STATUTORY INSTRUMENTS

2000 No. 2831

The Genetically Modified Organisms(Contained Use) Regulations 2000

PART I

INTERPRETATION AND GENERAL

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations 2000 and shall come into force on 15th November 2000.

Interpretation

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

"the 1974 Act" means the Health and Safety at Work etc. Act 1974;

"accident" means an 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;

"activity involving genetic modification" means a contained use;

"class", in relation to an activity involving genetic modification of micro-organisms, means one of the four classes described in Schedule 1;

"competent authority" means—

(a) as regards England and Wales, the Secretary of State, the Minister of Agriculture, Fisheries and Food and the Executive, acting jointly; and

(b) as regards Scotland, the Scottish Ministers and the Executive, acting jointly,

and the expressions "competent authority as regards England and Wales" and "competent authority as regards Scotland" shall be construed accordingly;

"contained use" means an activity in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are used to limit their contact with, and to provide a high level of protection for, humans and the environment;

"EEA State" means a State, other than the United Kingdom, which is a Contracting Party to the Agreement on the European Economic Area signed at Oporto on 2nd May 1992, as adjusted by the Protocol signed at Brussels on 17th March 1993(**1**) and adopted as respects the United Kingdom by the European Economic Area Act 1993(**2**);

"emergency plan" means a plan required by virtue of regulation 20;

(**1**) Cm 2073 and 2183.
(**2**) 1993 c. 51.

"emergency services" means the police, fire and ambulance services;

"the Executive" means the Health and Safety Executive;

"genetic modification" in relation to an organism means the altering of the genetic material in that organism in 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 listed in Part I of Schedule 2; and

(b) the techniques listed in Part II of Schedule 2 are not considered to result in genetic modification,

and "genetically modified" shall be construed accordingly;

"joint competent authority" means the competent authority as regards England and Wales and the competent authority as regards Scotland, acting jointly;

"micro-organism" means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, and includes a virus, a viroid, and an animal or plant cell in culture;

"notifier" means a person who has submitted a notification to the competent authority pursuant to regulation 9(1), 10(1), 11(1) or 12(1);

"organism" means a biological entity capable of replication or of transferring genetic material and includes a micro-organism, but does not include a human or a human embryo; and

"working day" means any day other than a Saturday, a Sunday, Christmas Day or Good Friday, or a bank holiday within the meaning given by the Banking and Financial Dealings Act 1971(**3**).

(2) In these Regulations—

(a) in relation to an activity involving genetic modification, any reference to an appropriate containment level is a reference to the containment level assigned to that activity in accordance with paragraphs 3(h) and 4 of Part II of Schedule 3;

(b) any reference to an activity involving genetic modification in a numbered class is a reference to an activity involving genetic modification of micro-organisms which has been classified as belonging to the class of that number in accordance with paragraph 3(i) and (j) of Part II of Schedule 3; and

(c) in relation to a notification submitted in accordance with regulation 13(1), any reference to the competent authority shall be construed as a reference to the joint competent authority.

(3) The provisions in—

(a) Part II of Schedule 8 shall be applied in accordance with Part I of that Schedule; and

(b) Tables 1a, 1b and 1c in Part II of Schedule 8 shall be applied in accordance with the notes set out at the end of the Table in question.

(4) In these Regulations, unless the context otherwise requires—

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

(**3**) 1971 c. 80.

Application

3.—(1) These Regulations shall have effect with a view to—

(a) protecting persons against risks to their health, whether immediate or delayed, arising from activities involving genetic modification of organisms; and

(b) protecting the environment against harm from activities involving genetic modification of micro-organisms.

(2) These Regulations (except regulation 17) shall not apply to the genetic modification of organisms solely by any of the techniques referred to in Part III of Schedule 2 nor to any organisms so modified.

(3) These Regulations shall not apply to any activity in which—

(a) genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are or are contained in—

(i) a product marketed in pursuance of either—

(aa) a consent granted by the Secretary of State, or, as regards Scotland, by the Scottish Ministers, under section 111(1) of the Environmental Protection Act 1990(**4**), or

(bb) a written consent given by the competent authority of an EEA State in accordance with Article 13(4) of Council Directive 90/220/EEC(**5**) on the deliberate release into the environment of genetically modified organisms,

and, in either case, that activity is conducted in accordance with any conditions or limitations attached to that consent,

(ii) a medicinal product for human or veterinary use marketed in accordance with Council Regulation (EEC) No. 2309/93(**6**), or

(iii) a novel food or novel food ingredient marketed in accordance with the provisions of Regulation (EC) No. 258/97 of the European Parliament and of the Council(**7**); or

(b) genetically modified organisms are released or marketed in cases or circumstances in which the consent of the Secretary of State, or, as regards Scotland, the Scottish Ministers, is required under section 111(1) of the Environmental Protection Act 1990.

(4) Regulations 8 to 15, 17(2) and (3), 18 and 19 shall not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(5) Regulation 6 shall apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air, except that, in making the assessment required by regulation 6(1), the person undertaking that assessment shall not be required to include the steps set out in paragraph 3(h) to (j) of Part II of Schedule 3.

(6) These Regulations shall not extend to Northern Ireland.

(7) In this regulation, "product" means a product consisting of or containing a genetically modified organism or a combination of genetically modified organisms.

(**4**) 1990 c. 43.
(**5**) OJ No. L117, 8.5.90, p. 15, as amended by Commission Directive 94/15/EC (OJ No. L103, 22.4.94, p. 20) and Commission Directive 97/35/EC (OJ No. L 169, 27.6.97, p. 72).
(**6**) OJ No. L 124, 24.8.93, p. 1, as amended by Commission Regulation (EC) 649/98 (OJ No. L 88, 24.3.98, p. 7).
(**7**) OJ No. L 43, 14.2.97, p. 1 (to be read with Corrigenda published in OJ L 173, 1.7.97, p. 12 and OJ L 187, 20.7.99, p. 74.

Meaning of "work" and "at work"

4. For the purpose of these Regulations and Part I of the 1974 Act, the meaning of "work" shall be extended to include any activity involving genetic modification and the meaning of "at work" shall be extended accordingly.

Modification of the Health and Safety at Work etc. Act 1974

5.—(1) Sections 2(1), (2) and (3) and 7 of the 1974 Act shall be modified in relation to an activity involving genetic modification so as to have effect as if the reference to an employer therein includes a reference to an educational establishment providing a course of study, and the reference to an employee therein includes a reference to a student of that educational establishment and that student shall be treated as the employee of that educational establishment, to the extent that the activity involving genetic modification is under the control of that educational establishment.

(2) Section 3(2) of the 1974 Act shall be modified in relation to an activity involving genetic modification so as to have effect as if the reference in that section to a self-employed person is a reference to any person (except a student) who is not an employer or an employee and the reference in that section to his undertaking includes a reference to such an activity.

(3) In this regulation—

(a) "educational establishment" means a university, polytechnic, college, school or similar educational or technical institute; and

(b) "student" means any person studying at an educational establishment.

PART II

RISK ASSESSMENT AND NOTIFICATION OF ACTIVITIES INVOLVING GENETIC MODIFICATION

Risk assessment of activities involving genetically modified micro-organisms

6.—(1) No person shall undertake any activity involving genetic modification of micro-organisms unless, before commencing that activity, he has ensured that a suitable and sufficient assessment of the risks created thereby to human health and the environment has been carried out.

(2) The person carrying out an assessment required by paragraph (1) shall take into account the matters set out in Part I of, and include the steps set out in Part II of, Schedule 3.

Risk assessment of activities involving genetically modified organisms other than micro-organisms

7.—(1) No person shall undertake any activity involving genetic modification of organisms other than micro-organisms unless, before commencing that activity, he has ensured that a suitable and sufficient assessment of the risks created thereby to human health has been carried out.

(2) The person carrying out an assessment required by paragraph (1) shall take into account the matters set out in Part I of, and include the steps set out in Part II of, Schedule 4.

Review and recording of risk assessments

8.—(1) Where—

(a) there is reason to suspect that an assessment is no longer valid; or

(b) there has been a significant change in the activity involving genetic modification to which an assessment relates,

the person undertaking the activity involving genetic modification to which the assessment relates shall ensure that the assessment is reviewed forthwith.

(2) The person undertaking an activity involving genetic modification—

(a) shall keep a record of the assessment relating to that activity, and any review of that assessment, for at least 10 years from the date of the cessation of that activity; and

(b) shall make such record available to the competent authority when requested to do so.

(3) In this regulation, "assessment" means an assessment carried out for the purposes of regulation 6 or regulation 7.

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

9.—(1) No person shall use premises for the first time for the purpose of undertaking an activity involving genetic modification, unless—

(a) he has submitted to the competent authority a notification informing it of his intention to do so and containing the information specified in Schedule 5; and

(b) he has received an acknowledgement from the Executive of receipt of that notification.

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

Notification of class 2 activities involving genetic modification of micro-organisms

10.—(1) Subject to the following paragraphs of this regulation, no person shall undertake an activity involving genetic modification of micro-organisms in class 2 unless he has submitted a notification to the competent authority informing it of his intention to do so and containing the information specified in Part I of Schedule 6.

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

(3) The competent authority shall ensure that any emergency plan has been prepared.

(4) No person shall undertake—

(a) for the first time an activity referred to in paragraph (1) at the premises referred to in a notification submitted in accordance with that paragraph unless—

(i) at least 45 days, or such shorter period of time as the competent authority may approve in writing, have elapsed since the date on which the acknowledgement was sent in accordance with paragraph (2) and the competent authority has not within the said period of 45 days or the shorter period of time approved by the competent authority, as the case may be, informed the notifier that he shall not undertake the activity in question, or

(ii) he has received the acknowledgement required by paragraph (2) and consent for activities involving genetic modification in class 3 or 4 has already been granted in respect of the premises to which the notification submitted in accordance with paragraph (1) refers;

(b) for the second or subsequent times an activity referred to in paragraph (1) at the premises referred to in a notification submitted in accordance with that paragraph unless he has received the acknowledgement required by paragraph (2).

(5) Where a person submits a notification in accordance with paragraph (1) in respect of an activity referred to in that paragraph which is not to be undertaken for the first time at the premises referred to in the notification, with the notification that person may request that the competent authority makes a decision whether or not to agree to his undertaking the activity in question.

(6) The competent authority shall make a decision requested in accordance with paragraph (5) within 45 days of the date on which the acknowledgement was sent in accordance with paragraph (2).

Notification of class 3 or class 4 activities involving genetic modification of micro-organisms

11.—(1) Subject to the following paragraphs of this regulation, no person shall undertake an activity involving genetic modification of micro-organisms in class 3 or class 4 unless he has—

(a) submitted to the competent authority a notification informing it of his intention to do so and containing the information specified in Part II of Schedule 6; and

(b) received the written consent of the competent authority to undertake the activity in question.

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

(3) Where a person proposes to undertake an activity referred to in paragraph (1) for the first time at the premises referred to in a notification submitted in accordance with that paragraph, the competent authority shall inform that person in writing of its decision to grant or refuse consent to undertake the activity in question not more than 90 days after the acknowledgement was sent in accordance with paragraph (2).

(4) Where a person proposes to undertake an activity referred to in paragraph (1) for the second or subsequent times at the premises referred to in a notification submitted in accordance with that paragraph, the competent authority shall inform that person in writing of its decision to grant or refuse consent to undertake the activity in question not more than 45 days after the acknowledgement was sent in accordance with paragraph (2).

(5) Before granting a consent under either paragraph (3) or paragraph (4), the competent authority shall ensure that any emergency plan has been prepared.

(6) Before deciding whether to grant or refuse a consent under either paragraph (3) or paragraph (4), the competent authority shall take into account any representations made to it by any person within 30 days of the date on which the Executive sent the acknowledgement of receipt in accordance with paragraph (2).

(7) A consent granted pursuant to this regulation may be granted subject to conditions.

Notification of activities involving genetic modification of organisms other than micro-organisms

12.—(1) Subject to the following paragraphs of this regulation, no person shall undertake an activity involving genetic modification of organisms other than micro-organisms unless he has submitted to the competent authority a notification informing it of his intention to do so and containing the information specified in Part III of Schedule 6.

(2) Paragraph (1) shall not apply to an activity involving genetic modification of organisms where that genetic modification results in a genetically modified organism (other than a micro-organism) which poses no greater risk to humans than its unmodified parental organism.

(3) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

(4) No person shall undertake any activity referred to in paragraph (1), unless at least 45 days, or such shorter period of time as the competent authority may approve in writing, have elapsed since the date on which the acknowledgement was sent in accordance with paragraph (3) and the competent authority has not within the said period of 45 days or the shorter period of time approved by the competent authority, as the case may be, informed the notifier that he shall not undertake the activity in question.

Notifications to the joint competent authority and of connected programmes of work

13.—(1) Where a notification is required—

(a) under regulation 9(1) in respect of premises which are situated in both England and Scotland; or

(b) under regulation 10(1), 11(1) or 12(1) in respect of an activity involving genetic modification which is to take place in both England and Scotland,

the notifier shall submit a single notification under the regulation in question to the joint competent authority.

(2) The competent authority may accept a single notification submitted under regulation 10(1), 11(1) or 12(1) in respect of a connected programme of work undertaken by the same person at—

(a) one site; or

(b) more than one site.

(3) The competent authority may accept a single notification submitted under regulation 10(1), 11(1) or 12(1) in respect of a single activity involving genetic modification undertaken by the same person at more than one site.

(4) In this regulation—

(a) "connected programme of work" means a series of activities involving genetic modification which form a coherent and integrated programme;

(b) "site" means premises of which the competent authority has been notified in accordance with regulation 9(1).

Duties on receiving notifications and additional information

14.—(1) The competent authority shall examine a notification submitted under regulation 9(1), 10(1), 11(1) or 12(1) for—

(a) conformity with the requirements of these Regulations;

(b) the accuracy and completeness of the information provided;

(c) the correctness of the assessment carried out pursuant to regulation 6(1) or 7(1) and submitted to the competent authority with the notification;

(d) the adequacy of the waste management and emergency response measures submitted with the notification; and

(e) in the case of a notification submitted under regulation 10(1) or regulation 11(1), the correctness of the class assigned to the activity involving genetic modification of micro-organisms.

(2) For the purpose of carrying out an examination of a notification in accordance with paragraph (1), the Executive may request in writing the notifier to provide such additional

information relating to the notification as it may specify, and, in such a case, when so requested by the Executive, the notifier shall not begin nor, subject to paragraph (3), continue, as the case may be, the activity involving genetic modification until the competent authority has given its approval in writing.

(3) Where the person who submitted a notification pursuant to regulation 9(1), 10(1), or 12(1) has commenced the activity involving genetic modification before the Executive requests additional information in accordance with paragraph (2)—

(a) the Executive may give to that person instructions concerning the cessation of the activity involving genetic modification;

(b) that person shall comply with any such instructions;

(c) subject to any such instructions, that person shall continue the activity involving genetic modification only to the extent necessary in order to store or destroy all genetically modified organisms resulting from the activity since its commencement.

(4) If requested to do so by the Secretary of State, the Minister of Agriculture, Fisheries and Food or the Scottish Ministers, the Executive shall request additional information under paragraph (2).

(5) Within 10 working days, the Executive shall acknowledge receipt of all additional information provided in response to a request made by the Executive under paragraph (2).

(6) The period of time between the date when the Executive requests additional information in accordance with paragraph (2) and the date when the Executive receives that additional information shall not be taken into account in calculating the period of days referred to in regulations 10(4), 10(6), 11(3), 11(4) or 12(4), as the case may be.

(7) Where—

(a) a notifier under regulation 9(1) has not commenced any activity involving genetic modification, or a notifier under regulation 10(1), 11(1) or 12(1), has not commenced the activity relating to genetic modification to which his notification relates; and

(b) the Executive requests additional information pursuant to paragraph (2); and

(c) the notifier in question does not provide that information within a period of six months of the date on which the Executive sent the request,

the competent authority may return the notification to that notifier.

Additional provisions relating to notifications

15.—(1) The competent authority may at any time by notice in writing to the person undertaking or proposing to undertake an activity involving genetic modification—

(a) set a limit of time for, or impose conditions with regard to, that activity;

(b) require that person to suspend, to terminate or not to commence that activity, as the case may be;

(c) revoke or vary a consent granted to that person under regulation 11,

and the person to whom the notice is addressed shall comply with that notice.

(2) A notifier shall forthwith send to the competent authority full details in writing of—

(a) any change in the information specified in paragraphs (a), (d) or (e) of Schedule 5 and provided by him in accordance with regulation 9(1);

(b) any new building—

(i) added by the notifier to the premises notified by him in accordance with regulation 9(1), and

(ii) under his control;

(c) any decision by him no longer to use premises notified by him in accordance with regulation 9(1) for the purposes of undertaking any activity involving genetic modification;

(d) any cessation for the time being of all activity involving genetic modification at premises notified by him in accordance with regulation 9(1);

(e) any cessation of an activity involving genetic modification notified by him in accordance with regulation 10(1), 11(1) or 12(1);

(f) any re-commencement by him of an activity involving genetic modification at premises in respect of which details of a cessation had previously been given by him under sub-paragraph (d) above;

(g) any use by him of additional premises in connection with a single activity involving genetic modification carried on solely by him at more than one site, provided that a notification has been submitted by him in accordance with regulation 9(1) in respect of the additional premises;

(h) any change in the information specified in—

(i) paragraphs (b) and (c) of Schedule 5 and provided by him in accordance with regulation 9(1), or

(ii) paragraph 1(c) or (d) of Part I of Schedule 6 and provided by him in accordance with regulation 10(1).

(3) Subject to paragraphs (4) and (5), where a notifier subsequently—

(a) makes a change in the premises or the activity involving genetic modification to which his notification relates which may have significant consequences for the risks arising from that activity; or

(b) becomes aware of any new information which may have significant consequences for the risks arising from that activity,

he shall forthwith send to the competent authority in writing full details of the change or the new information, as the case may be.

(4) Subject to paragraph (5), where a change referred to in paragraph (3)(a) would require a person to submit a notification in accordance with regulation 11(1), that person shall not make the change until—

(a) he has submitted a notification in accordance with that regulation; and

(b) he has received the written consent of the competent authority pursuant to regulation 11(1)(b).

(5) Paragraph (4) shall not apply where a person undertakes an activity involving genetic modification with the written consent of the competent authority granted pursuant to regulation 11(1)(b) and the change referred to in paragraph (3) would require that person to make a further notification under regulation 11(1).

(6) A notifier may withdraw his notification by giving written notice to the competent authority, provided that the notifier has not commenced the activity involving genetic modification to which the notification relates.

(7) In this regulation, the word “site” has the same meaning as it has in regulation 13.

(8) Anything required to be submitted or sent to the competent authority pursuant to these Regulations shall be submitted or sent in writing to the competent authority at Magdalen House, Stanley Precinct, Bootle, Merseyside L20 3QZ.

PART III

CONDUCT OF ACTIVITIES INVOLVING GENETIC MODIFICATION

Establishment of a genetic modification safety committee

16. A person who carries out an assessment pursuant to regulation 6 or 7 shall establish a genetic modification safety committee to advise him in relation to that assessment.

Principles of occupational and environmental safety

17.—(1) A person who undertakes an activity involving genetic modification shall ensure that—

(a) the exposure of humans and the environment to genetically modified micro-organisms is reduced to the lowest level that is reasonably practicable; and

(b) harm to humans arising from an activity involving genetic modification of organisms other than micro-organisms is reduced to the lowest level that is reasonably practicable.

(2) For any activity involving genetic modification of micro-organisms, the measures to be taken in order to comply with the duty under paragraph (1) shall include the general principles of good microbiological practice and of good occupational safety and hygiene set out in Schedule 7.

(3) For any activity involving genetic modification of organisms other than micro-organisms, the general principles set out in Schedule 7 shall be applied insofar as they are appropriate.

Containment and control measures for activities involving genetic modification of micro-organisms

18.—(1) Subject to paragraph (2), a person who undertakes an activity involving genetic modification of micro-organisms shall apply the containment measures set out in the applicable Table in Schedule 8, where and to the extent required in the column of the appropriate containment level.

(2) Where a risk assessment, or any review of that assessment carried out in accordance with regulation 8, shows that a particular containment measure of the appropriate containment level is not necessary for the activity involving genetic modification of micro-organisms to which the assessment relates, the person undertaking that activity, after providing full justification to, and with the written agreement of, the competent authority, need not apply that containment measure for the activity in question.

(3) A person who undertakes an activity involving genetic modification of micro-organisms shall review the containment measures applied by him in accordance with paragraph (1)—

(a) at suitably regular intervals; and

(b) forthwith if that person suspects that—

(i) the containment measures are no longer adequate,

(ii) the class in relation to the activity involving genetic modification of micro-organisms identified in the risk assessment is no longer appropriate, or

(iii) in the light of new scientific or technical knowledge, the risk assessment is no longer valid.

(4) In this regulation, "risk assessment" means an assessment carried out pursuant to regulation 6.

Containment and control measures for activities involving genetic modification of organisms other than micro-organisms

19.—(1) A person who undertakes an activity involving genetic modification of organisms other than micro-organisms shall apply the containment measures selected in accordance with the assessment made pursuant to regulation 7(1).

(2) That person shall review the containment measures applied by him in accordance with paragraph (1)—

(a) at suitably regular intervals; and

(b) forthwith if that person suspects that—

(i) the containment measures applied are no longer adequate, or

(ii) in the light of new scientific or technical knowledge, the assessment referred to in paragraph (1) is no longer valid.

Emergency plans

20.—(1) Where an assessment carried out pursuant to regulation 6(1) shows that, as a result of any reasonably foreseeable accident—

(a) the health or safety of persons outside the premises in which an activity involving genetic modification is carried on is liable to be seriously affected; or

(b) there is a risk of serious damage to the environment,

the person undertaking that activity shall ensure that, before the activity to which the assessment relates begins, a suitable plan is prepared with a view to securing the health and safety of those persons and the protection of the environment.

(2) Where an assessment carried out pursuant to 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 undertaken is liable to be seriously affected, the person undertaking that activity shall ensure that, before the activity to which the assessment relates begins, a suitable plan is prepared with a view to securing the health and safety of those persons.

(3) Every emergency plan—

(a) shall include the measures to be taken in the event of an accident to which the plan relates; and

(b) shall be reviewed and, where necessary, revised at suitably regular intervals.

(4) The person undertaking the activity involving genetic modification which is the subject of an emergency plan shall—

(a) inform the emergency services and any body or authority liable to be affected by an accident to which the plan relates of the contents of the plan and of any relevant revisions made in pursuance of paragraph (3); and

(b) make the plan and any such revisions publicly available.

Information relating to accidents

21.—(1) Where an accident occurs, the person undertaking the activity involving genetic modification shall forthwith inform the competent authority of the accident and shall provide the following information—

(a) the circumstances of the accident;

(b) the identity and quantity of the genetically modified organisms concerned;

(c) any information necessary to assess the effects of the accident on the health of the general population and on the environment; and

(d) any measures taken in response to the accident.

(2) Where the competent authority is informed of an accident in pursuance of paragraph (1), it shall—

(a) ensure that any necessary measures are taken;

(b) immediately inform those EEA States which 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—

(i) the information provided under paragraph (1)(a), (b) and (d),

(ii) information on the effectiveness of the measures taken in response to the accident, and

(iii) an analysis of the accident, including recommendations to limit its effects and to avoid similar accidents in the future.

PART IV

DISCLOSURE OF INFORMATION AND PUBLICITY

Disclosure of information provided pursuant to regulations 9 to 15

22.—(1) The information provided pursuant to regulations 9 to 15 shall not be treated as relevant information for the purposes of section 28 of the 1974 Act.

(2) Subject to paragraph (3), where, either in a notification submitted under regulation 9(1), 10(1), 11(1), or 12(1), or in response to a request made in pursuance of regulation 14(2) or when providing information in accordance with regulation 15(2) or 15(3), a person indicates that he is providing information which should be kept confidential on one or more of the grounds set out in regulation 4(2)(a) to (c) and (e) of the Environmental Information Regulations 1992(**8**)—

(a) that person shall give full justification for that indication to the competent authority; and

(b) after consulting that person, the competent authority shall decide which, if any, information shall be kept confidential and shall inform him of its decision.

(3) Subject to paragraph (8), paragraph (2) shall not apply to the following information, which shall not be kept confidential—

(a) the name and address of the notifier;

(b) in the case of a notification relating to an activity involving genetic modification of a micro-organism—

(i) the location of the activity,

(ii) the general characteristics of the genetically modified micro-organism,

(iii) the class of the activity involving genetic modification of the micro-organism,

(iv) the containment measures, and

(**8**) S.I.1992/3240, as amended by S.I. 1998/1447.

(v) the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

(4) Information which a notifier has indicated should be kept confidential and in relation to which the competent authority has not yet made a decision under paragraph (2)(b) and information which the competent authority has decided shall be kept confidential shall not be disclosed except—

(a) to the extent necessary to evaluate the notification; and

(b) to the European Commission.

(5) Where the competent authority has made a decision under paragraph (2)(b) that certain information shall not be kept confidential, that information shall not be disclosed until there has elapsed a period of 14 days following the day on which the competent authority informed the person providing the information of its decision except—

(a) to the extent necessary to evaluate the notification; and

(b) to the European Commission.

(6) A person who receives information by virtue of paragraph (4)(a) or (5)(a) shall not use that information except for the purposes of the competent authority.

(7) Information contained in a notification which has been withdrawn shall not be disclosed after the competent authority has received written notice in accordance with regulation 15(6).

(8) Notwithstanding paragraph (3), where the competent authority is satisfied on the basis of 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 competent authority shall withhold that information to the extent that, and for so long as, it is necessary to protect those rights.

(9) Subject to paragraph (10), where, pursuant to paragraph (2) or (8), a notifier has indicated that—

(a) he has provided confidential information; or

(b) withholding information is necessary in order to protect his intellectual property rights,

he shall forthwith inform the competent authority in writing of any change in circumstances which may affect the justification given under paragraph (2)(a) or the evidence submitted under paragraph (8), as the case may be.

(10) Paragraph (9) shall not apply if the competent authority has informed the notifier that the information in question is not to be kept confidential or withheld.

(11) Where—

(a) the competent authority has decided to keep information confidential pursuant to paragraph (2)(b) or has withheld information pursuant to paragraph (8); and

(b) the notifier has informed the competent authority of any change in circumstances pursuant to paragraph (9),

the competent authority shall, after consulting the notifier where appropriate, review whether the information in question should continue to be kept confidential or withheld and shall inform the notifier of the result of that review.

(12) For the purposes of this regulation, "general characteristics" in relation to a genetically modified micro-organism, means characteristics other than genus, species, genotype, serotype and strain.

Disclosure of information provided pursuant to regulation 21

23.—(1) The information provided pursuant to regulation 21 shall not be treated as relevant information for the purposes of section 28 of the 1974 Act.

(2) Subject to paragraph (3), where a person indicates that information provided by him pursuant to regulation 21 should be kept confidential on one or more of the grounds set out in regulation 4(2)(a) to (c) and (e) of the Environmental Information Regulations 1992—

(a) he shall give full justification for that indication to the competent authority; and

(b) after consulting that person, the competent authority shall decide which, if any, information shall be kept confidential and shall inform that person of its decision.

(3) Subject to paragraph (7), paragraph (2) shall not apply to the following information, which shall not be kept confidential—

(a) the name and address of the person providing the information;

(b) in the case of an accident relating to an activity involving genetic modification of a micro-organism—

(i) the location of the accident,

(ii) the general characteristics of genetic modification of the micro-organism,

(iii) the class of the activity involving genetic modification of the micro-organism,

(iv) the containment measures, and

(v) the evaluation of actual and foreseeable effects, in particular any harmful effects on human health and the environment.

(4) Information which the person providing that information has indicated should be kept confidential and in relation to which the competent authority has not yet made a decision under paragraph (2)(b) and information which the competent authority has decided shall be kept confidential shall not be disclosed except to the extent necessary to enable the competent authority to comply with its obligations under regulation 21(2).

(5) Where the competent authority has made a decision under paragraph (2)(b) that certain information shall not be kept confidential, that information shall not be disclosed until there has elapsed a period of 14 days following the day on which the competent authority informed the person providing the information of its decision, except to the extent necessary to enable the competent authority to comply with its obligations under regulation 21(2).

(6) A person who receives information by virtue of paragraph (4) or (5) shall not use that information except for the purposes of the competent authority.

(7) Notwithstanding paragraph (3), where the competent authority is satisfied on the basis of detailed evidence submitted to it by the person providing the information and, where appropriate, after consultation with that person, 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 competent authority shall withhold that information to the extent that, and for so long as, it is necessary to protect those rights.

(8) Subject to paragraph (9), where, pursuant to paragraph (2) or (7), a person has indicated—

(a) that certain information is confidential; or

(b) withholding information is necessary in order to protect his intellectual property rights,

he shall forthwith inform the competent authority in writing of any change in circumstances which may affect the justification given under paragraph (2)(a) or the evidence submitted under paragraph (7), as the case may be.

(9) Paragraph (8) shall not apply if the competent authority has informed the person providing the information that the information in question is not be be kept confidential or withheld.

(10) Where—

(a) the competent authority has decided to keep information confidential pursuant to paragraph (2)(b) or has withheld information pursuant to paragraph (7); and

(b) the person who provided the information has informed the competent authority of a change in circumstances pursuant to paragraph (8),

the competent authority shall, after consulting that person where appropriate, review whether the information in question should continue to be kept confidential, and shall inform that person of the result of that review.

(11) In this regulation, "general characteristics" in relation to a genetically modified micro-organism has the same meaning as it has in regulation 22.

Register of notifications

24.—(1) The competent authority shall maintain a register of every notification submitted under regulations 9 to 12.

(2) The register referred to in paragraph (1) shall contain—

(a) in relation to every notification submitted under regulations 9 to 12—

(i) the name, address and telephone number and any fax number and any e-mail address of the notifier,

(ii) the date on which the receipt of the notification was acknowledged by the Executive, and

(iii) if the competent authority receives details of a matter referred to in sub-paragraphs (a) to (g) of regulation 15(2) or in regulation 15(3), confirmation that such details have been received;

(b) in relation to each notification submitted under regulation 10(1), 11(1) or 12(1), the date of any cessation of the activity involving genetic modification to which the notification relates.

(3) The register referred to in paragraph (1) shall also contain—

(a) in relation to each notification submitted under regulation 9(1)—

(i) the information specified in paragraphs (d) to (g), (h)(ii) and (h)(iii) of Schedule 5, and

(ii) if the competent authority has been informed of an accident under regulation 21 at the premises to which the notification relates, confirmation that the information has been received;

(b) in relation to each nofication submitted under regulation 10(1), the information specified in paragraph 1(e) to (l) of Part I of Schedule 6;

(c) in relation to each notification submitted under regulation 11(1)—

(i) the information specified in paragraph 2(e) to (m) of Part II of Schedule 6 and,

(ii) if appropriate, confirmation that a consent under regulation 11(3) or regulation 11(4), as the case may be, has been granted;

(d) in relation to each notification submitted under regulation 12(1), the information specified in paragraph 3(e) to (k) of Part III of Schedule 6,

but the register shall not contain any information which the competent authority has decided shall be kept confidential under regulation 22(2)(b) or shall be withheld under regulation 22(8).

(4) Information shall be entered in the register within 14 days of its receipt by the competent authority, except that, where a notifier has requested that certain information—

(a) be kept confidential in accordance with regulation 22(2); or

(b) be withheld in accordance with regulation 22(8),

that information shall be entered in the register not less than 14 days and not more than 28 days following the day on which the competent authority informed the notifier of its decision not to keep that information confidential or not to withhold that information, as the case may be.

(5) Where a person withdraws a notification under regulation 15(6), information relating to that notification, which has been entered in the register, shall be removed from the register by the competent authority.

(6) The competent authority may remove from the register—

(a) information relating to an activity involving genetic modification ten years after being notified in accordance with regulation 15(2)(d) or (e) that the activity has ceased; and

(b) information relating to premises ten years after being notified in accordance with regulation 15(2)(c) of a decision no longer to use such premises for the purposes of undertaking any activity involving genetic modification.

(7) Copies of the register as regards Great Britain shall be maintained at the offices of the Executive at—

(a) Rose Court, 2 Southwark Bridge, London SE1 9HS; and

(b) Magdalen House, Stanley Precinct, Bootle, Merseyside L20 3QZ.

(8) Copies of that part of the register maintained in accordance with this regulation by the competent authority as regards Scotland and the joint competent authority shall be maintained at the offices of the Executive at Belford House, 59, Belford Road, Edinburgh EH4 3UE.

(9) A copy of that part of the register which relates to—

(a) premises in respect of which a notification has been submitted in accordance with regulation 9(1) situated in an area served by a main office of the Executive; and

(b) an activity involving genetic modification, in respect of which a notification has been submitted in accordance with regulation 10(1), 11(1) or 12(1), undertaken at such premises,

shall be maintained at that main office.

(10) The copies of the register shall be open to inspection by members of the public at any reasonable time.

PART V

MISCELLANEOUS AND GENERAL

Exemption certificates

25.—(1) Subject to paragraph (2), the competent authority may, by a certificate in writing, exempt—

(a) any person or class of persons; or

(b) any genetically modified organism or class of genetically modified organisms,

from all or any of the requirements of, 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 competent authority shall not grant an 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 enactments which apply to the case,

it is satisfied about the matters referred to in paragraph (3).

(3) The matters about which the competent authority shall be satisfied for the purposes of paragraph (2) are—

(a) that the health and safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it; and

(b) that the environment will not be prejudiced in consequence of the exemption where the exemption is concerned with a requirement of, or a prohibition imposed by, these Regulations which relates to an activity involving genetic modification of a micro-organism.

Enforcement and civil liability

26.—(1) Subject to paragraph (2) and to the extent they would not otherwise do so, the provisions of—

(a) sections 16 to 26 (approved codes of practice and enforcement), sections 33 to 42 (provisions as to offences) and section 47 (civil liability) of the 1974 Act; and

(b) the Health and Safety (Training for Employment) Regulations 1990(**9**),

shall apply to these Regulations as if they were health and safety regulations for the purposes of that Act, and any function of the Health and Safety Commission under any other provision of the 1974 Act which is exercisable in relation to any function of the Executive under or in respect of health and safety regulations (including their enforcement) shall be exercisable as if these Regulations were, to the extent they would not otherwise be so, health and safety regulations for the purposes of that Act.

(2) A failure to discharge a duty—

(a) placed on the competent authority or the Executive by these Regulations; or

(b) placed on any other person by Schedule 11,

shall not be an offence, and section 33(1)(c) of the 1974 Act shall have effect accordingly.

(3) Notwithstanding regulation 3 of the Health and Safety (Enforcing Authority) Regulations 1998(**10**), the enforcing authority for these Regulations shall be the Executive.

Fees for notifications and applications

27.—(1) The fee specified in column 2 of the table in Schedule 9 shall be payable by a notifier to the competent authority in relation to any notification or application referred to in the corresponding entry in column 1 of that table.

(2) No fee shall be returned to a notifier where the competent authority returns a notification pursuant to regulation 14(7) or a notifier withdraws his notification pursuant to regulation 15(6).

Transitional provisions

28. Schedule 10 shall have effect.

Appeals

29.—(1) Any person who is aggrieved by a decision of the competent authority—

(**9**) S.I. 1990/1380.
(**10**) S.I. 1998/494.

(a) that he shall not undertake an activity involving genetic modification referred to in regulation 10(1), 11(1) or 12(1);

(b) not to agree pursuant to regulation 18(2) that he need not apply a particular containment measure for the activity involving genetic modification in question;

(c) to revoke an exemption certificate granted to him pursuant to regulation 25(1);

(d) to grant to him an exemption certificate subject to a condition or a limit of time pursuant to regulation 25(1),

may appeal to the appropriate person.

(2) Any person who is aggrieved by—

(a) a request to him made pursuant to regulation 14(2);

(b) an instruction given to him pursuant to regulation 14(3);

(c) a notice given to him pursuant to regulation 15(1),

may appeal to the appropriate person.

(3) Any person who is aggrieved by a decision of the competent authority—

(a) made pursuant to regulation 22(2)(b) or regulation 23(2)(b), not to keep confidential information provided by that person to the competent authority in accordance with these Regulations;

(b) made pursuant to regulation 22(8) or regulation 23(7), not to withhold information,

may appeal to the appropriate person.

(4) The provisions of Schedule 11 shall apply where an aggrieved person appeals to the appropriate person.

(5) Where an appeal is brought under this regulation, none of the following, that is to say—

(a) a decision of the competent authority other than a decision referred to in paragraph (3);

(b) an instruction given pursuant to regulation 14(3);

(c) the operation of paragraphs (2) or (6) of regulation 14;

(d) a notice given pursuant to regulation 15(1),

shall be suspended pending the final determination of the appeal.

(6) Where an appeal is brought under paragraph (3) in respect of any information provided pursuant to regulation 21, pending the final determination of the appeal, the information shall not be disclosed except to the extent necessary to enable the competent authority to comply with its obligations under paragraph (2)(a), (b) and (d) of that regulation.

(7) Where an appeal is brought under paragraph (3) in respect of information provided pursuant to regulations 9 to 15—

(a) pending the final determination of the appeal, the information shall not be disclosed except—

(i) to the extent necessary to evaluate the notification, and

(ii) to the European Commission;

(b) if—

(i) the appeal is finally determined in favour of the competent authority, and

(ii) the information is required to be entered in the register maintained in accordance with regulation 24,

the information shall be entered in that register within fourteen days following the day on which the appeal is finally determined.

(8) In this regulation, "the appropriate person" means—

(a) the Secretary of State, in the case of—

(i) an appeal under paragraph (1), (2)(c) or (3) against a decision of, or a notice given by, the competent authority as regards England and Wales, or

(ii) an appeal under paragraph (2)(a) or (b) against a request or instruction relating to—

(aa) the undertaking or proposed undertaking of an activity involving genetic modification, or

(bb) premises which are the subject of a notification under regulation 9(1) and which are situate,

in England or Wales;

(b) the Secretary of State and the Scottish Ministers, acting jointly, in the case of—

(i) an appeal under paragraph (1), (2)(c) or (3) against a decision of, or a notice given by, the competent authority as regards Scotland or the joint competent authority, or

(ii) an appeal under paragraph 2(a) or (b) against a request or instruction relating to—

(aa) the undertaking or proposed undertaking of an activity involving genetic modification, or

(bb) premises which are the subject of a notification under regulation 9(1) and which are situate,

in Scotland or in both England and Scotland, as the case may be.

Extension outside Great Britain

30. These Regulations shall apply in relation to premises and activities involving genetic modification outside Great Britain to which sections 1 to 59 and 80 to 82 of the 1974 Act apply by virtue of the Health and Safety at Work etc. Act 1974 (Application Outside Great Britain) Order 1995(**11**) as they apply to premises and activities involving genetic modification within Great Britain.

Revocations, amendments and savings

31.—(1) The following are revoked—

(a) the Genetically Modified Organisms (Contained Use) Regulations 1992(**12**);

(b) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996(**13**);

(c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1998(**14**).

(2) In paragraph (3)(h) of regulation 8 of the Genetically Modified Organisms (Deliberate Release) Regulations 1992(**15**), for the words "under regulation 11 of the Genetically Modified Organisms (Contained Use) Regulations 1992", there shall be substituted the words "under regulation 16 of the Genetically Modified Organisms (Contained Use) Regulations 2000".

(3) The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996(**16**) shall be amended as follows—

(**11**) S.I. 1995/263.
(**12**) S.I. 1992/3217.
(**13**) S.I. 1996/967.
(**14**) S.I. 1998/1548.
(**15**) S.I. 1992/3280. Paragraph (3) of regulation 8 was amended by S.I. 1995/304; there are other amendments not relevant to these Regulations.
(**16**) S.I. 1996/1106, to which there are amendments not relevant to these Regulations.

(a) in regulation 1(3), in the definition of "the Contained Use Regulations", for the words "the Genetically Modified Organisms (Contained Use) Regulations 1992", there shall be substituted the words "the Genetically Modified Organisms (Contained Use) Regulations 2000";

(b) in paragraph (2)(b)(i) of regulation 3, for the words "Schedule 1", there shall be substituted the words "Schedule 2"; and

(c) in paragraph (2)(b)(ii) of regulation 3, for the words "regulation 3(3) of, and Part III of Schedule 1" there shall be substituted the words "regulation 3(2) of, and Part III of Schedule 2".

(4) In paragraph 12(5) of Schedule 3 to the Control of Substances Hazardous to Health Regulations 1999(**17**), for the words "Genetically Modified Organisms (Contained Use) Regulations 1992", there shall be substituted the words "Genetically Modified Organisms (Contained Use) Regulations 2000."

(5) In the Health and Safety (Fees) Regulations 2000(**18**), regulation 17 and Schedule 14 shall be omitted.

(6) Every record required to be kept under regulation 7(5) of the Genetically Modified Organisms (Contained Use) Regulations 1992 shall, notwithstanding paragraph (1), be kept in the same manner and for the same period as specified in that regulation as if these Regulations had not been made.

Signed by authority of the Secretary of State

Michael Meacher
Minister of State,
Department of the Environment, Transport and the Regions

17th October 2000

(**17**) S.I. 1999/437.
(**18**) S.I. 2000/2482.