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

2002 No. 541

ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002

Made *4th December 2002*

Coming into force in accordance with regulation 1(1)

ARRANGEMENT OF REGULATIONS

SCHEDULES

The Scottish Ministers, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**a**) and of all other powers enabling them in that behalf hereby make the following Regulations, a draft of which has, in accordance with paragraph 2(2) of Schedule 2 to that Act been laid before, and approved by resolution of, the Scottish Parliament:

PART I

GENERAL

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 and shall come into force on the day after the day on which they are made.

(2) These Regulations extend to Scotland only.

Interpretation

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

"the Act" means the Environmental Protection Act 1990(**b**);

"the Advisory Committee on Releases to the Environment" means the committee appointed for the purposes of, and in accordance with, section 124 of the Act;

"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 consisting of or including genetically modified organisms which is permitted to be marketed by a consent granted under section 111(1) of the Act or otherwise 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;

"community council" means a community council constituted under section 51 of the Local Government (Scotland) Act 1973(**c**);

"the Contained Use Directive" means Council Directive 1990/219/EEC(**d**) on the contained use of genetically modified micro-organisms as amended by Commission Directive 1994/51/EC(**e**) and Council Directive 1998/81/EC(**f**);

(a) 1972 c.68; section 2(2) was amended by the Scotland Act 1998 (c.46), Schedule 8, paragraph 15(3). The function conferred upon the Minister of the Crown under section 2(2) of the European Communities Act 1972, insofar as within devolved competence, was transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998.
(b) 1990 c.43.
(c) 1973 c.65.
(d) O.J. No. L 117, 8.5.90, p.1.
(e) O.J. No. L 297, 18.11.94, p.29.
(f) O.J. No. L 330, 5.12.98, p.13.

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

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**);

"electronic communication" has the same meaning as in the Electronic Communications Act 2000(**e**);

"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 virtue of regulation 11(1)(c) and regulation 16(2)(c) respectively;

"the First Simplified Procedure (crop plants) Decision" means Commission Decision 1994/730/EC(**f**), as amended by the Deliberate Release Directive;

"the Food Standards Agency" means the Food Standards Agency established under section 1 of the Food Standards Act 1999(**g**);

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

"the Health and Safety Executive" means the Health and Safety Executive established under section 10 of the Health and Safety at Work etc. Act 1974(**h**);

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

"local authority" means a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994(**i**);

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

"the register" means the public register kept by the Scottish Ministers under section 122 of the Act;

"Regulation 2309/93" has the same meaning as it has in Schedule 1;

"the 1992 Regulations" means the Genetically Modified Organisms (Deliberate Release) Regulations 1992(**j**).

(2) Expressions used in these Regulations have, unless the contrary intention appears, the meaning which they bear in Part VI of the Act and in regulations 8, 9, 14, 15, 33 and 34 the prescribing of cases, circumstances, descriptions and matters shall be treated as being cases, circumstances, descriptions and matters prescribed in accordance with and under the Act.

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

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

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

Purpose of Part VI of the Act and meaning of "genetically modified organisms" etc.

3.—(1) Section 106 of the Act (purpose of Part VI and meaning of "genetically modified organisms" etc.) is amended as follows.

(2) For subsection (1) (purpose of Part VI) substitute–

"(1) This Part 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.".

(a) O.J. No. L 106, 17.4.01, p.1.
(b) O.J. No. L 117, 8.5.90, p.15.
(c) O.J. No. L 103, 22.4.94, p.20.
(d) O.J. No. L 169, 27.6.97, p.72.
(e) 2000 c.7.
(f) O.J. No. L 292, 12.11.94, p.31.
(g) 1999 c.28.
(h) 1974 c.37.
(i) 1994 c.39.
(j) S.I. 1992/3280, as amended by S.I. 1993/152, 1995/304, 1997/1900 and 2000/2831.

(3) In subsection (4) (definition of organism which is genetically modified)–

(a) insert after "this Part"–

", subject to subsection (4C) below,"; and

(b) for paragraph (a) (modification of prescribed artificial technique) substitute–

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

(4) After subsection (4) insert–

"(4A) subject to subsections (4B) and (4C) below, genes or other genetic material in an organism are "artificially modified" for the purposes of subsection (4) above if they are altered otherwise than by a process which occurs naturally in mating or natural recombination.

(4B) For the purposes of subsection (4) above–

(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 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 paragraph.

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

(4D) In subsections (4B) and (4C) above, "prescribed" means prescribed by regulations made by the Scottish Ministers.".

(5) Subsections (5) (techniques which may be prescribed as genetic modification) and (6) (direct or indirect means of modification immaterial) are omitted.

Meaning of "damage to the environment" etc.

4.—(1) Section 107 of the Act (meaning of "damage to the environment" etc.) is amended as follows.

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

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

(3) In subsection (3) (meaning of "damage to the environment") the words "to the living organisms supported by the environment" are omitted.

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

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

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

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

(6) For subsection (11) (meaning of "marketed") substitute–

"(11) Genetically modified organisms of any description are "marketed" 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 force of the first regulations made by the Scottish Ministers under section 106(4B)(a) (power to prescribe techniques, alteration by which shall be taken to be artificial modification)(**a**) of the Act, genes or other genetic material shall be taken, for the

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(a) Section 106(4) is amended by regulation 3(3) and section 106(4A) to (4D) is inserted by regulation 3(4).

purposes of subsection (4) of that section, 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 force of the first regulations made by the Scottish Ministers under section 106(4B)(b) (power to prescribe techniques, alteration by which shall not be taken to be artificial modification) of the Act, genes or other genetic material shall not be taken, for the purposes of subsection (4) of that section, to be artificially modified by reason only of being altered by the use of any of the following techniques:–

(a) in vitro fertilisation;

(b) natural processes including conjugation, transduction or transformation;

(c) polyploidy induction:

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; or

(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 force of the first regulations made by the Scottish Ministers under section 106(4C) (power to prescribe organisms which shall be taken not to be genetically modified) of the Act, an organism shall be taken, for the purposes of Part VI of the Act, 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 or for renewal of consent to 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 the 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; and

(c) include any bibliographic references 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 an applicant for consent

7.—(1) Notwithstanding paragraph (2), wherever an applicant for a 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 or in written form, whether before or after consent is granted, the applicant shall submit that document both in writing and in an electronic form acceptable to the Scottish Ministers.

(2) A reference in these Regulations to anything done in writing or produced in written form which does not fall within the provisions of paragraph (1) includes a reference to an electronic communication which has been recorded and is consequently capable of being reproduced.

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 section 111(1)(a) of the Act 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 section 111(7) of the Act in which persons are exempt from the requirements of section 111(1)(a) of the Act, insofar as those requirements apply to the release of genetically modified organisms, are all cases and circumstances 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 – general provisions

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

(2) The Scottish Ministers may accept that 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 application 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 2, where the application is for consent to release any genetically modified higher plant; or

(ii) Schedule 3 in any other case,

to the extent 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 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 any competent authority of any Member State (including the Scottish Ministers) in accordance with Article 6 of the Deliberate Release Directive or Article 5 of the 1990 Directive;

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

(d) a summary, in the format established by the Commission under Articles 11(1) and 30(2) 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 where the data or results are confidential 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 the applicant sends that application to the Scottish Ministers, cause to be published in any newspaper to be specified by the Scottish Ministers a notice approved by the Scottish Ministers 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 of the release;

(e) a statement that information about the application will be placed on the register by the Scottish Ministers within 12 days of their receipt of the application;

(f) the means by which the register can be inspected; and

(g) a statement that the Scottish Ministers shall, within a period which they shall specify in accordance with these Regulations, have regard to any representations made to them in writing relating to risks of damage to the environment(**a**) posed by the release of the genetically modified organisms,

and that person shall–

(i) immediately send to the Scottish Ministers confirmation that such information was placed in such newspaper and the date on which the information was published in the newspaper; and

(ii) if requested to do so by the Scottish Ministers, send a copy of such newspaper containing the advertisement to them.

(2) A notice published under paragraph (1) need not contain the information referred to in subparagraphs (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 Scottish Ministers 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, subject to paragraph (5), not more than ten days after that person sends that application to the Scottish Ministers, give to the following persons notice in writing that the application has been made and the information prescribed in paragraph (1)(a) to (g) (save insofar as paragraph (2) permits such information to be excluded from the notice referred to in paragraph (1)):–

(a) the local authority and community council for the area of each proposed release;

(b) the owner of the site of each proposed release, if such person is not 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 2000(**b**) where relevant;

(d) any National Park Authority designated under section 6 of the National Parks (Scotland) Act 2000(**c**) for the area of each proposed release;

(e) Scottish Natural Heritage established under section 1 of the Natural Heritage (Scotland) Act 1991(**d**); and

(f) such other body as the Scottish Ministers may notify the applicant that they consider appropriate,

and shall immediately send to the Scottish Ministers copies of the notices given under this paragraph.

(5) Notwithstanding paragraph (4), the applicant shall give any body which the Scottish Ministers consider appropriate, for the purposes of paragraph (4)(f), the notice referred to in paragraph (4) within ten days of receipt by the applicant of the notification of such body as the Scottish Ministers consider appropriate.

(a) As defined in section 107(2), (3) and (6) of the Act as amended by regulation 4(2) to (4).
(b) S.I. 2000/2831.
(c) 2000 asp 10.
(d) 1991 c.28.

Transitional provisions in respect of applications to release

13. Where the Scottish Ministers, before the coming into force date of these Regulations, have received an application for consent to release genetically modified organisms pursuant to the 1992 Regulations and have not as at that date determined the application–

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

(b) the applicant shall submit in writing to the Scottish Ministers 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 the date occurring three months after the coming into force date of these Regulations;

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

(d) if the information required by paragraph (b) has not been submitted in writing by the date occurring three months after the coming into force date of these Regulations, the Scottish Ministers 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 section 111(1)(a) of the Act in relation to marketing genetically modified organisms are all cases and circumstances in relation to the marketing of genetically modified organisms.

Exempt activities

15. The cases and circumstances prescribed for the purposes of sections 108(7) and 111(7) of the Act in which persons are exempt from the requirements of section 108(1)(a) of the Act (to carry out a risk assessment) and of section 111(1)(a) of the Act (to obtain consent), respectively, 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 (including culture collections);

(c) genetically modified organisms other than micro-organisms referred to in 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 Regulation 2309/93 is marketed;

(f) a novel food or novel food ingredient within the scope of Regulation EC No. 258/1997 of the European Parliament and of the Council(**a**) as amended by Commission Regulation (EC) No. 1852/2001(**b**) is marketed.

Applications for consent to market

16.—(1) An application for a consent to market genetically modified organisms under section 111(1) of the Act must be made in writing to the Scottish Ministers.

(a) O.J. No. L 43, 14.2.97, p.1

(b) O.J. No. L 253, 21.9.01, p.17.

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

(a) subject to paragraph (4), the information prescribed in–

(i) Schedule 2 where the application is for consent to market any genetically modified higher plant; or

(ii) Schedule 3 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 same genetically modified organisms, or of the same combination of genetically modified organisms, which has been carried out by the applicant anywhere, and information from any previous application for consent to release the same genetically modified organisms, or the same combination of genetically modified organisms, which the applicant has made to any competent authority of any Member State (including the Scottish Ministers) in accordance with Article 6 of the Deliberate Release Directive or Article 5 of the 1990 Directive;

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

(d) subject to paragraph (4), the information prescribed in Schedule 4;

(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 4;

(i) a proposal for packaging; and

(j) a summary of the application in the format established by the Commission under Articles 13(2)(h) and 30(2) 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 if the data or results are confidential 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 paragraph (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 data or 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 the application by that person to the satisfaction of the Scottish Ministers that, on the basis of the results of any release in pursuance of and in accordance with a consent for a deliberate release granted by any competent authority of any Member State (including the Scottish Ministers) in accordance with Article 6(5) of the Deliberate Release Directive or Article 6(2) of the 1990 Directive, or on other substantive, reasoned scientific grounds, that the marketing and use of the product consisting of or including the genetically modified organisms do not pose a risk of damage to the environment, the applicant may omit from the application part or all of the information prescribed in Part II of Schedule 4.

Transitional provision in respect of applications to market

17. Where the Scottish Ministers have received an application for consent to market genetically modified organisms before the coming into force date of these Regulations pursuant to the 1992 Regulations and have 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 in writing to the Scottish Ministers 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 the date occurring three months after the coming into force date of these Regulations;

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

(d) if, by the coming into force date of these Regulations, the information required by regulation 16(2) of the 1992 Regulations has been forwarded to the Commission, the Scottish Ministers shall ensure that the information is supplemented and, if they consider it necessary, revised on the receipt by the Scottish Ministers of the further information required by paragraph (b) in the light of their obligations under these Regulations; and

(e) if the information required by paragraph (b) has not been submitted in writing by the date occurring three months after the coming into force date of these Regulations, the Scottish Ministers may refuse to proceed with the application.

Applications for renewal of consent to market

18.—(1) Where a consent has been granted under section 111(1) of the Act to market genetically modified organisms which were first marketed in Scotland, any application to renew that consent shall be made in writing to the Scottish Ministers–

(a) before 17th October 2006 where the consent was granted before the coming into force date of these Regulations; or

(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 the consent to market was granted–

(i) after the coming into force date of these Regulations, a report on the results of the monitoring carried out in accordance with the requirements of regulation 28(f); or

(ii) before that date, a report on the results of any monitoring carried out on the relevant product;

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

(d) as appropriate, a proposal for amending, complementing 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 first marketed in Scotland which was granted under section 111(1) of the Act before the coming into force date of these Regulations and for which no application for renewal under paragraph (1) has been received by the Scottish Ministers before 17th October 2006 shall be treated as having expired on that date.

(4) Any consent to market genetically modified organisms marketed in Scotland which was granted under section 111(1) of the Act before the coming into force date of these Regulations and for which an application for renewal under paragraph (1) is refused shall be treated as having expired on 17th October 2006 or the date of refusal of the application, whichever is the later.

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

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

19.—(1) Section 111 of the Act (consents required by certain persons) is amended as follows:–

(a) in subsection (6)–

(i) after the word "period" where it appears for the first time insert "and in such form and manner"; and

(ii) after the word "period" where it appears for the second time insert "and in the specified form and manner"; and

(b) after subsection (6) (power of Scottish Ministers to require further information) insert–

"(6ZA) A notice under subsection (6) 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 Scottish Ministers of any information in accordance with section 111(6A) of the Act (requirement for applicant to notify new information regarding risks of damage to the environment)(**a**) shall submit in writing to the Scottish Ministers a revised version of the original application for consent amended to take account of the new information.

Duties of the Scottish Ministers in relation to applications for consent to release

20. Following receipt of an application for consent to release genetically modified organisms the Scottish Ministers 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 in writing to the Scottish Ministers relating to any risks of damage being caused to the environment(**b**) 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 the Scottish Ministers;

(c) ensure that within thirty days of the date that the application was received by them a summary of that application in the format established by the Commission under Articles 11(1) and 30(2) of the Deliberate Release Directive is forwarded to the Commission;

(d) examine the application for its conformity with the requirements of the Act 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 prepared in accordance with regulation 6; and

(f) take into account and give due weight to–

(i) any representations made to them before the end of the period specified in paragraph (b) relating to risks of damage being caused to the environment by the release; and

(ii) any comments made by the 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 Scottish Ministers on applications for consent to release

21.—(1) The Scottish Ministers shall not grant consent to release genetically modified organisms under section 111(1) of the Act as it relates to the protection of human health without the agreement of the Health and Safety Executive.

(2) The Scottish Ministers shall not determine an application to release genetically modified organisms before the end of a period of sixty days beginning on the day on which the application for consent was received.

(3) The Scottish Ministers shall–

(a) communicate in writing their decision on an application for a consent to release genetically modified organisms to the applicant; and

(b) ensure that the Commission is informed of their decision,

before the end of a period of ninety days beginning with the day on which the application was received and shall include in any refusal of consent the reason for the decision.

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

(a) any period beginning with the day on which the Scottish Ministers give notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending on the day on which that information is received by the Scottish Ministers; or

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(a) Section 111(6A) was added by S.I. 1992/3280.

(b) As defined in section 107(2), (3) and (6) of the Act as amended by regulation 4(2) to (4).

(b) any period of time during which the Scottish Ministers are considering representations submitted by any persons in accordance with regulation 20(b), provided that this consideration shall not prolong the ninety day period referred to in paragraph (3) by more than thirty 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 Scottish Ministers as soon as reasonably practicable after completion of the release and thereafter, at such intervals as the Scottish Ministers shall consider appropriate on the basis of the results of the environmental risk assessment.

(6) The Scottish Ministers shall ensure that the information submitted to them in accordance with paragraph (5) is sent to the Commission.

Variation or revocation of consents to release

22.—(1) The Scottish Ministers shall only vary or revoke a consent to release genetically modified organisms under section 111(10) of the Act without the agreement of the holder of the consent where new information has become available to them which they consider would affect the assessment of the risk of damage being caused to the environment by the release.

(2) The Scottish Ministers shall not revoke or vary a consent to release genetically modified organisms under section 111(10) of the Act as it relates to the protection of human health without the agreement of the Health and Safety Executive.

Duties of the Scottish Ministers in relation to applications for consent to market

23.—(1) On receipt of an application for consent to market genetically modified organisms the Scottish Ministers shall–

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

(b) ensure that a summary of that application in the format established by the Commission under Articles 13(2)(h) and 30(2) of the Deliberate Release Directive is forwarded immediately to the Commission and to the competent authorities of the other Member States;

(c) without delay examine the application for its conformity with the requirements of the Act and of these Regulations and, if necessary, request the applicant to supply additional information;

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

(i) send to the applicant an assessment report prepared in accordance with Schedule 5 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 their decision, supported by an assessment report prepared in accordance with Schedule 5 which indicates that the genetically modified organisms should not be marketed; and

(e) once they are satisfied the application conforms to the requirements prescribed in regulation 16 and in any event no later than when they send their assessment report in accordance with subparagraph (d), ensure that a copy of the application is forwarded to the Commission.

(2) The Scottish Ministers shall ensure that–

(a) their assessment report;

(b) any further information they have received from the applicant pursuant to the service of a notice under section 111(6) of the Act(**a**); and

(c) any additional information on which they have based their assessment report,

are forwarded to the Commission–

(i) in the circumstances described in paragraph (1)(d)(i), before the end of a period of ninety days beginning with the day on which the Scottish Ministers received the application; and

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(a) Section 111(6) of the Act is amended by regulation 19(1).

(ii) in the circumstances described in paragraph (1)(d)(ii), no sooner than fifteen days from the date the Scottish Ministers sent the assessment report to the applicant and no later than 105 days from the date they received the application.

(3) The ninety day periods prescribed in paragraphs (1) and (2) shall not include any period beginning with the day on which the Scottish Ministers give notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending on the day on which that information is received by the Scottish Ministers.

(4) Where the Scottish Ministers intend to arrange for an assessment report which indicates that the genetically modified organisms to which an application relates should be permitted to be marketed to be forwarded to the Commission, they shall first consult the Health and Safety Executive and shall not arrange for their favourable opinion on the application as it relates to the protection of human health to be forwarded to the Commission where the Health and Safety Executive has informed them that it does not fulfil the requirements of the Act and of these Regulations.

Decisions by the Scottish Ministers on applications for consents to market

24.—(1) In the cases of subparagraphs (a) or (b), the Scottish Ministers may and in the case of subparagraph (c), the Scottish Ministers shall grant an application for consent to market genetically modified organisms only where they have prepared an assessment report which indicates that the genetically modified organisms should be marketed and–

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

(b) a comment or a reasoned objection has been raised by either a Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 15(1) of the Deliberate Release Directive within a 105 day period beginning on the date the Commission circulated the assessment report; or

(c) an objection has been raised and maintained by a competent authority of any Member State or the Commission in accordance with Articles 15 or 20 of the Deliberate Release Directive and the Commission has adopted a decision in accordance with Article 18(1) of the Deliberate Release Directive in favour of granting consent.

(2) The Scottish Ministers shall–

(a) inform the applicant; and

(b) ensure that the other Member States and the Commission are informed,

of any decision by the Scottish Ministers to grant consent to market genetically modified organisms within thirty days of its grant.

(3) For the purpose of calculating the final forty-five day period of the 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, notwithstanding paragraph (4), 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 Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species(**a**) and Council Directive 2002/55/EC on the marketing of vegetable seed(**b**).

(6) For the purpose of granting consent to market a genetically modified organism contained in forest reproductive material, the period of the first consent shall, notwithstanding paragraph (4), end at the latest ten years after the date of the first inclusion of basic material containing the

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(a) O.J. No. L 193, 20.7.02, p.1.
(b) O.J. No. L 193, 20.7.02, p.33.

genetically modified organism on an official national register of basic material in accordance with Council Directive 1999/105/EC(**a**).

Duties on the Scottish Ministers 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 Scottish Ministers 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 Act 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 5 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 their decision, supported by an assessment report which indicates that the genetically modified organisms should not continue to be marketed; and

(d) ensure that a copy of the application and their assessment report is forwarded to the Commission.

(2) Where the Scottish Ministers intend to arrange for an assessment report which indicates that the genetically modified organisms to which an application relates should be permitted to be marketed to be forwarded to the Commission, they shall first consult the Health and Safety Executive and shall not arrange for their favourable opinion on the application as it relates to the protection of human health to be forwarded to the Commission where the Health and Safety Executive has informed them that it does not fulfil the requirements of the Act and of these Regulations.

Decisions by the Scottish Ministers on applications for renewals of consents to market

26.—(1) In the cases of subparagraphs (a) or (b), the Scottish Ministers may and in the case of subparagraph (c), the Scottish Ministers shall grant an application to renew a consent to market genetically modified organisms only where they have prepared an assessment report which indicates that the genetically modified organisms should continue to be marketed and–

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

(b) a reasoned objection has been raised by either a competent authority of any Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 17(7) and (8) of the Deliberate Release Directive within a seventy-five day period beginning on the day the Commission circulated the assessment report; or

(c) an objection has been raised and maintained by a competent authority of any Member State or the Commission in accordance with Articles 17 or 20 of the Deliberate Release Directive and the Commission has adopted a decision in accordance with Article 18(1) of the Deliberate Release Directive in favour of granting consent.

(2) The Scottish Ministers shall–

(a) inform the applicant; and

(b) ensure that the other Member States and the Commission are informed,

of any decision by the Scottish Ministers to renew the consent to market genetically modified organisms within thirty days of its renewal.

(3) The renewed consent to market genetically modified organisms shall be given for ten years unless the Scottish Ministers consider that a shorter or longer period is justified, in which case they shall give their reasons therefor in writing.

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

(a) O.J. No. L 11, 15.1.00, p.17.

Genetically modified organisms containing antibiotic resistance markers

27.—(1) The Scottish Ministers 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 marketing; and

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

(2) Where prior to 31st December 2004 in the case of marketing and 31st December 2008 in the case of release, an application is made for consent to release or market genetically modified organisms containing antibiotic resistance markers, the Scottish Ministers 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 marketing of the genetically modified organisms referred to in paragraph (1) within the time limits specified in that paragraph.

PART V

GENERAL PROVISION FOR CONSENTS

General provisions of consents to market

28. A consent to market genetically modified organisms granted by the Scottish Ministers under section 111(1) of the Act shall specify–

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

(b) the period of validity of the consent;

(c) the conditions for marketing 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 Scottish Ministers on request;

(e) the labelling requirements, in accordance with paragraph 8 of Schedule 4, which shall include a requirement to notify the Scottish Ministers 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 of it, which may include an obligation to provide information at an appropriate level on the location of the genetically modified organisms that are grown.

General conditions on consents to release or market genetically modified organisms

29.—(1) Section 112 of the Act (consents: limitations and conditions) is amended as follows.

(2) In subsection (1) (power of Scottish Ministers to impose limitations and conditions) at the end 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 subsection (5) (implied condition when releasing or marketing)–

(a) in paragraph (b) (obligation to notify Scottish Ministers of new information etc.)–

(i) before the word "of" where it appears for the second time insert "forthwith";

(ii) omit subparagraph (ii); and

(iii) after that subparagraph 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 paragraph (c) (duty as regards preventing damage to environment) substitute–

"(c) take such measures as are necessary to prevent damage to the environment being caused as a result of the release, or, as the case may be, the marketing of the organisms;"; and

(c) after that paragraph insert–

"(d) notify the Scottish Ministers forthwith of the measures (if any) taken as a result of new information becoming available or an unforeseen event occurring as described in 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 Scottish Ministers in such form and manner as they may specify.".

Proof of compliance with consent conditions

30. In section 119 of the Act (onus of proof as regards techniques and evidence) in subsection (1) (accused to prove use of best available techniques) after "the accused to prove" insert "the matters described in subsection (1A) below.

(1A) The matters referred to in subsection (1) above are–

(a) in the case of an offence under section 118(1)(c) above consisting in a failure to comply with the general condition implied by section 112(5)(c) above–

(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, marketing 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 Scottish Ministers shall ensure that any new information which becomes available to them which they consider could have consequences for the risks of damage being caused to the environment by marketing the genetically modified organisms shall be forwarded immediately to the Commission and the competent authority of each Member State.

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

(3) Subject to paragraph (4), where an application for consent or for renewal of consent to market genetically modified organisms has been made to the Scottish Ministers and the information referred to in paragraph (1) becomes available to them after the consent has been granted or renewed, the Scottish Ministers shall within sixty days after receipt of the new information, ensure that there is forwarded to the Commission an assessment report prepared in accordance with Schedule 5 indicating whether the conditions of the consent should be varied and if so, how, or whether the consent should be revoked.

(4) The Scottish Ministers shall not arrange for an assessment report to be forwarded if that assessment report indicates that the consent to market genetically modified organisms as it relates to the protection of human health should be varied or revoked without the agreement of the Health and Safety Executive.

(5) Where the Scottish Ministers have indicated that the consent should be varied or revoked and either–

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

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

they shall vary or revoke the consent as proposed and they shall inform the applicant, and ensure that the other Member States and the Commission are informed, that they have done so within thirty days of the sixty day period specified in subparagraph (a) or of the resolution referred to in subparagraph (b), as the case may be.

(6) The Scottish Ministers shall only vary or revoke a consent to market genetically modified organisms under section 111(10) of the Act–

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

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

PART VI

SAFEGUARD

Safeguard

32.—(1) The Scottish Ministers may serve a prohibition notice under section 110 of the Act to prohibit an act which is authorised by a consent granted in respect of an approved product only if their opinion that doing such an act would involve a risk of causing damage to the environment is based on detailed grounds as the 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 Scottish Ministers consider that the risk of damage being caused to the environment is severe they shall serve a prohibition notice requiring such measures to be taken as they may consider appropriate and once any work required by the notice has been carried out they shall enter details of that work on the register.

(3) In cases to which paragraphs (1) and (2) apply, the Scottish Ministers shall ensure that the Commission and the other Member States are immediately informed of the Scottish Ministers' actions and that at the same time–

(a) the reasons for taking such actions;

(b) the results of the review by the Scottish Ministers of the environmental risk assessment;

(c) the opinion of the Scottish Ministers 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 information on which their decision to take action was based,

are provided to the Commission and the other Member States.

(4) A prohibition notice served under section 110 of the Act 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 Scottish Ministers 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 Scottish Ministers exercising a function under section 110 of the Act shall, in any case to which section 126(3) (requirement to act jointly with the Food Standards Agency) of the Act applies, be treated as references to the Scottish Ministers and the Food Standards Agency acting jointly.

PART VII

CONFIDENTIALITY

Confidentiality

33.—(1) For the purposes of section 123(7) of the Act (exclusion from the register of certain information) 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 organism to which the information relates;

(b) the intended use of the genetically modified organism 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; and

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

(2) In section 123 of the Act (exclusion from register of certain information) in subsection (7) (particulars included even if commercially confidential)–

(a) after "section 122(1)(a)," insert "(c),";

(b) in paragraph (b), after the word "the" where it appears for the first time insert "general"; and

(c) 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 Scottish Ministers 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; and

(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) 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 Scottish Ministers;

(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 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 Scottish Ministers have 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 Scottish Ministers are or become 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), they shall enter so much of that more detailed information on the register as they consider appropriate.

(5) In relation to consents granted under section 111(1) of the Act–

(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 Scottish Ministers 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, where applicable, a copy of the varied consent; and

(d) a summary of any advice the Scottish Ministers have 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, or proposed to be released or grown pursuant to a consent, as the case may be:–

(a) any information provided to the Scottish Ministers in accordance with section 111(6A) or 112(5)(b)(i) of the Act;

(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 Scottish Ministers in accordance with section 112(5)(b)(iii)(**a**) of the Act.

(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 Scotland pursuant to a consent to market insofar as that information is supplied to the Scottish Ministers in accordance with the monitoring requirements imposed in the consent.

(9) Any decision adopted by the Commission in accordance with Article 18 of the Deliberate Release Directive and such decisions are prescribed as matters relating to Part VI of the Act for the purposes of section 122(1)(h) of the Act.

(10) 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 date on which the offence was committed;

(e) the date on which the person was convicted; and

(f) the penalty imposed and any order made by the court under section 120 of the Act (power of the court to order cause of offence to be remedied).

Keeping the register

35.—(1) The information on the register shall be made available to the public by such means as the Scottish Ministers shall consider appropriate.

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

(3) The information prescribed in regulation 34(3) (a) to (g) shall be placed on the register within twelve days of receipt by the Scottish Ministers of the application for consent to release or market.

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

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

(a) Section 112(5)(b)(iii) has been inserted by regulation 29(3)(iii).

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

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

(8) The information prescribed in regulations 34(6) and 34(10) shall be placed on the register within fourteen days of its receipt by the Scottish Ministers.

(9) The information prescribed in regulation 34(7) shall be placed on the register within fourteen days of its receipt by the Scottish Ministers.

(10) The information prescribed in regulation 34(8) shall be placed on the register within fourteen days of its receipt by the Scottish Ministers.

(11) The information prescribed in regulation 34(9) shall be placed on the register within fourteen days of the decision having been notified to the Scottish Ministers.

(12) The information prescribed in regulation 34(10) in relation to any particular conviction shall be removed from the register when that conviction is spent within the meaning of the Rehabilitation of Offenders Act 1974(**a**).

Publication of representations

36.—(1) Subject to paragraph (2), the Scottish Ministers shall, within a period of twenty-eight days after granting consent to or rejecting an application for the release of genetically modified organisms, make available to the public by whatever means they shall consider appropriate details of where, when and how 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 representation has asked the Scottish Ministers to treat that information as confidential.

PART IX

CONSEQUENTIAL AND OTHER AMENDMENTS AND REVOCATIONS

Consequential and other amendments - agency arrangements

37. The Scotland Act 1998 (Agency Arrangements) (Specification) (No. 2) Order 2002(**b**) shall be amended in accordance with Schedule 6.

Revocations

38. The Regulations set out in column 1 of Schedule 7 are revoked to the extent specified in the corresponding entry in relation to those Regulations in column 3 of that Schedule.

ROSS FINNIE
A member of the Scottish Executive

St Andrew's House,
Edinburgh
4th December 2002

(a) 1974 c.53.
(b) S.I. 2002/800.

Regulation 2(1)

SCHEDULE 1

DEFINITION OF REGULATION 2309/93

"Regulation 2309/93" means Council Regulation (EEC) No. 2309/1993(**a**) laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products as amended by–

Community Instrument	*Reference*
Commission Regulation 1995/542/EC	O.J. No. L 55, 11.3.95, p.15
Commission Regulation 1995/540/EC	O.J. No. L 55, 11.3.95, p.5
Commission Regulation 1996/2141/EC	O.J. No. L 286, 8.11.96, p.6
Commission Regulation 1998/1069/EC	O.J. No. L 153, 27.5.98, p.11
Commission Regulation 1998/649/EC	O.J. No. L 88, 24.3.98, p.7

(a) O.J. No. L 214, 24.8.93, p.1.

Regulations 11(1) and 16(2)

SCHEDULE 2

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, that is–
   (a) family name;
   (b) genus;
   (c) species;
   (d) subspecies;
   (e) cultivar/breeding line; and
   (f) common name.

4. Information concerning–
   (a) the reproduction of the plant, that is–
      (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, that is–
   (a) its ability to form structures for survival or dormancy; and
   (b) any specific factors affecting survivability.

6. Information concerning the dissemination of the plant, that is–
   (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. Information concerning 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 THE 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 source (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 higher plant or any carrier or foreign DNA remaining in the genetically modified higher 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 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; and

(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 recipient plant in the following respects:–

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

(b) dissemination; and

(c) survivability.

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

18. Any change to the ability of the genetically modified higher 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 higher plant to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the genetically modified higher 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 higher 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 site or sites.

29. The proximity of the release site or 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.

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–

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

(b) any measures to minimise or prevent dispersal of any reproductive organ of the genetically modified higher 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.

Regulations 11(1) and 16(2)

SCHEDULE 3

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 THE ORGANISMS

1. 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 conditions.

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; and

(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 genetic modifications.

2. 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. Information on the degree to which the vector is limited to the DNA required to perform the intended function.

3. Characteristics of the modified organisms

19. The methods used for the modification.

20. The methods used–

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

(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.

4. Characteristics of the genetically modified organisms in their final form

25. The description of genetic 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 organism.

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

28. The rate and level of expression of the new genetic material in the organism, and the method and sensitivity of measurement of that rate and level.

29. The activity of the expressed protein.

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 genetically modified 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 modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(c) the capacity of the organisms for colonisation;

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

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

(ii) communicability;

(iii) infective dose;

(iv) host range 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; and

(e) the other product hazards.

PART III

INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

5. The release

34. The description of the proposed deliberate release, including the purpose of the release and the foreseen products of the release.

35. The foreseen 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 methods to be used for the release.

39. The quantity of organisms to be released.

40. The disturbance of the site, including the type and method of cultivation, 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 genetically modified 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.

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

45. The geographical location and national grid reference of the site onto which the release will be made, or in the case of applications for consent to market or renewed consent to market 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. A comparison of the natural habitat of the recipient organism 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 GENETICALLY MODIFIED ORGANISMS AND THE ENVIRONMENT

7. 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.

8. Interactions with the environment

57. The predicted habitat of the genetically modified organisms.

58. The studies on the behaviour and characteristics of the genetically modified 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 and/or undesirable traits in the genetically modified organism.

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 genetically modified organisms could be disseminated.

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

65. The competitive advantage of the genetically modified 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 genetically modified 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 organism, 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 genetically modified organisms in biogeochemical processes.

72. Any other potential interactions of the organisms with the environment.

PART V

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

9. Monitoring techniques

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

74. Specificity (to identify the genetically modified 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.

10. Control of the release

77. Methods and procedures to avoid and/or minimise the spread of the genetically modified 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.

11. Waste treatment

80. Type of waste generated.

81. Expected amount of waste.

82. Description of treatment envisaged.

12. Emergency response plans

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

84. Methods, such as eradication of the genetically modified 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 area 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

88. 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.

Regulations 16(2), 16(5) and 28

SCHEDULE 4

INFORMATION TO BE INCLUDED IN APPLICATIONS 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 of control samples.

4. A description of how the product and the genetically modified organism as or in the product 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 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, skilled trades or consumer use by the public at large.

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 genetically modified organism 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 Scottish Ministers, and details of nucleotide sequences or other type of information which is necessary to identify the genetically modified organism product and its progeny, for example the methodology for detecting and identifying the genetically modified organism 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. Information regarding 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 Scottish Ministers, which are consistent with Part C of Annex VII of the Deliberate Release Directive, so that the Scottish Ministers can be effectively informed of any adverse effect.

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 production 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.

Regulations 23(1), 25(1) and 31(3)

SCHEDULE 5

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. An identification of any known risks to human health and the environment resulting from the release into the environment of the recipient non-modified organism.

3. A description of the result of the genetic modification in the 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 to human health and 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 carried out in accordance with regulation 6.

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 on its own or in a product and under which conditions, or not placed on the market for reasons which are specified, or whether the views of other competent authorities and the Commission are sought for on specified aspects of the environmental risk assessment carried out in accordance with regulation 6. Where it is concluded that the genetically modified organisms should not be placed on the market the Scottish Ministers shall give reasons for their conclusion.

Regulation 37

SCHEDULE 6

AMENDMENT TO THE SCOTLAND ACT 1998 (AGENCY ARRANGEMENTS) (SPECIFICATION) (NO. 2) ORDER 2002

For paragraphs (d) and (e) of the Schedule to the Scotland Act 1998 (Agency Arrangements) (Specification) (No. 2) Order 2002(**a**) substitute–

"(ca) Section 126(5)(b) of the Environmental Protection Act 1990 (function of consulting the Food Standards Agency).

(cb) Regulation 16(5) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (function of consideration whether applicant may omit certain information from an application for consent to market genetically modified organisms).

(cc) Regulation 20 of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (functions on receiving applications for consent to release genetically modified organisms).

(cd) Regulation 23(1) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (functions on receipt of applications for consent to market genetically modified organisms).

(ce) Regulations 23(4) and 31(4) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (function of consulting the Health and Safety Executive).

(cf) Regulation 27(2) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (function of evaluating information in environmental risk assessments).

(cg) Regulation 35 of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (function of maintaining the register).".

(a) S.I. 2002/800.

Regulation 38

SCHEDULE 7

REVOCATIONS

Regulations revoked	*References*	*Extent*
The Genetically Modified Organisms (Deliberate Release) Regulations 1992	S.I. 1992/3280 as amended by the Genetically Modified Organisms (Deliberate Release) Regulations 1993 (S.I. 1993/152), the Genetically Modified Organisms (Deliberate Release) Regulations 1995 (S.I. 1995/304), the Genetically Modified Organisms (Deliberate Release) and Risk Assessment–Amendment) Regulations 1997 (S.I. 1997/1900) and the Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2000/2831)	The whole Regulations other than for the purposes of regulations 9 and 13 of those Regulations
The Genetically Modified Organisms (Deliberate Release) Regulations 1993	S.I. 1993/152	The whole Regulations
The Genetically Modified Organisms (Deliberate Release) Regulations 1995	S.I. 1995/304	The whole Regulations
The Genetically Modified Organisms (Deliberate Release and Risk Assessment-Amendment) Regulations 1997	S.I. 1997/1900	Regulation 2
The Genetically Modified Organisms (Contained Use) Regulations 2000	S.I. 2000/2831	Regulation 31(2)

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement, in respect of Scotland, Directive 2001/18/EC of the European Parliament and of the Council 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 marketing 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 (pre-existing) provisions of Part VI of the Environmental Protection Act 1990 ("the Act") and partly by the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (as subsequently amended).

These Regulations include amendments to the Act, applicable only to Scotland, required to implement the Directive and revoke, subject to exceptions, the 1992 Regulations.

The statutory basis for the requirement to obtain consent for the release or marketing of genetically modified organisms is section 111(1) of the Act. 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 sections 106, 107 and 127(1) of the Act. Regulations 3 and 4 amend a number of these definitions to reflect provisions of the Directive. Regulation 3 also amends the power in section 106 for the Scottish Ministers to prescribe techniques which result in organisms becoming "genetically modified". However under regulation 5, until the coming into force of the first regulations made by the Scottish Ministers prescribing such techniques, references in the Act to "genetically modified organisms" will be interpreted by reference to the modification techniques described in that regulation.

Parts II and III of the Regulations impose requirements for applications for consent to release and 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 section 112 of the Act (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 section 110 of the Act 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 section 123(7) of the Act.

Part VIII includes the requirement for different categories of information to be included in the public register to be kept by the Scottish Ministers under section 122 of the Act.

Part IX and Schedule 6 principally update the Scotland Act 1998 (Agency Arrangements) (Specification) (No. 2) Order 2002 in consequence of the implementation of the Directive, which permits the Scottish Ministers to enter into agency arrangements with the Secretary of State to allow her to carry out specified functions on behalf of the Scottish Ministers. It also corrects an omission from that Order. Such agency arrangements will not affect the Scottish Ministers' powers or responsibilities in relation to these functions.

Schedule 7 provides for certain revocations of the Genetically Modified Organisms (Deliberate Release) Regulations 1992 and amending instruments.