

1994 No. 143

HEALTH AND SAFETY

**Genetically Modified Organisms (Contained Use)
Regulations (Northern Ireland) 1994**

Made 12th April 1994

Coming into operation 1st June 1994

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The Department of Economic Development, the Department of Agriculture and the Department of the Environment being Departments designated(a) for the purpose of section 2(2) of the European Communities Act 1972(b) in relation to the control and regulation of genetically modified organisms, acting jointly in the exercise of the powers conferred on them by the said section 2, and the Department of Economic Development, acting as the Department concerned(c), in exercise of the powers conferred by Articles

(a) S.I. 1991/775

(b) 1972 c. 68

(c) See Article 2(2) of S.I. 1978/1039 (N.I. 9)

2(5), 17(1) to (5), 40(2), (4) and (6) and 55(2) of, and paragraphs 1(1) and (5), 3(1), 5(1), 7, 8, 9, 10, 12(1), 13, 14(1), 15 and 19 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978(a) and of every other power enabling them in that behalf, after consultation in accordance with Article 46(1) of that Order with the Health and Safety Agency for Northern Ireland and such other bodies as appeared to them to be appropriate, hereby make the following Regulations:—

PART I

INTERPRETATION AND GENERAL

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 1994 and shall come into operation on 1st June 1994.

Interpretation

2.—(1) In these Regulations—

“the 1991 Regulations” shall be construed in accordance with regulation 23;

“accident” means any incident involving a significant and unintended release of genetically modified organisms in the course of an activity involving genetic modification which presents an immediate or delayed hazard to human health or to the environment;

“approved” means approved in writing for the time being by the Department;

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

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

“the Department” means the Department of Economic Development;

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

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

(b) the techniques listed in Part II of that Schedule are not considered to result in genetic modification,

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

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

“the notifier” shall be construed in accordance with regulation 10(1);

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

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

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

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

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

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

(2) Genetically modified organisms shall be classified—

(a) in the case of micro-organisms—

(i) as Group I micro-organisms if they comply with such of the criteria set out in Part I of Schedule 2 as are applicable to the particular case, determined in accordance with the guidelines set out in Part II of that Schedule which gives effect to Commission Decision 91/448/EEC(a), or

(ii) as Group II micro-organisms if they do not comply with the said criteria; or

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

(3) The Interpretation Act (Northern Ireland) 1954(b) shall apply to these Regulations as it applies to a Measure of the Northern Ireland Assembly.

(a) O.J. No. L239, 28.8.91, p. 23

(b) 1954 c. 33 (N.I.)

Application

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

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

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

(4) In so far as these Regulations relate to the protection of the environment, they shall only apply to genetically modified micro-organisms.

(5) These Regulations shall have effect without prejudice to any requirement imposed by or under any statutory provision which relates to public health or the protection of the environment.

Meaning of "work" and "at work"

4. For the purpose of these Regulations and Parts I and II of the Health and Safety at Work (Northern Ireland) Order 1978(a) the meaning of the word "work" shall be extended to include any activity involving genetic modification and the meaning of "at work" shall be extended accordingly.

Modification of Article 5(2) of the Health and Safety at Work (Northern Ireland) Order 1978

5. Article 5(2) of the Health and Safety at Work (Northern Ireland) Order 1978 shall be modified in relation to an activity involving genetic modification so as to have effect as if the reference to a self-employed person were a reference to any person who is not an employer or an employee and the reference to his undertaking included a reference to such an activity.

PART II**NOTIFICATION OF AND CONSENT FOR ACTIVITIES INVOLVING GENETIC MODIFICATION***Prohibition of certain work with genetically modified organisms outside containment*

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

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

(a) S.I. 1978/1039 (N.I. 9); Article 5(2) was modified by S.R. 1982 No. 273

- (a) genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of, where such organisms are or are contained in a product marketed in pursuance of—
- (i) a consent granted by the Department of the Environment for Northern Ireland under Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991(a), or
 - (ii) a written consent given by another competent authority of a member State in accordance with Article 13(4) of Council Directive 90/220/EEC(b) on the deliberate release into the environment of genetically modified organisms, and
- in either case, the operation is conducted in accordance with any conditions or limitations attached to that consent,
- (b) genetically modified organisms are released or marketed in circumstances in which the consent of the Department of the Environment for Northern Ireland is required under Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991.
- (3) In this regulation, “product” means a product consisting of or containing a genetically modified organism or a combination of genetically modified organisms.

Risk assessment

7.—(1) A person shall not—

- (a) use any premises for activities involving genetic modification for the first time; or
- (b) undertake any activity involving genetic modification,

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

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

- (a) classifying any genetically modified organisms involved in the activity in accordance with the provisions of Schedule 2; and
- (b) where appropriate, making decisions about the levels of containment required for the activity concerned.

(3) A person making the assessment required by paragraph (1) shall in doing so—

- (a) in particular, take due account of the matters set out in Schedule 3 in as far as they are relevant; and
- (b) in a case in which the Department has approved a method in relation to the activity involving genetic modification concerned or in relation to a particular element of that assessment; undertake the assessment in accordance with that method.

(a) S.I. 1991/1714 (N.I. 19)

(b) O.J. No. L117, 8.5.90, p. 15

(4) An assessment made under paragraph (1) shall be reviewed forthwith if—

- (a) there is reason to suspect that the assessment is no longer valid; or
- (b) there has been a significant change in the activity to which the assessment relates.

(5) The person making the assessment required by paragraph (1) shall make a record of it and of any subsequent review under paragraph (4) and shall keep that record for at least 10 years from the date on which use of the premises or the activity, as the case may be, to which the assessment related, ceased.

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

8.—(1) Subject to paragraphs (2) to (6) and to regulation 10, a person shall not undertake any activity involving genetic modification at any premises for the first time, unless he has notified the Department of his intention to do so at least 90 days in advance or before such shorter time as the Department may approve and with that notification has furnished the information specified in Schedule 4.

(2) In the case of activities involving the genetic modification of micro-organisms, separate notifications shall be made of an intention to use the premises for activities involving genetically modified micro-organisms classified as Group I or Group II.

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

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

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

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

Notification of individual activities involving genetic modification

9.—(1) Subject to paragraphs (2) to (7) and to regulation 10, a person shall not undertake any activity involving genetic modification unless he has notified the Department of his intention to do so at least 60 days in advance or before such shorter time as the Department may approve and has furnished the information specified in the following paragraphs and, except in the case of an activity to which paragraph (5) applies, the activity may be commenced after

the expiry of the relevant period if by then the Department has not objected in writing.

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

- (a) a Type A operation involving only micro-organisms classified as Group I; or
- (b) an activity involving genetically modified organisms other than micro-organisms and which satisfy the criteria set out in Part III of Schedule 2,

it shall be a sufficient compliance with paragraph (1) if the person undertaking the activity keeps a record of such activities and at the end of each calendar year notifies the Department—

- (i) of the total number of risk assessments under regulation 7 undertaken during that year;
- (ii) where appropriate, that he is intending to continue to undertake such activities; and
- (iii) that the information notified to the Department in accordance with regulation 8 remains correct.

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

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

- (a) a Type A operation involving genetically modified micro-organisms classified as Group II; or
- (b) an activity involving genetically modified organisms other than micro-organisms and which do not satisfy the criteria set out in Part III of Schedule 2,

the information to be furnished for the purposes of paragraph (1) shall be that specified in Parts I and II of Schedule 5.

(5) In the case of an activity which is a Type B operation involving genetically modified micro-organisms classified as Group II, the information to be furnished for the purposes of paragraph (1) shall be that specified in Parts I, II and III of Schedule 5 and the activity shall be commenced only after the Department has given its consent.

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

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

Additional provisions relating to notifications and consents

10.—(1) Where necessary for the purpose of evaluating a notification made under regulation 8 or 9, the Department may require in writing the person making that notification (“the notifier”) to give such additional

information relating to such notification as it may specify and, in such a case, the notifier shall not proceed with the activity involving genetic modification until the Department gives its approval, and the period between the time when the Department requires the information to be given and the notifier responds to the satisfaction of the Department shall not be taken into account in calculating any period of time referred to in these Regulations.

(2) Any consent given by the Department under regulation 8 or 9 may be given subject to conditions or to a limit of time and may be revoked or varied at any time and in such a case the person undertaking the activity shall comply with those conditions.

(3) In so far as it relates to the protection of the environment, the Department shall not give, vary or revoke a consent under regulation 8 or 9, or give its approval under paragraph (1), without the agreement of the Department of the Environment for Northern Ireland.

(4) Where the notifier subsequently makes a significant change in the use of any premises or in any activity to which the notification relates or becomes aware of any new information which would affect the information previously furnished, he shall forthwith notify the Department thereof.

(5) If information subsequently becomes available to the Department which could have significant consequences for the risks to human health or the environment created by an activity involving genetic modification which has been notified to it, it may require the notifier to modify the conditions under which the activity is undertaken, or to suspend or terminate the activity.

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

Establishment of a genetic modification safety committee

11. A person who makes an assessment in accordance with regulation 7(1) shall establish a genetic modification safety committee to advise him in relation to the making of that assessment.

PART III

CONDUCT OF ACTIVITIES INVOLVING GENETIC MODIFICATION

Standards of occupational and environmental safety and containment

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

- (a) to keep workplace and environmental exposure to any physical, chemical and biological agent adequately controlled;
- (b) to exercise engineering control methods at source and to supplement these with appropriate personal protective clothing and equipment where necessary;
- (c) to test and maintain control measures and equipment;

- (d) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;
- (e) to provide training of personnel; and
- (f) to formulate and implement local rules for the safety of personnel.

(2) For the purpose of paragraph (1) “adequate” in relation to the control of an agent means adequate having regard only to the nature of the agent and the nature and degree of exposure to such an agent.

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

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

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

Emergency plans

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

(2) Subject to paragraph (3), the person preparing an emergency plan under paragraph (1) shall consult such persons, bodies and authorities as are appropriate and shall inform the emergency services in writing of the plan and of the hazards to which the plan relates.

(3) Where an emergency plan required by paragraph (1) relates to a reasonably foreseeable accident which is liable to affect another member State, the person preparing that emergency plan shall, in addition to consulting the persons, bodies and authorities described in paragraph (2), forthwith consult the Department.

In this paragraph “reasonably foreseeable accident” shall be construed in accordance with paragraph (1).

(4) Where the Department has been consulted in accordance with paragraph (3), it shall consult the other member State in the drawing up and implementation of the emergency plan referred to in paragraph (3).

In this paragraph “the other member State” shall be construed in accordance with paragraph (3).

(5) Where the Department is required to be consulted in accordance with paragraph (3) the person preparing the emergency plan under paragraph (1)

shall not conclude the preparation of that plan without the consent of the Department.

(6) Subject to paragraph (5), where an emergency plan has been prepared in accordance with paragraph (1) the person undertaking the activity involving genetic modification shall take appropriate measures to inform persons who are liable to be affected by an accident of the safety measures to be taken and the correct behaviour to be adopted in the event of an accident.

(7) The information required to be given in pursuance of paragraph (6) shall be repeated and brought up to date at appropriate intervals and shall be made publicly available.

Notification of accidents

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

- (a) the circumstances of the accident;
- (b) the identity and quantity of genetically modified organisms released;
- (c) any information necessary to assess the effects of the accident on the health of the general population and on the environment; and
- (d) the emergency measures taken.

(2) Where the Department receives a notification in pursuance of paragraph (1), the Department shall—

- (a) ensure that any emergency, medium and long term measures are taken;
- (b) immediately inform any other member State that could be affected by the accident;
- (c) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit their effects; and
- (d) send to the European Commission the information provided for under paragraph (1), together with an analysis of the accident and details of any recommendations made in accordance with sub-paragraph (c).

PART IV

DISCLOSURE OF INFORMATION NOTIFIED AND PUBLICITY

Disclosure of information notified

15.—(1) The information notified in pursuance of regulations 8 to 10 shall not be treated as relevant information for the purposes of Article 30 of the Health and Safety at Work (Northern Ireland) Order 1978.

(2) Where the notifier indicates that the disclosure of certain information might harm his competitive position and should therefore be kept confidential, full justification for that indication shall be given and in such a case after consulting the notifier the Department shall decide which information shall be kept confidential and shall inform the notifier of its decision.

(3) Nothing in paragraph (2) shall apply to the following information which shall not be kept confidential—

- (a) the name and address of the notifier;
- (b) the location of the activity involving genetic modification;
- (c) the purpose of the activity;
- (d) the description of the genetically modified organism involved;
- (e) methods and plans for monitoring the genetically modified organism and for emergency response; and
- (f) the evaluation of foreseeable effects and in particular pathogenic effects and ecologically disruptive effects.

(4) Notwithstanding paragraph (3), where the Department is satisfied on the basis of detailed evidence submitted to it by the notifier and where appropriate, after consultation with the notifier, that it is necessary to withhold, for the time being, certain of the information specified in paragraph (3) in order to protect his intellectual property rights, the Department shall withhold that information to the extent and for so long as it is necessary to protect those rights.

(5) Information which is kept confidential in accordance with paragraph (2) or withheld in accordance with paragraph (4) shall be disclosed only—

- (a) to the Department of the Environment for Northern Ireland;
- (b) to the Department of Agriculture for Northern Ireland;
- (c) to the Health and Safety Executive(a);
- (d) to the European Commission or the competent authority for another member State;
- (e) for the purpose of any legal proceedings;
- (f) with the consent of the notifier; or
- (g) to the extent necessary to evaluate the notification.

(6) A person who receives information in accordance with sub-paragraph (g) of paragraph (5) shall not use that information except for a purpose of the Department or the Department of the Environment for Northern Ireland.

(7) Where the notifier has requested that certain information in the notification shall be kept confidential in accordance with paragraph (2) or withheld in accordance with paragraph (4), the Department shall not disclose any of that information (except in accordance with paragraph (5)) until at least 14 days after it has reached a decision under the relevant paragraph.

(8) After consulting the notifier, the Department may review any decision made under paragraph (2) or (4) and shall inform the notifier of the result of that review.

(9) Where the notifier withdraws a notification to which regulations 8 to 10 relate, the Department shall not thereafter disclose any of the information furnished with such notification.

(a) Established under 1974 c. 37 section 10(1)

Register of notifications

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

(2) The register referred to in paragraph (1) shall contain in relation to each such notification—

- (a) such of the information referred to in regulation 15(3) as has not been withheld in accordance with paragraph (4) of that regulation; and
- (b) a statement as to whether or not the consent of the Department has been given.

(3) The information referred to in paragraph (2)(a) shall be entered in the register within 14 days of its receipt by the Department and the information referred to in paragraph 2(b) within 14 days of the decision whether to give the consent or not having been made, except that where the notifier has requested that certain information specified in regulation 15(3) be withheld in accordance with regulation 15(4), that information shall only be entered in the register not less than 14 days but not more than 28 days after the Department has made a decision not to withhold that information.

(4) Copies of the register referred to in paragraph (1) shall be maintained at the office of the Department at 83 Ladas Drive, Belfast, BT6 9FJ.

PART V

ADDITIONAL DUTIES PLACED ON THE DEPARTMENT

Duties on receiving notifications

17. The Department shall examine a notification under regulation 8 or 9 for—

- (a) the conformity with the requirements of these Regulations;
- (b) the accuracy and completeness of the information given;
- (c) the correctness of the classification of the organisms to which the notification relates in accordance with Schedule 2; and
- (d) where appropriate, the adequacy of the waste management, safety and emergency response measures.

Information to be sent to the Department of the Environment

18. Forthwith after receipt, the Department shall send to the Department of the Environment for Northern Ireland a copy in each case of—

- (a) any notification received under regulation 8 or 9;
- (b) any requirement for further information under regulation 10(1) and any response thereto; and
- (c) any notification relating to an accident under regulation 14,

and if requested to do so by the Department of the Environment for Northern Ireland shall require the notifier to give additional information under regulation 10(1).

Reports to the European Commission

19. The Department shall send to the European Commission reports of notifications for which a consent is required under regulation 9(5) and summary reports of the application of these Regulations in accordance with Article 18 of Council Directive No. 90/219/EEC(a) on the contained use of genetically modified micro-organisms.

PART VI

MISCELLANEOUS AND GENERAL

Exemption certificates

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

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

- (a) the conditions, if any, that it proposes to attach to the exemption; and
- (b) any requirements imposed by or under any statutory provision which applies to the case,

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

Enforcement and civil liability

21.—(1) In so far as any provision of regulations 6 to 14 is made under section 2 of the European Communities Act 1972(b)—

- (a) the provisions of the Health and Safety at Work (Northern Ireland) Order 1978 relating to enforcement and offences shall apply to that provision as if that provision had been made under Article 17 of that Order; and
- (b) in the event of a breach of duty imposed by that provision, it shall confer a right of action in civil proceedings if that breach of duty causes damage.

(a) O.J. No. L117, 8.5.90, p. 1

(b) 1972 c. 68

(2) Notwithstanding regulation 4 of the Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1993(a) ("the 1993 Regulations") the enforcing authority for these Regulations shall be the Department, except that in so far as these Regulations relate to agricultural activities within the meaning of regulation 2(1) of the 1993 Regulations the enforcing authority shall be the Department of Agriculture for Northern Ireland.

Fees for notifications

22.—(1) Fees shall be payable in accordance with paragraph (2) by a notifier to the Department in relation to any matter referred to in that paragraph.

(2) The fees referred to in paragraph (1) shall be—

- (a) subject to sub-paragraph (b), on each notification of the intention to use premises for activities involving genetic modification for the first time under regulation 8, £100;
- (b) on each notification of the intention to use premises for activities involving genetic modification for the first time, where a consent is required under regulation 8(3), £130;
- (c) subject to sub-paragraph (d), on each notification of individual activities involving genetic modification under regulation 9, £180;
- (d) on each notification of individual activities involving genetic modification for which a consent is required under regulation 9(5), £270.

(3) This regulation shall not apply to any notification made for the purposes of regulation 24(1) or (3) (which relates to transitional provisions).

Revocation

23. Subject to regulation 24, the Genetic Manipulation Regulations (Northern Ireland) 1991(b) ("the 1991 Regulations") are hereby revoked.

Transitional provisions

24.—(1) Where before 1st June 1994 a person had notified the Department of his intention to undertake activities involving genetic modification which complied with regulation 5(1) and (2)(a) of the 1991 Regulations as then in operation, that notification shall be treated as satisfying the requirements of regulation 8 except that regulation 8(3) shall apply to that activity on or after 1st June 1995.

(2) Before 30th August 1994 it shall be a sufficient compliance with regulation 8 if the notifier commences the activity having notified his intention to do so 30 days in advance or such shorter time in advance as the Department may approve and regulation 8(3) shall not apply to activities commenced before 30th August 1994 until 1st June 1995.

(a) S.R. 1993 No. 147

(b) S.R. 1991 No. 238

(3) Where before 1st June 1994 a person had notified the Department of his intention to undertake activities involving genetic modification which complied with regulation 5(1) and (2)(b) of the 1991 Regulations as then in operation, that notification shall be treated as satisfying the requirements of regulation 9 except that regulation 9(5) shall apply to that activity on or after 1st June 1995.

(4) Before 31st July 1994 it shall be a sufficient compliance with regulation 9 if the notifier of an activity involving genetic modification had notified it in accordance with that regulation 30 days in advance or such shorter time in advance as the Department may approve and regulation 9(5) shall not apply to activities commenced before 31st July 1994 until 1st June 1995.

(5) Regulation 10 shall apply to any notification made on or after 1st June 1994.

Sealed with the Official Seal of the Department of Economic Development on 12th April 1994.

(L.S.)

Philip B. Strong

Assistant Secretary

Sealed with the Official Seal of the Department of Agriculture on 12th April 1994.

(L.S.)

I. C. Henderson

Assistant Secretary

Sealed with the Official Seal of the Department of the Environment on 12th April 1994.

(L.S.)

R. W. Rogers

Assistant Secretary

Definition of genetic modification**PART I****EXAMPLES OF TECHNIQUES CONSTITUTING GENETIC MODIFICATION**

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

- (a) recombinant DNA techniques consisting of the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside the cell, into any virus, bacterial plasmid or other vector system so as to allow their incorporation into a host organism in which they do not occur naturally but in which they are capable of continued propagation;
- (b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; and
- (c) cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART II**TECHNIQUES WHICH ARE NOT CONSIDERED TO RESULT IN GENETIC MODIFICATION**

2. The following techniques are not considered to result in genetic modification if they do not involve the use of recombinant-DNA molecules or genetically modified organisms—

- (a) *in vitro* fertilization;
- (b) conjugation, transduction, transformation or any other natural process; and
- (c) polyploidy induction.

PART III**TECHNIQUES TO WHICH THESE REGULATIONS DO NOT APPLY**

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

- (a) mutagenesis;
- (b) the construction and use of somatic hybridoma cells (for example for the production of monoclonal antibodies);
- (c) cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods;
- (d) self-cloning of non-pathogenic naturally occurring micro-organisms which fulfil the criteria of Group I for recipient micro-organisms; and
- (e) self-cloning of non-pathogenic naturally occurring organisms other than micro-organisms which fulfil the criteria of Part III of Schedule 2.

Criteria for the classification of genetically modified organisms**PART I****CRITERIA AS APPLICABLE FOR CLASSIFICATION OF GENETICALLY MODIFIED MICRO-ORGANISMS AS GROUP I MICRO-ORGANISM****1. Recipient or parental organism**

- (a) non-pathogenic;
- (b) no adventitious agents;
- (c) proven and extended history of safe use or built-in biological barriers, which, without interfering with optimal growth in the reactor or fermenter, confer limited survivability and replicability, without adverse consequences in the environment.

2. Vectors/Insert

- (a) well characterised and free from known harmful sequences;
- (b) limited in size as much as possible to the genetic sequences required to perform the intended function;
- (c) should not increase the stability of the construct in the environment (unless that is a requirement of intended function);
- (d) should be poorly mobilisable;
- (e) should not transfer any resistance markers to micro-organisms not known to acquire them naturally (if such acquisition could compromise use of drugs to control disease agents).

3. Genetically modified micro-organisms

- (a) non-pathogenic;
- (b) as safe in the reactor or fermenter as recipient or parental organism, but with limited survivability and/or replicability without adverse consequences in the environment.

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

- (a) those constructed entirely from a single prokaryotic recipient (including its indigenous plasmids and viruses) or from a single eukaryotic recipient (including its chloroplasts, mitochondria, plasmids, but excluding viruses);
- (b) those that consist entirely of genetic sequences from different species that exchange these sequences by known physiological processes.

PART II**GUIDELINES AS APPLICABLE FOR CLASSIFICATION OF GENETICALLY MODIFIED MICRO-ORGANISMS AS GROUP I MICRO-ORGANISMS**

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

5. Characteristics of the recipient or parental organism(s)

(1) Non-pathogenic

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

- (a) the recipient or parental strain should have an established record of safety in the laboratory and/or industry, with no adverse effects on human health and the environment;
- (b) the recipient or parental strain does not meet the conditions of head (a) but it belongs to a species for which there is a long record of biological work including safety in the laboratory and/or industry, showing no adverse effects on human health and the environment;
- (c) if the recipient or parental organism is a strain which does not satisfy the conditions of head (a) and belongs to a species for which there is no record of biological work including safe use in the laboratory and/or industry, appropriate testing (including, if necessary, animals) must be carried out, in order to establish non-pathogenicity and safety in the environment;
- (d) if a non-virulent strain of an acknowledged pathogenic species is used, the strain should be as deficient as possible in genetic material that determines virulence so as to ensure no reversion to pathogenicity. In the case of bacteria, special attention should be given to plasmid or phage-borne virulence determinants.

(2) No adventitious agents

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

(3) The recipient or parental strain/cell line should have proven and extended history of safe use or built-in biological barriers, which, without interfering with optimal growth in the reactor or fermenter, confer limited survivability and replicability, without adverse consequences in the environment (applicable only for Type B operations).

6. Characteristics of the vector

(1) The vector should be well characterised

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

(a) Information on composition and construction

- (i) the type of the vector should be defined (virus, plasmid, cosmid, phasmid, transposable element, minichromosome, etc.);
- (ii) the following information on the constituent fragments of the vector should be available—
 - (aa) the origin of each fragment (progenitor genetic element, strain of organism in which the progenitor genetic element naturally occurred),
 - (bb) if some fragments are synthetic, their functions should be known;
- (iii) the methods used for construction should be known.

(b) Information on vector structure

- (i) the size of the vector should be known and expressed in basepairs or D;
- (ii) the function and relative positions of the following should be known—
 - (aa) structural genes,

- (bb) marker genes for selection (antibiotic resistance, heavy metal resistance, phage immunity, genes coding for degradation of xenobiotics, etc.),
- (cc) regulatory elements,
- (dd) target sites (nic-sites, restriction endonuclease sites, linkers, etc.),
- (ee) transposable elements (including provirus sequences),
- (ff) genes related to transfer and mobilisation function (for example with respect to conjugation, transduction or chromosomal integration),
- (gg) replicon(s).

(2) The vector should be free from harmful sequences

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

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

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

(5) The vector should be poorly mobilisable

(a) If the vector is a plasmid—

- (i) it should have a restricted host-range;
- (ii) it should be defective in transfer-mobilisation factors for example Tra^- , Mob^+ , for Type A operations or Tra^- , Mob^- , for Type B operations.

(b) If the vector is a virus, cosmid or phasmid—

- (i) it should have a restricted host-range;
- (ii) it should be rendered non-lysogenic when used as a cloning vector (for example defective on the cI-lambda repressor).

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

7. *Required characteristics of the insert*

(1) The insert should be well characterised

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

- (a) The origin of the insert should be known (genus, species, strain).
- (b) The following information on the library from which the insert originated, should be known—
 - (i) the source and method for obtaining the nucleic acid of interest (cDNA, chromosomal, mitochondrial, etc.);
 - (ii) the vector in which the library was constructed (for example λ gt 11, pBR 322, etc.) and the site in which the DNA was inserted;
 - (iii) the method used for identification (colony, hybridization, immuno-blot, etc.);
 - (iv) the strain used for library construction.

- (c) If the insert is synthetic, its intended function should be identified.
- (d) The following information on the structure of the insert is required—
 - (i) information on structural genes, regulatory elements;
 - (ii) size of the insert;
 - (iii) restriction endonuclease sites flanking the insert;
 - (iv) information on transposable elements and provirus sequences.

(2) The insert should be free from harmful sequences—

- (a) the function of each genetic unit in the insert should be defined (not applicable for Type A operations);
 - (b) the insert should not contain genes coding for potentially harmful or pathogenic traits (for example virulence determinants, toxins, etc.), (unless for Type A operations, such genes constitute an essential part of the insert without, under any circumstances, resulting in a harmful or pathogenic phenotype of the genetically modified micro-organism).
- (3) The insert should be limited in size as much as possible to the genetic sequences required to perform the intended function.
- (4) The insert should not increase the stability of the construct in the environment (unless that is a requirement of intended function).
- (5) The insert should be poorly mobilisable.

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

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

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

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

- (2) (a) The genetically modified micro-organism should be as safe (to man and the environment) as the recipient or parental strains (applicable only for Type A operations);
- (b) the genetically modified micro-organisms should be as safe in the reactor or fermenter as the recipient or parental strains, but with limited survivability and/or replicability outside the reactor or fermenter without adverse consequences in the environment (applicable only for Type B operations).

9. *Other genetically modified micro-organisms that could be included in Group 1 if they meet the conditions in paragraph 8*

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

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

PART III

CRITERIA FOR THE CLASSIFICATION OF ORGANISMS OTHER THAN
MICRO-ORGANISMS

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

- (a) which is not a genetically modified micro-organism; and
- (b) which is as safe in the containment facility as any recipient or parental organism.

**Matters to be taken into account in making a risk
assessment under Regulation 7***Characteristics of the donor, recipient or (where appropriate) parental organism*

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

- (a) the name, species, subspecies and strain of the organism;
- (b) the degree of relatedness between the donor, recipient and (where appropriate) parental organism in relation to which the assessment is being carried out;
- (c) the sources of the organism;
- (d) the reproductive cycle of the organism;
- (e) history of prior genetic modifications to the organism;
- (f) the stability of the genetic traits of the organism;
- (g) the nature of the pathogenicity, virulence, infectivity, toxicity, and vectors of disease transmission of the organism;
- (h) the base sequence, frequency of mobilisation and specificity of the organism's indigenous vectors;
- (i) the presence in the organism of genes which confer resistance;
- (j) the host range of an organism which is a parasite or pathogen;
- (k) the organism's other potentially significant physiological traits, and the stability of those traits;
- (l) the organism's natural habitat and geographic distribution;
- (m) the climactic characteristics of the organism's natural habitat;
- (n) the significant involvement of the organism in environmental processes, including nitrogen fixation and pH regulation;
- (o) the interaction of the organism with other organisms in the environment and its effect on those organisms, including its likely competitive or symbiotic properties;
- (p) the ability of the organism to form survival structures, including seeds, spores or sclerotia.

Characteristics of the modified organism

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

- (a) the description of the modification, including the technique used or proposed to be used to introduce a vector or insert into the organism;
- (b) the nature and source of the vector introduced into the organism;
- (c) the function of the genetic modification and/or of the new nucleic acid;
- (d) the structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organism;
- (e) the stability of the genetic traits introduced into the organism;
- (f) the frequency of mobilisation of inserted vector or genetic transfer capability;
- (g) the rate and level of expression of the new genetic material in the organism, and the method and sensitivity of measurement of that rate and level;
- (h) the activity of the expressed protein.

Health considerations

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

- (a) toxic or allergenic effects of non-viable organisms and/or their metabolic products;
- (b) product hazards;
- (c) comparison of the modified micro-organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
- (d) capacity for colonization;
- (e) if the organism is pathogenic to humans who are immunocompetent—
 - (i) diseases caused and mechanism of pathogenicity including invasiveness and virulence,
 - (ii) communicability,
 - (iii) infective dose,
 - (iv) host range, possibility of alteration,
 - (v) possibility of survival outside of human host,
 - (vi) presence of vectors or means of dissemination,
 - (vii) biological stability,
 - (viii) antibiotic-resistance patterns,
 - (ix) allergenicity,
 - (x) availability of appropriate therapies.

Environmental considerations

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

- (a) the factors affecting survival, multiplication and dissemination of the modified organism in the environment;
- (b) the available techniques for detection, identification, and monitoring of the modified organism in the environment;
- (c) the available techniques for detecting transfer of the new genetic material to other organisms;
- (d) the known and predicted habitats of the modified organism;
- (e) the ecosystems to which the modified organism could be disseminated as a result of an escape;
- (f) the anticipated mechanism and result of interaction between the modified organism and the organisms which might be exposed in case of the escape of the organism;
- (g) the known or predicted effects of the organism on plants and animals, including pathogenicity, infectivity, toxicity, virulence, vector or pathogen allergenicity, colonisation, predation, parasitism, symbiosis and competition;
- (h) the known or predicted involvement of the organism in biogeochemical processes, including nitrogen fixation and pH regulation;
- (i) the availability of methods for decontamination of the area in case of release to the environment.

Information required for a notification under Regulation 8(1)

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

- (a) the name and address of the person responsible for carrying out the activity and the names of persons responsible for supervision, monitoring and safety together with details of their training and qualifications;
- (b) address of the premises where the activity is to be carried on and its grid reference and, where appropriate, a description of the sections of the installation;
- (c) a description of the nature of the activity to be undertaken, the likely scale of the operation and in particular, in the case of genetically modified micro-organisms, their classification in accordance with regulation 2(2);
- (d) a summary of the risk assessment undertaken in accordance with regulation 7;
- (e) the names of the members of the genetic modification safety committee and the capacity in which each member serves;
- (f) comments made by the genetic modification safety committee on the local arrangements for risk assessment;
- (g) the names of the biological and deputy biological safety officers concerned with the intended activities (if any);
- (h) the name of the supervisory medical officer (if any);
- (i) the arrangements for health surveillance (if any); and
- (j) any other information the Department may require for the purpose of maintaining the register referred to in regulation 16.

Information required for a notification under Regulation 9

PART I

INFORMATION REQUIRED UNDER REGULATION 9(3)

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

- (a) the name and address of the person responsible for carrying out the activity;
- (b) address of the premises where the activity is to be carried out;
- (c) the date of the notification referred to in regulation 8(1);
- (d) the parental organism used, or where applicable the host-vector system used;
- (e) the source and the intended function of the genetic material involved in the modification;
- (f) the identity and characteristics of the genetically modified organism;
- (g) the purpose of the activity including the expected results;
- (h) where appropriate the culture volumes to be used or the scale of the activity;
- (i) details of waste treatment including levels of live genetically modified micro-organisms in the waste; and
- (j) a summary of the risk assessment required in accordance with regulation 7 and of the comments of the genetic modification safety committee on that risk assessment.

PART II

INFORMATION REQUIRED UNDER REGULATION 9(4)

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

- (a) a description of the sections of the installation involved and the methods for handling the organisms;
- (b) a description of the predominant meteorological conditions and the potential sources of danger arising from the location of the installation;
- (c) a description of the protective and supervisory methods to be applied throughout the duration of the activity; and
- (d) in the case of micro-organisms, the containment level to which the micro-organism has been allocated in accordance with the risk assessment made in accordance with regulation 7(1) and in any case the safety precautions to be observed.

PART III

INFORMATION REQUIRED UNDER REGULATION 9(5)

3. In addition to the information required under Parts I and II a notification made for the purposes of regulation 9(5) shall, subject to paragraph 4, contain the information specified in paragraph 5.

4. If it is not technically possible, or if it does not appear necessary to give the information specified in paragraph 5, the reason shall be stated. The level of detail required in response to each subset of considerations is likely to vary according to the nature and scale of the proposed activity. In the case of information already submitted to the Department by the notifier under these Regulations (or the 1991 Regulations) reference may be made to that information by him.

5. The additional information required is—

(a) information about the genetically modified micro-organisms—

- (i) the identity and characteristics of the genetically modified micro-organisms,
- (ii) the purpose of the contained use or the nature of the product,
- (iii) the host-vector system to be used where applicable,
- (iv) the culture volume to be used,
- (v) behaviour and characteristics of the micro-organisms in the case of changes in the conditions of containment or release into the environment,
- (vi) overview of the potential hazards associated with the release of the micro-organisms into the environment, and
- (vii) substances which are or may be produced in the course of use of the micro-organisms other than the intended product;

(b) information about personnel—

- (i) the maximum number of persons working in the installation, and
- (ii) the number of persons who will work directly with the micro-organisms;

(c) information about the installation—

- (i) the activity in which the micro-organisms are to be used,
- (ii) the technological processes used,
- (iii) a description of the sections of the installation involved, and
- (iv) the predominant meteorological conditions and specific hazards arising from the location of the installation;

(d) information about waste management—

- (i) types, quantities and potential hazards of wastes arising from the use of the micro-organisms,
- (ii) waste management techniques used including recovery of liquid or solid wastes and the inactivation techniques used, and
- (iii) ultimate form and destination of inactivated wastes;

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

- (i) the sources of hazards and conditions under which accidents might occur,
- (ii) the preventive measures applied such as safety equipment, alarm systems, containment methods and procedures and available resources,
- (iii) a description of information given to workers, and
- (iv) the information necessary for the Department to evaluate any emergency plan prepared in accordance with regulation 13;

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

(g) any other information the Department may require for the purpose of maintaining the register referred to in regulation 16.

Containment measures for micro-organisms classified as Group II

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

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

TABLE

<i>Specifications</i>	<i>Containment Levels</i>		
	<i>B2</i>	<i>B3</i>	<i>B4</i>
1. Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system)	Yes	Yes	Yes
2. Exhaust gases from the closed system should be treated so as to:	Minimise release	Prevent release	Prevent release
3. Sample collection, addition of materials to a closed system and transfer of viable micro-organisms to another closed system, should be performed so as to:	Minimise release	Prevent release	Prevent release
4. Bulk culture fluids should not be removed from the closed system unless the viable micro-organisms have been:	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to:	Minimise release	Prevent release	Prevent release

TABLE

<i>Specifications</i>	<i>Containment Levels</i>		
	<i>B2</i>	<i>B3</i>	<i>B4</i>
6. Closed systems should be located within a controlled area	Optional	Optional	Yes, and purpose-built
(a) Biohazard signs should be posted	Optional	Yes	Yes
(b) Access should be restricted to nominated personnel only	Optional	Yes	Yes, via airlock
(c) Personnel should wear protective clothing	Yes, work clothing	Yes	Yes, a complete change
(d) Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
(e) Personnel should shower before leaving the controlled area	No	Optional	Yes
(f) Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes
(g) The controlled area should be adequately ventilated to minimise air contamination	Optional	Optional	Yes
(h) The controlled area should be maintained at an air pressure negative to atmosphere	No	Optional	Yes
(i) Input air and extract air to the controlled area should be HEPA filtered	No	Optional	Yes

TABLE

<i>Specifications</i>	<i>Containment Levels</i>		
	<i>B2</i>	<i>B3</i>	<i>B4</i>
(j) The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Yes	Yes
(k) The controlled area should be sealable to permit fumigation	No	Optional	Yes
7. Effluent treatment before final discharge	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated physical means

EXPLANATORY NOTE

(This note is not part of the Regulations.)

1. These Regulations implement as regards Northern Ireland Council Directive 90/219/EEC (O.J. No. L117, 8.5.90, p. 1) on the contained use of genetically modified micro-organisms. The Regulations also revoke the Genetic Manipulation Regulations (Northern Ireland) 1991 ("the 1991 Regulations").

2. These Regulations have effect with a view to protecting persons and the environment from risks arising from activities involving the contained use of genetically modified organisms.

3. These Regulations do not apply to certain techniques listed in Part III of Schedule 1. Regulations 8 to 12 do not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

Part I (Interpretation and general — Regulations 1 to 5)

4. In addition to defining the terms used and the scope of the Regulations, this Part extends the meaning of "work" in Parts I and II of the Health and Safety at Work (Northern Ireland) Order 1978 to include any activity involving the contained use of genetically modified organisms.

Part II (Notification of and consent for activities involving genetic modification — Regulations 6 to 11)

5. Part II prohibits the use of premises for activities involving the contained use of genetically modified organisms for the first time and also individual activities involving the contained use of those organisms unless a suitable risk assessment has been made. Provision is also made for prior notification of such first use of premises or individual activities to the Department of Economic Development (“the Department”) and in certain specified cases the first use of premises for the activity concerned can be commenced only with the Department’s consent.

6. Regulation 11 provides for the establishment of a genetic modification safety committee to advise in relation to any risk assessment required under the Regulations.

Part III (Conduct of activities involving genetic modification — Regulations 12 to 14)

7. The regulations in Part III specify standards of occupational and environmental safety required for the conduct of activities involving the contained use of genetically modified organisms and make provision in connection with the preparation of emergency plans where, as a result of a reasonably foreseeable accident, there is a risk to the health of persons outside the premises in which the activity is carried on or to the environment. Where another member State is liable to be affected by the reasonably foreseeable accident, the Department is required to consult that member State in the drawing up and implementation of the emergency plan. Information in relation to emergency plans must be made publicly available and updated. Where an accident occurs certain information is required to be notified to the Department which is under a duty to inform any other member State that could be affected and to send certain information to the European Commission.

Part IV (Disclosure of information notified and publicity — Regulations 15 and 16)

8. Part IV specifies the circumstances in which information provided to the Department is to be disclosed and also provides for a public register of notifications requiring consent to be kept.

Part V (Additional duties placed on the Department — Regulations 17 to 19)

9. Part V imposes duties on the Department to examine notifications received and send particulars notified to the Department of the Environment for Northern Ireland. The Department is also required to send to the European Commission reports of notifications for which a consent is required.

Part VI (Miscellaneous and general — Regulations 20 to 24)

10. Part VI provides for, in certain circumstances, exemptions from the Regulations to be granted by the Department, for enforcement by the Department or, in specified circumstances, by the Department of Agriculture,

and for fees to be charged by the Department in relation to notifications. Regulation 24 contains transitional provisions relating to notifications made under the 1991 Regulations so that they continue to have effect in certain circumstances.

11. Schedule 1 sets out examples of techniques which constitute genetic modification and the techniques which are not considered to result in genetic modification.

Schedule 2 sets out the criteria for classification of organisms.

Schedule 3 sets out the matters to be investigated and assessed in making a risk assessment under regulation 7.

Schedule 4 sets out the information required in relation to a notification of intention to use premises for activities involving genetic modification for the first time.

Schedule 5 sets out the information to be furnished where a person intends to undertake certain activities involving genetic modification.

Schedule 6 sets out containment measures to be applied in relation to activities involving certain genetically modified micro-organisms.

12. A person who contravenes these Regulations is guilty of an offence under Article 31 of the Health and Safety at Work (Northern Ireland) Order 1978.