of the methods for post-release treatment of the site or sites.

37. A description of the post-release treatment methods for the genetically modified plant material including wastes.

38. A description of monitoring plans and techniques.

39. A description of any emergency plans.

40. Methods and procedures to protect the site.

PART VIII

INFORMATION ON METHODOLOGY

41. A description of the methods used or a reference to standardised or internationally recognised methods used to compile the information required by this Schedule, and the name of the body or bodies responsible for carrying out the studies.

SCHEDULE 2

regulations 11 and 16

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR CONSENT TO RELEASE OR MARKET ORGANISMS OTHER THAN GENETICALLY MODIFIED HIGHER PLANTS

PART I

GENERAL INFORMATION

1. The name and address of the applicant, and the name, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the release of the organisms, and for the supervision, monitoring and safety of the release.

2. The title of the project.

PART II

INFORMATION RELATING TO ORGANISMS

Characteristics of donor, parental and recipient organisms

3. Scientific name and taxonomy.

4. Usual strain, cultivar or other name.

5. Phenotypic and genetic markers.

6. The degree of relatedness between donor and recipient or between parental organisms.

7. The description of identification and detection techniques.

8. The sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.

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

10. The organisms with which transfer of genetic material is known to occur under natural condition.

11. Verification of the genetic stability of the organisms and factors affecting that stability.

12. The following pathological, ecological and physiological traits -

(a) the classification of hazard according to existing Community rules concerning the protection of human health and the environment;

(b) the generation time in natural ecosystems, sexual and asexual reproductive cycle;

(c) information on survivability, including seasonability and the ability to form survival structures, including seeds, spores and sclerotia;

(d) pathogencity, 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.

13. The sequence, frequency of mobilisation and specificity of indigenous vectors, and the presence in those vectors of genes which confer resistance to environmental stresses.

14. The history of previous genetic modifications.

Characteristics of the vector

15. The nature and source of the vector.

16. 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.

17. The frequency of mobilisation, genetic transfer capabilities and/or methods of determination of the inserted vector.

18. The degree to which the vector is limited to the DNA required to perform the intended function.

Characteristics of the modified organisms

19. The methods used for the modification.

20. The methods used –

(a) to construct the insert or inserts and to introduce it or them into the recipient organism;

(b) to delete a sequence.

21. The description of any insert and/or vector construction.

22. 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.

23. The methods and criteria used for selection.

24 The sequence, functional identity and location of the altered, inserted or deleted nucleic acid segment or segments in question, and in particular any known harmful sequence.

Characteristics of the genetically modified organisms in their final form

25. The description of genetic trait or traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

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

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

28. 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.

29. The activity of the gene product.

30. The description of identification and detection techniques, including techniques for the identification and detection of the inserted sequence and vector.

31. The sensitivity, reliability (in quantitative terms), and specificity of detection and identification techniques.

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

33. In relation to human health, animal health and plant health –

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

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

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

(d) if the organisms are pathogenic to humans who are immunocompetent –

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

(ii) communicability,

(iii) infective dose,

(iv) host range and possibility of alteration,

(v) possibility of survival outside of human host,

(vi) presence of vectors or means of dissemination,

(vii) biological stability,

(viii) antibiotic resistance patterns,

(ix) allergenicity, and

(x) availability of appropriate therapies.

(e) the other product hazards.

PART III

INFORMATION RELATING TO THE CONDITIONS OF RELEASE

The release

34. The description of the proposed deliberate release, including the initial purpose or purposes of the release and any intention to use the genetically modified organism as or in a product in the future.

35. The intended dates of the release and time planning of the experiment including frequency and duration of releases.

36. The preparation of the site before the release.

37. The size of the site.

38. The method or methods to be used for the release.

39. The quantity of organisms to be released.

40. The disturbance on the site, including the type and method of cultivation, and mining, irrigation or other activities.

41. The worker protection measures taken during the release.

42. The post-release treatment of the site.

43. The techniques foreseen for elimination or inactivation of the organisms at the end of the experiment or other purpose of the release.

44. Information on, and the results of, previous releases of the organisms, and in particular, releases on a different scale or into different ecosystems.

The environment (both on the site and in the wider environment)

45. The geographical location and national grid reference of the site or sites onto which the release will be made, or the foreseen areas of use of the product.

46. The physical or biological proximity of the site of the organisms to humans and other significant biota.

47. The proximity to significant biotopes, protected areas or drinking water supplies.

48. The climatic characteristics of the region or regions likely to be affected.

49. The geographical, geological and pedological characteristics.

50. The flora and fauna, including crops, livestock and migratory species.

51. The description of the target and non-target ecosystems likely to be affected.

52. The comparison of the natural habitat of the recipient organisms with the proposed site or sites of release.

53. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

PART IV

INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE ORGANISMS AND THE ENVIRONMENT

Characteristics affecting survival, multiplication and dissemination

54. The biological features which affect survival, multiplication and dispersal.

55. The known or predicted environmental conditions which may affect survival, multiplication and dissemination, including wind, water, soil, temperature and pH.

56. The sensitivity to specific agents.

Interactions with the environment

57. The predicted habitat of the organisms.

58. 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.

59. 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.

60. The likelihood of post-release selection leading to the expression of unexpected or undesirable traits in the genetically modified organisms.

61. 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.

62. The routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact and burrowing.

63. The description of ecosystems to which the organisms could be disseminated.

64. The potential for excessive population increase of the organisms in the environment.

65. The competitive advantage of the organisms in relation to the unmodified recipient or parental organisms.

66. The identification and description of the target organisms if applicable.

67. The anticipated mechanism and result of interaction between the released organisms and the target organisms, if applicable.

68. The identification and description of non-target organisms which may be adversely affected by the release of the genetically modified organisms, and the anticipated mechanisms of any identified adverse interaction.

69. The likelihood of post release shifts in biological interactions or in the host range.

70. The known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens.

71. The known or predicted involvement of the organisms in biogeochemical processes.

72. Any other potentially significant interactions of the organisms with the environment.

PART V

INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

Monitoring techniques

73. Methods for tracing the organisms and for monitoring their effects.

74. Specificity (to identify the organisms, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques.

75. Techniques for detecting transfer of the donated genetic material to other organisms.

76. Duration and frequency of the monitoring.

Control of the release

77. Methods and procedures to avoid and/or minimise the spread of the organisms beyond the site of release or the designated area for use.

78. Methods and procedures to protect the site from intrusion by unauthorised individuals.

79. Methods and procedures to prevent other organisms from entering the site.

Waste treatment

80. Type of waste generated.

81. Expected amount of waste.

82. Description of treatment envisaged.

Emergency response plans

83. Methods and procedures for controlling the organisms in case of unexpected spread.

84. Methods, such as eradication of the organisms, for decontamination of the areas affected.

85. Methods for disposal or sanitation of plants, animals, soils, and any other thing exposed during or after the spread.

86. Methods for the isolation of the areas affected by the spread.

87. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

PART VI

INFORMATION ON METHODOLOGY

A description of the methods used or a reference to standardised or internationally recognised methods used to compile the information required by this Schedule, and the name of the body or bodies responsible for carrying out the studies.

SCHEDULE 3 regulation 16(2)(d) and (h) and (5)

INFORMATION TO BE INCLUDED IN AN APPLICATION FOR CONSENT TO MARKET GENETICALLY MODIFIED ORGANISMS

PART I

GENERAL INFORMATION

1. The proposed commercial name of the product and names of the genetically modified organisms in the product, and any specific identification, name or code used by the applicant to identify the genetically modified organism.

2. The name and address in the Community of the person who is responsible for the placing on the market, whether it be the manufacturer, importer or distributor.

3. The name and address of the supplier or suppliers of control samples.

4. A description of how the product and the genetically modified organism are intended to be used, highlighting any differences in use or management of the genetically modified organism compared to similar non-genetically modified products.

5 A description of the geographical area or areas and types of environment where the product is intended to be used within the Community, including, where possible, an estimate of the scale of use in each area.

6 A description of the intended categories of users of the product, such as industry, agriculture or consumer use by the public.

7. Information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular products to facilitate post marketing control and inspection. This information should include where appropriate the lodging of samples of the genetically modified organism or its genetic material with the Department, and details of nucleotide sequences or other type of information which is necessary to identify the product

and its progeny, for example the methodology for detecting and identifying the product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified.

8. The proposed labelling, which must include, in a label or an accompanying document, at least in summarised form, a commercial name of the product, a statement that "This product contains genetically modified organisms", the name of the genetically modified organism and the name and address of the person established in the Community who is responsible for the placing on the market, and how to access the information in the publicly accessible part of the register.

PART II

ADDITIONAL RELEVANT INFORMATION

9. The measures to be taken in the event of the escape of the organisms in the product or misuse of the product.

10. Specific instructions or recommendations for storage and handling of the product.

11. Specific instructions for carrying out monitoring and reporting to the applicant and, if required, the Department, which are consistent with Part C of Annex VII of the Deliberate Release Directive.

12 The proposed restrictions in the approved use of the genetically modified organism, such as where the product may be used and for what purposes.

13. The proposed packaging.

14. The estimated product in and/or imports to the Community.

15. Any proposed additional labelling, which may include, at least in summarised form, the information referred to in paragraphs 4 and 5 of Part I of this Schedule, or paragraphs 9 to 12 of this Part.

SCHEDULE 4 regulations 23, 25 and 31

INFORMATION TO BE INCLUDED IN AN ASSESSMENT REPORT

1. An identification of the characteristics of the recipient organism which are relevant to the assessment of the relevant genetically modified organisms.

2. A description of the way in which the characteristics of the organisms have been affected by genetic modification.

3. An identification of any known risks of damage to the environment resulting from the release into the environment of the recipient non-modified organism.

4. An assessment of whether the genetic modification has been characterised sufficiently for the purpose of evaluating any risks to human health and the environment.

5. An identification of any new risks of damage to the environment that may arise from the release of the relevant genetically modified organisms as compared to the release of the corresponding non-modified organism, based on the environmental risk assessment.

6. A conclusion which addresses the proposed use of the product, risk management and the proposed monitoring plan, and states whether the relevant genetically modified organisms should be placed on the market and under which conditions, or should not be placed on the market, including reasons for that conclusion, and whether the views of the competent authorities and the Commission are sought for on specific aspects of the environmental risk assessment and what those aspects are.

SCHEDULE 5

regulation 38

REVOCATIONS

Regulations revoked	*References*	*Extent*
The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994	S.R. 1994 No. 144 as amended by the Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations (NI) 1995 (S.R. 1995 No. 413), the Genetically Modified Organisms (Deliberate Release and Risk Assessment) (Amendment) Regulations (NI) 1997 (S.R. 1997 No. 534 and the Genetically Modified Organisms (Contained Use) Regulations (NI) (S.R. 2001 No. 295).	The whole Regulations
The Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations (NI) 1995	S.R. 1995 No. 413	The whole Regulations
The Genetically Modified Organisms (Deliberate Release and Risk Assessment) (Amendment) Regulations (NI) 1997	S.R. 1997 No. 534	Regulation 2
The Genetically Modified Organisms (Contained Use) Regulations (NI) 2001	S.R. 2001 No. 295	Regulation 31(2)

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement, in respect of Northern Ireland, Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms ("the Directive") which replaced Council Directive 1990/220/EEC (as amended) of the same title.

The subject matter of the Directive and its predecessor is the control of the deliberate release into the environment and the placing on the market of genetically modified organisms by means of the imposition of a requirement to obtain consent for those activities and to comply with the conditions imposed on the consent. The changes introduced by the Directive strengthen the existing control regime, particularly in respect of post marketing monitoring.

Directive 1990/220/EEC was implemented partly by the provisions of the Genetically Modified Organisms (NI) Order 1991 ("the Order") and partly by the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994 (subsequently amended).

These Regulations include amendments to the Order required to implement the Directive and revoke the 1994 Regulations. The Order is also amended to take account of the Advisory Committee on Releases to the Environment.

The statutory basis for the requirement to obtain consent for the release or marketing of genetically modified organisms is Article 8 (1) of the Order. The cases and circumstances in which consent is required are prescribed in these Regulations. A general requirement to obtain consent for the release or marketing of genetically modified organisms is imposed by regulation 8 (for release) and regulation 14 (for marketing). This general requirement is subject to the exemptions provided for in regulations 9 (for release) and 15 (for marketing).

The definitions used in the provisions relating to the control regime are contained in Articles 2, 3, and 4 of the Order. Regulations 3 and 4 amend a number of these definitions to reflect the Directive. Regulation 3 also amends the power in Article 3 for the Department to prescribe techniques which result in organisms becoming "genetically modified". However, on coming into operation of these Regulations, references in the Order to "genetically modified organisms" will be interpreted by reference to the modification techniques described in regulation 5.

Parts II and III of the Regulations impose requirements for applications for consent to release and place on the market, respectively, genetically modified organisms (including transitional provisions).

Part IV lays down the procedure for dealing with applications from their receipt to their determination (and, in the case of consents to release, their subsequent variation or revocation). For release consents this includes provisions for public consultation and for marketing consents (and renewals of such consents) their agreement at European Community level.

Part V includes general requirements for marketing consents and amends Article 9 of the Order (which imposes conditions on consents). It also provides for what should happen when new information becomes available which affects the risk assessment for the marketing of a genetically modified organism.

Part VI supplements Article 7 of the Order insofar as it allows action to be taken to prohibit the marketing of a genetically modified organism which has consent so as to bring it into line with the taking of "safeguard action" under the Directive. Part VII prescribes additional categories of information to be made public notwithstanding that they may be commercially confidential, for the purposes of Article 20(7) of the Order.

Copies of the Directive may be obtained at http://europa.eu.int/eur-lex/en/index.html and from the Stationery Office Ltd., 16 Arthur Street, Belfast, BT1 4GD

£5·50

Published by The Stationery Office Limited

Printed in the UK by The
Stationery Office Limited
under the authority and
superintendence of Carol
Tullo, Controller of
Her Majesty's Stationery
Office being the Government
Printer for Northern Ireland and
the Officer appointed to print the
Acts of the Northern Ireland Assembly

Dd. N857. C3. 3/03. Gp. 130. 14567.

ISBN 0-337-95010-5

9 780337 950100