STATUTORY INSTRUMENTS

2000 No. 2831

HEALTH AND SAFETY

The Genetically Modified Organisms(Contained Use) Regulations 2000

Made - - - -	*17th October 2000*
Laid before Parliament	*25th October 2000*
Coming into force - -	*15th November 2000*

The Secretary of State, being the Minister designated(**1**) under section 2(2) of the European Communities Act 1972(**2**) in relation to the control and regulation of genetically modified organisms and in the exercise of the powers conferred on him by the said section 2(2)(**3**) and by sections 15(1), (2), (3)(b) and (c), (4)(a), (5)(b) and (9), 43(2), (4), (5) and (6), 52(2) and (3) and 82(3)(a) of, and paragraphs 1(1)(b) and (c), (2), (4) and (5), 4(1), 5, 6(1), 8(2), 9, 11, 13(1) and (3), 14, 15(1), 16 and 20 of Schedule 3 to, the Health and Safety at Work etc. Act 1974(**4**) ("the 1974 Act") and of all other powers enabling him in that behalf and for the purpose of giving effect without modifications to proposals submitted to him by the Health and Safety Commission under section 11(2)(d) of the 1974 Act after the carrying out by the said Commission of consultations in accordance with section 50(3) of that Act, hereby makes 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 2000 and shall come into force on 15th November 2000.

(**1**) S.I.1991/755.
(**2**) 1972 c. 68; the enabling powers conferred by section 2(2) were extended by virtue of section 1 of the European Economic Area Act 1993 (c. 51).
(**3**) As regards Scotland, see also section 57(1) of the Scotland Act 1998 (c. 46), which provides that, despite the transfer to the Scottish Ministers by virtue of that Act of functions in relation to observing and implementing obligations under Community law, any function of a Minister of the Crown in relation to any matter shall continue to be exerciseable by him as regards Scotland for the purposes specified in section 2(2) of the European Communities Act 1972.
(**4**) 1974 c. 37; sections 11(2), 15(1), 43(6), 50 and 52(3) were amended by section 116 of, and paragraphs 4, 6, 12, 16 and 17 respectively of Schedule 15 to, the Employment Protection Act 1975 (c. 71).

[DETR 1810]

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(**5**) and adopted as respects the United Kingdom by the European Economic Area Act 1993(**6**);

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

"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);

(**5**) Cm 2073 and 2183.
(**6**) 1993 c. 51.

"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(**7**).

(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.

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(**8**), or

(**7**) 1971 c. 80.
(**8**) 1990 c. 43.

(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(**9**) 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(**10**), 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(**11**); 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.

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.

(**9**) 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).
(**10**) 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).
(**11**) 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.

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(**12**)—

(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

(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.

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

(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(**13**),

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.

(**13**) S.I. 1990/1380.

(3) Notwithstanding regulation 3 of the Health and Safety (Enforcing Authority) Regulations 1998(**14**), 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—

(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),

(**14**) S.I. 1998/494.

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(**15**) as they apply to premises and activities involving genetic modification within Great Britain.

(**15**) S.I. 1995/263.

Revocations, amendments and savings

31.—(1) The following are revoked—

(a) the Genetically Modified Organisms (Contained Use) Regulations 1992(**16**);

(b) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996(**17**);

(c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1998(**18**).

(2) In paragraph (3)(h) of regulation 8 of the Genetically Modified Organisms (Deliberate Release) Regulations 1992(**19**), 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(**20**) shall be amended as follows—

(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(**21**), 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(**22**), 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.

(**16**) S.I. 1992/3217.
(**17**) S.I. 1996/967.
(**18**) S.I. 1998/1548.
(**19**) 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.
(**20**) S.I. 1996/1106, to which there are amendments not relevant to these Regulations.
(**21**) S.I. 1999/437.
(**22**) S.I. 2000/2482.

Signed by authority of the Secretary of State

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

17th October 2000

SCHEDULE 1

Regulation 2(1)

CLASSES OF ACTIVITY INVOLVING GENETIC MODIFICATION

Class	*Description*
1	Activities of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment.
2	Activities of low risk, for which containment level 2 is appropriate to protect human health and the environment.
3	Activities of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.
4	Activities of high risk, for which containment level 4 is appropriate to protect human health and the environment.

SCHEDULE 2

Regulations 2(1) and 3(2)

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

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

(c) cell 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 provided that they do not involve the use of genetically modified organisms made by techniques other than those listed in Part III or the use of recombinant nucleic acid molecules, namely—

(a) in vitro fertilisation;

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

(c) polyploidy induction.

PART III

TECHNIQUES TO WHICH THESE REGULATIONS DO NOT APPLY

3. These Regulations (except regulation 17) shall not apply to the following techniques of genetic modification, provided that they do not involve the use of recombinant nucleic acid molecules or of genetically modified organisms other than those recombinant nucleic acid molecules or genetically modified organisms produced by one or more of the following techniques of genetic modification—

(a) mutagenesis;

(b) cell fusion (including protoplast fusion) of prokaryotic species which can exchange genetic material through homologous recombination;

(c) cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions;

(d) self-cloning, where the resulting organism is unlikely to cause disease or harm to humans, animals or plants.

4. In paragraph 3—

(a) "self-cloning" means the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent), whether or not altered by enzymic or mechanical processes, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by homologous recombination; and

(b) self-cloning may include the use of recombinant vectors, with an extended history of safe use in the particular organism, to manipulate and reinsert the nucleic acid sequences, but the vectors shall not consist of any genetic elements other than those designed for vector structure, vector replication, vector maintenance or marker genes.

SCHEDULE 3

Regulations 2(2), 3(5) and 6(2)

PART I

MATTERS TO BE TAKEN INTO ACCOUNT IN CARRYING OUT ANASSESSMENT FOR THE PURPOSES OF REGULATION 6

1. The following matters shall be taken into account in carrying out an assessment for the purposes of regulation 6—

(a) any potentially harmful effects, in particular those associated with—

(i) the recipient micro-organism,

(ii) the inserted genetic material (originating from the donor organism),

(iii) the vector,

(iv) the donor micro-organism (where that donor micro-organism is used during the activity involving genetic modification), and

(v) the resulting genetically modified micro-organism;

(b) the characteristics of the activity;

(c) the severity of the potentially harmful effects; and

(d) the likelihood of the potentially harmful effects being realised.

2. In paragraph 1, "potentially harmful effects" includes—

(a) disease to humans including allergenic or toxic effects;

(b) disease to animals or plants;

(c) adverse effects resulting from the inability to treat disease or offer an effective prophylaxis;

(d) adverse effects resulting from establishment or dissemination of the genetically modified micro-organisms in the environment;

(e) adverse effects resulting from the natural transfer of genetic material to or from other organisms;

(f) adverse effects resulting from the likely interaction of the genetically modified micro-organism with other organisms at the premises where the activity involving genetic modification is to be conducted.

PART II

STEPS TO BE INCLUDED WHEN CARRYING OUT AN ASSESSMENT FOR THE PURPOSES OF REGULATION 6

3. An assessment carried out for the purposes of regulation 6 shall include—

(a) identification of any harmful properties of the recipient and, where appropriate, the donor micro-organism;

(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties;

(c) consideration of relevant Community legislation, including Council Directive 90/679/EEC(**23**) on the protection of workers from risks related to exposure to biological agents at work, other classification schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modifed micro-organisms;

(d) identification of the provisional level of risk associated with the genetically modified micro-organism;

(e) consideration of—

(i) the characteristics of the environment likely to be exposed,

(ii) the characteristics of the activity involving genetic modification of micro-organisms, and

(iii) any activities involving genetic modification of micro-organisms which cannot be adequately controlled by standard laboratory procedures, and which present risks which require controls for each individual case;

(f) adjustment of the provisional level of risk in the light of the matters referred to in sub-paragraph (e) above;

(**23**) OJ No. L 374, 31.12.90, p. 1, as amended by Council Directive 93/88/EEC (OJ No. L 268, 29.10.93, p. 71), Commission Directive 95/30/EC (OJ No. L 155, 6.7.95, p. 41), Commission Directive 97/59/EC (OJ No. L 282, 15.10.1997, p. 33) and Commission Directive 97/65/EC (OJ No. L 335, 6.12.1997, p. 17).

(g) selection of the appropriate containment measures from those specified in the applicable Table in Schedule 8 on the basis of the provisional level of risk as adjusted in accordance with sub-paragraph (f) above;

(h) assignment of the activity involving genetic modification of micro-organisms to the appropriate containment level, in accordance with paragraph 4;

(i) classification of that activity in the class of the same number as that of the appropriate containment level; and

(j) review and reconsideration of that classification in the light of the completed assessment.

4. To assign an activity involving genetic modification of micro-organisms to the appropriate containment level for the purposes of paragraph 3(h), the person carrying out the assessment for the purposes of regulation 6 shall—

(a) first identify for each selected containment measure the column in the applicable Table in Schedule 8 having the lowest number in which that selected containment measure is shown as being required, regardless of whether or not such requirement is subject to any qualification;

(b) then select the highest number of all the columns identified in accordance with sub-paragraph (a) above; and

(c) then assign the activity involving genetic modification in question to the containment level of that highest number.

5. In paragraph 4, "selected containment measure" means an appropriate containment measure selected in accordance with paragraph 3(g).

SCHEDULE 4

Regulation 7(2)

PART I

MATTERS TO BE TAKEN INTO ACCOUNT IN CARRYING OUT AN ASSESSMENT FOR THE PURPOSES OF REGULATION 7

1. The following matters shall be taken into account in carrying out an assessment for the purposes of regulation 7—

(a) the identification of any potentially harmful effects, in particular those associated with—

(i) the recipient organism,

(ii) the inserted genetic material (originating from the donor organism),

(iii) the vector,

(iv) the donor organism, and

(v) the resulting genetically modified organism;

(b) the characteristics of the activity involving genetic modification;

(c) the severity of the potentially harmful effects; and

(d) the likelihood of the potentially harmful effects being realised.

2. In paragraph 1, "potentially harmful effects" includes—

(a) disease to humans including allergenic or toxic effects;

(b) acting as a human disease vector or reservoir;

(c) adverse effects to humans arising from change in behaviour or in physical nature;

(d) adverse effects arising from the inability to treat human disease or offer effective prophylaxis.

PART II

STEPS TO BE INCLUDED WHEN CARRYING OUT AN ASSESSMENT FOR THE PURPOSES OF REGULATION 7

3. An assessment carried out for the purposes of regulation 7 shall include—

(a) identification of the harmful properties of the recipient and, where appropriate, the donor organism;

(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the existing properties of the recipient;

(c) identification of the provisional level of risk associated with the genetically modified organisms;

(d) selection of containment and other protective measures on the basis of—

(i) the provisional level of risk, and

(ii) the characteristics of the activity involving genetic modification;

(e) adjustment of the level of risk in the light of the matters referred to in sub-paragraph (d) above; and

(f) review and reconsideration of the containment and other protective measures in the light of the steps required by sub-paragraphs (a) to (e) above.

SCHEDULE 5

Regulations 9(1), 15(2) and 24(3)

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 9(1)

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

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

(b) the name of the employee of the notifier with specific responsibility for the supervision and safety of activities involving genetic modification;

(c) information on the training and qualifications of that employee;

(d) details of the genetic modification safety committee established pursuant to regulation 16;

(e) the address of the premises where the activity involving genetic modification is to be carried out and a general description of the premises;

(f) the nature of the work to be undertaken;

(g) the class of any activity involving genetic modification of micro-organisms;

(h) where the first activity to be carried out in those premises is an activity involving genetic modification in class 1—

(i) a summary of the assessment of that activity made for the purposes of regulation 6(1),

(ii) any advice received in relation to that assessment from the genetic modification safety committee established pursuant to regulation 16,

(iii) information on waste management, and

(iv) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the emergency plan and of any relevant revisions made in pursuance of regulation 20(3); and

(i) where the first activity to be carried out in those premises involves genetic modification of organisms which are not micro-organisms and that activity is not notifiable under regulation 12(1)—

(i) a copy of the assessment made for the purposes of regulation 7(1), and

(ii) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the plan and of any relevant revisions made in pursuance of regulation 20(3).

SCHEDULE 6 Regulations 10(1), 11(1), 12(1),15(2) and 24(3)

PART I

INFORMATION REQUIRED FOR A NOTIFICATION UNDERREGULATION 10(1)

1. A notification required for the purposes of regulation 10(1) shall contain the following information—

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

(b) the centre number allocated by the competent authority in respect of the premises at which the activity involving genetic modification of micro-organisms is to be undertaken and the date of the notification required by regulation 9(1) relating to those premises;

(c) the name of the employee of the notifier with specific responsibility for supervision and safety;

(d) information on the training and qualifications of that employee;

(e) the recipient or parental micro-organism to be used;

(f) the donor micro-organism to be used;

(g) where applicable, the host-vector system to be used;

(h) the source and intended function of the genetic material involved in the modification;

(i) the identity and characteristics of the genetically modified micro-organism;

(j) the purpose of the activity involving genetic modification of micro-organisms, including its expected results;

(k) the approximate culture volumes to be used;

(l) a description of the containment and other protective measures to be applied, including—

(i) information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination, and

(ii) justification for not applying any containment measure at containment level 2;

(m) a copy of the assessment carried out pursuant to regulation 6(1);

(n) any advice received in relation to that assessment from the genetic modification safety committee established pursuant to regulation 16;

(o) the information necessary for the competent authority to evaluate any emergency plan; and

(p) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the plan and of any relevant revisions made in pursuance of regulation 20(3).

PART II

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 11(1)

2. A notification required for the purposes of regulation 11(1) shall contain the following information—

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

(b) the centre number allocated by the competent authority in respect of the premises at which the activity involving genetic modification of micro-organisms is to be undertaken and the date of the notification required by regulation 9(1) relating to those premises;

(c) the name of the employee of the notifier with specific responsibility for supervision and safety;

(d) information on the training and qualifications of that employee;

(e) the recipient or parental micro-organism to be used;

(f) the donor micro-organism to be used;

(g) where applicable, the host-vector system to be used;

(h) the source and intended function of the genetic material involved in the modification;

(i) the identity and characteristics of the genetically modified micro-organism;

(j) the culture volumes to be used;

(k) a description of the containment and other protective measures to be applied, including—

(i) information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination,

(ii) in the case of activities involving genetic modification of micro-organisms in class 3, justification for not applying any containment measure at containment level 3, and

(iii) in the case of activities involving genetic modification of micro-organisms in class 4, justification for not applying any containment measure at containment level 4;

(l) the purpose of the activity involving genetic modification of micro-organisms, including its expected results;

(m) a description of the parts of the installation;

(n) information on any accident prevention and emergency plans, including—

(i) any specific hazards arising from the location of the installation,

(ii) the preventive measures applied, including safety equipment, alarm systems and containment methods,

(iii) procedures and plans for verifying the continuing effectiveness of the containment measures,

(iv) a description of the information provided to workers,

(v) the information necessary for the competent authority to evaluate any emergency plan, and

(vi) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the plan and of any relevant revisions made in pursuance of regulation 20(3); and

(o) a copy of the assessment referred to in regulation 6(1).

PART III

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 12(1)

3. A notification required for the purposes of regulation 12(1) shall contain the following information—

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

(b) the centre number allocated by the competent authority in respect of the premises at which the activity involving genetic modification of organisms other than micro-organisms is to be undertaken and the date of the notification required by regulation 9(1) relating to those premises;

(c) the name of the employee of the notifier with specific responsibility for supervision and safety;

(d) information on the training and qualifications of that employee;

(e) the recipient or parental organism to be used;

(f) the donor organism to be used;

(g) where applicable, the host-vector system to be used;

(h) the sources and intended functions of the genetic material involved in the modification;

(i) the identity and characteristics of the genetically modified organism;

(j) the purpose of the activity involving genetic modification of organisms other than micro-organisms, including its expected results;

(k) a description of the containment and other protective measures to be applied, including information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination;

(l) a copy of the assessment referred to in regulation 7(1);

(m) the information necessary for the competent authority to evaluate any emergency plan; and

(n) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of that plan and of any relevant revisions made in pursuance of regulation 20(3).

SCHEDULE 7

Regulation 17(2) and (3)

GENERAL PRINCIPLES OF GOOD MICROBIOLOGICAL PRACTICE AND OF GOOD OCCUPATIONAL SAFETY AND HYGIENE

The general principles of good microbiological practice and of good occupational safety and hygiene are as follows—

(a) keeping workplace and environmental exposure to any genetically modified micro-organism to the lowest reasonably practicable level;

(b) exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment where necessary;

(c) testing adequately and maintaining control measures and equipment;

(d) testing, where necessary, for the presence of viable process organisms outside the primary physical containment;

(e) providing appropriate training of personnel;

(f) formulating and implementing local codes of practice for the safety of personnel, as required;

(g) displaying biohazard signs where appropriate;

(h) providing washing and decontamination facilities for personnel;

(i) keeping adequate records;

(j) prohibiting in the work area eating, drinking, smoking, applying cosmetics or the storing of food for human consumption;

(k) prohibiting mouth pipetting;

(l) providing written standard operating procedures where appropriate to ensure safety;

(m) having effective disinfectants and specified disinfection procedures available in case of spillage of genetically modified micro-organisms; and

(n) providing safe storage for contaminated laboratory equipment and materials where appropriate.

SCHEDULE 8

Regulations 2(3) and 18(1)

CONTAINMENT MEASURES

PART I

1. In this Schedule—

"GMMs" means genetically modified micro-organisms;

"HEPA" means High Efficiency Particulate Air;

"inactivation" means the complete or partial destruction of GMMs so as to ensure that any contact between the GMMs and humans or the environment is limited to an extent commensurate with the risks identified in the risk assessment and to provide a high level of protection for humans and the environment;

"plant growth facilities" means a structure, whether permanent or impermanent, designed and used principally for growing plants in a controlled and protected environment; and

"risk assessment" means the assessment carried out in accordance with regulation 6.

2. For the purposes of this Schedule, where, in the final column of Table 1b or 1c, a measure is specified as—

(a) a modification, it shall be read in substitution for the relevant measure in Table 1a;

(b) additional, it shall be read as an addition to the measures in Table 1a, subject to the substitution, where appropriate, of an individual measure in Table 1a by a measure specified as a modification in the Table in question.

3. For the purposes of this Schedule—

(a) Table 1a describes containment measures applicable to activities involving genetic modification of micro-organisms in laboratories;

(b) Table 1a, read with Table 1b, describes containment measures applicable to activities involving genetic modification of micro-organisms in plant growth facilities;

(c) Table 1a, read with Table 1c, describes containment measures applicable to activities involving genetic modification of micro-organisms in animal units;

(d) Table 2 describes containment measures applicable to activities involving genetic modification of micro-organisms in premises other than those referred to in Tables 1a, 1b and 1c.

PART II

Table 1a:

Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Laboratories

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
1	Laboratory suite: isolation **(Note 1)**	not required	not required	required	required
2	Laboratory: sealable for fumigation	not required	not required	required	required
	Equipment				

NOTES

1. In the Table above, "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.
2. Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.
3. Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.
4. Where the autoclave is outside the laboratory in which the activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
3	Surfaces impervious to water, resistant to acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean	required for bench	required for bench	required for bench and floor	required for bench, floor ceiling and walls
4	Entry to lab via airlock **(Note 2)**	not required	not required	required where and to extent the risk assessment shows it is required	required
5	Negative pressure relative to the pressure of the immediate surroundings	not required	required where and to extent the risk assessment shows it is required	required	required
6	Extract and input air from the laboratory shall be HEPA filtered	not required	not required	HEPA filters required for extract air	HEPA filters required for input and extract air **(Note 3)**
7	Microbiological safety cabinet/ enclosure	not required	required where and to extent the risk assessment shows it is required	required, and all procedures with infective materials required to be contained within a cabinet/ enclosure	Class III cabinet required

NOTES

1. In the Table above, “isolation” means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.
2. Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.
3. Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.
4. Where the autoclave is outside the laboratory in which the activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
8	Autoclave	required on site	required in the building	required in the laboratory suite **(Note 4)**	double ended autoclave required in laboratory
	System of work				
9	Access restricted to authorised personnel only	not required	required	required	required (via airlock key procedure)
10	Specific measures to control aerosol dissemination	not required	required so as to minimise	required so as to prevent	required so as to prevent
11	Shower	not required	not required	required where and to extent the risk assessment shows it is required	required
12	Protective clothing	suitable protective clothing required	suitable protective clothing required	suitable protective clothing required; footwear required where and to extent the risk assessment shows it is required	complete change of clothing and footwear required before entry and exit
13	Gloves	not required	required where and to extent the risk assessment shows they are required	required	required

NOTES

1. In the Table above, "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.
2. Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.
3. Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.
4. Where the autoclave is outside the laboratory in which the activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
14	Efficient control of disease vectors (eg rodents and insects) which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required	required	required
15	Specified disinfection procedures in place	required where and to extent the risk assessment shows they are required	required	required	required
	Waste				
16	Inactivation of GMMs in effluent from handwashing sinks and showers and similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
17	Inactivation of GMMs in contaminated material and waste	required by validated means	required by validated means	required by validated means	required by validated means
	Other measures				
18	Laboratory to contain its own equipment	not required	not required	required, so far as is reasonably practicable	required
19	An observation window or	required where and to extent the risk	required where and to extent the risk	required	required

NOTES

1. In the Table above, “isolation” means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.
2. Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.
3. Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.
4. Where the autoclave is outside the laboratory in which the activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	alternative is to be present so that occupants can be seen	assessment shows it is required	assessment shows it is required		
20	Safe storage of GMMs	required where and to extent the risk assessment shows it is required	required	required	secure storage required
21	Written records of staff training	not required	required where and to extent the risk assessment shows they are required	required	required

NOTES
1. In the Table above, "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.
2. Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.
3. Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.
4. Where the autoclave is outside the laboratory in which the activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

Table 1b:

Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Plant Growth Facilities (to be read with Table 1a as indicated in paragraph 3)

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
	Building					
1	Permanent structure **(Note 1)**	required where and to extent the risk assessment	required	required	required	Modification

NOTE
1. A permanent structure refers to a fixed structure with walls, a roof and a floor. Where the permanent structure is a greenhouse, that structure shall also have a continuous waterproof covering and self-closing lockable outer doors, and be located on a site designed to prevent the entry of surface run-off water.

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
		shows it is required				
	Equipment					
2	Entry via a separate room with two interlocking doors	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required (via airlock key procedure)	Additional
3	Control of contaminated run-off water	required where and to extent the risk assessment shows it is required	required so as to prevent run-off	required so as to prevent run-off	required so as to prevent run-off	Additional
	System of work					
4	Effective control of disease vectors such as insects, rodents and arthropods which could disseminate GMMs	required	required	required	required	Additional
5	Effective control of pollen, seeds and other plant material which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required so as to minimise dissemination	required so as to prevent dissemination	required so as to prevent dissemination	Additional
6	Procedures for transfer of living material between the plant	required so as to minimise dissemination	required so as to prevent dissemination	required so as to prevent dissemination	required so as to prevent dissemination	Additional

NOTE

1. A permanent structure refers to a fixed structure with walls, a roof and a floor. Where the permanent structure is a greenhouse, that structure shall also have a continuous waterproof covering and self-closing lockable outer doors, and be located on a site designed to prevent the entry of surface run-off water.

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
	growth facilities, protective structure and laboratory shall control dissemination of GMMs					

NOTE
1. A permanent structure refers to a fixed structure with walls, a roof and a floor. Where the permanent structure is a greenhouse, that structure shall also have a continuous waterproof covering and self-closing lockable outer doors, and be located on a site designed to prevent the entry of surface run-off water.

Table 1c:

Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Animal Units (to be read with Table 1a as indicated in paragraph 3)

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
	Facilities					
1	Isolation of animal unit **(Note 1)**	required where and to extent the risk assessment shows it is required	required	required	required	Modification
2	Animal facilities **(Note 2)** separated by lockable doors	required where and to extent the risk assessment shows they are required	required	required	required	Additional
3	Animal facilities (cages, etc)	required where and to extent	required where and to extent	required	required	Additional

NOTES
1. In the Table above, “animal unit” means a building, or separate area within a building, containing an animal facility and other areas including changing rooms, showers, autoclaves and food storage areas.
2. In the Table above and in Note 1 above, “animal facility” means a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures on animals.
3. In the Table above, “isolators” means transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
	designed to facilitate decontamination (waterproof and easily washable material)	the risk assessment shows they are required	the risk assesment shows they are required			
4	Floor, walls and ceiling easily washable	required where and to extent the risk assessment shows they are required	required for floor	required for floor and walls	required for floor, walls and ceiling	Modification
5	Appropriate filters on isolators or isolated rooms **(Note 3)**	not required	required where and to extent the risk assessment shows they are required	required	required	Additional
6	Incinerator for disposal of animal carcasses	required to be accessible	required to be accessible	required to be accessible	required to be on site	Additional
7	Appropriate barriers at the room exit, and at drains or ventilation duct work	required	required	required	required	Additional
8	Animals kept in appropriate containment facilities, such as cages, pens,	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	Additional

NOTES

1. In the Table above, “animal unit” means a building, or separate area within a building, containing an animal facility and other areas including changing rooms, showers, autoclaves and food storage areas.
2. In the Table above and in Note 1 above, “animal facility” means a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures on animals.
3. In the Table above, “isolators” means transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

	Containment Measures	*Containment Levels*				*Additional/ modification*
		1	*2*	*3*	*4*	
	tanks or isolators					

NOTES
1. In the Table above, "animal unit" means a building, or separate area within a building, containing an animal facility and other areas including changing rooms, showers, autoclaves and food storage areas.
2. In the Table above and in Note 1 above, "animal facility" means a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures on animals.
3. In the Table above, "isolators" means transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

Table 2:

Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Premises other than those referred to in Tables 1a, 1b and 1c

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	General				
1	Viable micro-organisms shall be contained in a system which separates the process from the workplace and wider environment (closed system)	required where and to extent the risk assessment shows it is required	required	required	required
2	Closed systems located within a controlled area	not required	required where and to extent the risk assessment shows they are required	required	required and required to be purpose built
3	Control of exhaust gases from the closed system	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
4	Control of aerosols during sample collection, addition of material to a	required where and to extent the risk assessment shows it is required	required so as to minimise release	required so as to prevent release	required so as to prevent release

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	closed system or transfer of material to another closed system				
5	Inactivation of bulk culture fluids before removal from the closed system	required where and to extent the risk assessment shows it is required	required by validated means	required by validated means	required by validated means
6	Seals shall be designed so as to minimise or prevent release	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
7	The controlled area designed to contain spillage of the entire contents of the closed system	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required	required
8	The controlled area sealable to permit fumigation	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required
9	Biohazard signs posted	required where and to extent the risk assessment shows it is required	required	required	required
	Equipment				
10	Entry via airlock	not required	not required	required where and to extent the risk assessment shows it is required	required
11	Surfaces resistant to water, acids, alkalis, solvents,	required for any bench	required for any bench	required for floor and any bench	required for bench, floor, ceiling and walls

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
	disinfectants and decontamination agents and easy to clean				
12	Specific measures to adequately ventilate the controlled areas in order to minimise air contamination	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required
13	The controlled area maintained at an air pressure negative to the immediate surroundings	not required	not required	required where and to extent the risk assessment shows it is required	required
14	Extract and input air from the controlled area shall be HEPA filtered	not required	not required	required for extract air, optional for input air	required for input and extract air
	System of work				
15	Access restricted to authorised personnel only	not required	required	required	required
16	Decontamination and washing facilities provided for personnel	required	required	required	required
17	Personnel shall shower before leaving the controlled area	not required	not required	required where and to extent the risk assessment shows it is required	required
18	Personnel shall wear protective clothing	work clothing required	work clothing required	required	complete change required

	Containment Measures	*Containment Levels*			
		1	*2*	*3*	*4*
					before exit and entry
19	Written procedures and records of staff training	not required	not required	required	required
	Waste				
20	Inactivation of GMMs in effluent from handwashing sinks and showers or similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
21	Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	required by validated means	required by validated means	required by validated means	required by validated means

SCHEDULE 9

Regulation 27(1)

FEES FOR NOTIFICATIONS AND APPLICATIONS

Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1).	£200
Notification of an activity involving genetic modification in class 2 under regulation 10(1), except a notification to which paragraph 4(1) or paragraph 5(1) of Schedule 10 applies.	£400
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification in class 2 under regulation 10(1).	£400

Notification of an activity involving genetic modification in class 3 under regulation 11(1), except a notification to which paragraph 4(2) or paragraph 5(2) of Schedule 10 applies.	£430
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification in class 3 under regulation 11(1).	£430
Notification of an activity involving genetic modification in class 4 under regulation 11(1), except a notification to which paragraph 4(2) or paragraph 5(2) of Schedule 10 applies.	£500
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification in class 4 under regulation 11(1).	£500
Notification of an activity involving genetic modification of organisms other than micro-organisms under regulation 12(1).	£400
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification of organisms other than micro-organisms under regulation 12(1).	£400
Notification of additional information under regulation 15(3).	£300
Application for the written agreement of the competent authority under regulation 18(2) where the application is made after a notification has been submitted pursuant to regulation 9(1), 10(1), 11(1) or 12(1).	£300

SCHEDULE 10

Regulation 28

TRANSITIONAL PROVISIONS

Interpretation

1. In this Schedule—

(a) "the 1992 Regulations" means the Genetically Modified Organisms (Contained Use) Regulations 1992(**24**);

(b) "the relevant date" means the date on which these Regulations come into force; and

(c) a reference to a numbered sub-paragraph is a reference to the sub-paragraph so numbered in the paragraph in which that reference occurs.

Risk assessment

2.—(1) Where a person undertakes an activity involving genetic modification of micro-organisms which he commenced before the relevant date, he shall ensure that an assessment is carried out in accordance with regulation 6 as if the date of the commencement of that activity were 15th December 2000.

(2) Where a person undertakes an activity involving genetic modification of organisms other than micro-organisms which he commenced before the relevant date, he shall ensure that an assessment is carried out in accordance with regulation 7 as if the date of the commencement of that activity were 15th December 2000.

Notification of premises

3. Where before the relevant date a person had notified the Executive in accordance with regulation 8(1) of the 1992 Regulations of his intention to undertake an activity involving genetic modification at premises for the first time, the requirements of regulation 9 shall be deemed to be satisfied, provided that, before 15th February 2001, that person submits to the competent authority a notification containing—

(a) the information specified in paragraph (g) of Schedule 5; and

(b) the information specified in paragraph (h)(iii) and (iv) of Schedule 5 where the activity involving genetic modification is a class 1 activity to be undertaken on or after 15th February 2001 at the premises referred to in the notification submitted pursuant to regulation 8(1) of the 1992 Regulations.

Notification of activities involving genetic modification

4.—(1) Where a person had notified the Executive of his intention to undertake an activity involving genetic modification of micro-organisms in accordance with regulation 9(1) of the 1992 Regulations and immediately before the relevant date that person was entitled under the 1992 Regulations to undertake that activity, and where that activity involving genetic modification of micro-organisms is in class 2, the requirements of regulation 10 shall be deemed to be satisfied in relation to that activity, provided that before 15th February 2001 that person submits to the competent authority a notification containing—

(a) in the case of an activity referred to in regulation 9(2)(a) of the 1992 Regulations, the information specified in Part I of Schedule 6;

(b) in the case of an activity referred to in regulation 9(3) or regulation 9(4)(a) of the 1992 Regulations, the information specified in paragraphs (c), (d), (l), (m), (o) and (p) of Part I of Schedule 6; and

(c) in the case of an activity referred to in regulation 9(5) of the 1992 Regulations, the information specified in paragraphs (c), (d), (l)(ii) and (p) of Part I of Schedule 6.

(2) Where a person had notified the Executive of his intention to undertake an activity involving genetic modification of micro-organisms in accordance with regulation 9(1) of the 1992 Regulations

(**24**) S.I. 1992/3217, as amended by S.I. 1996/967, 1998/1548.

and immediately before the relevant date that person was entitled under the 1992 Regulations to undertake that activity, and where that activity involving genetic modification of micro-organisms is in class 3 or class 4, the requirements of regulation 11 shall be deemed to be satisfied in relation to that activity, provided that—

(a) before 15th January 2001, that person submits to the competent authority a notification containing the information specified in Part II of Schedule 6; and

(b) before 15th February 2001, the competent authority gives its consent in writing to continue to undertake the activity involving genetic modification of micro-organisms in question.

(3) Where a person had notified the Executive of his intention to undertake an activity involving the genetic modification of organisms other than micro-organisms in accordance with regulation 9(1) of the 1992 Regulations and immediately before the relevant date that person was entitled under the 1992 Regulations to undertake that activity, the requirements of regulation 12 shall be deemed to be satisfied.

(4) Where a person submits a notification in accordance with this paragraph, he shall at the same time provide the competent authority with a short description of the activity involving genetic modification to which the notification relates.

Notification of proposed activities involving genetic modification

5.—(1) Where a person had notified the Executive of his intention to undertake an activity involving genetic modification of micro-organisms in accordance with regulation 9(1) of the 1992 Regulations but immediately before the relevant date that person was not entitled under the 1992 Regulations to undertake that activity for any reason other than the reason mentioned in sub-paragraph (4), and where that activity involving genetic modification of micro-organisms is in class 2, that person may submit to the competent authority a notification containing—

(a) in the case of an activity referred to in regulation 9(2)(a) of the 1992 Regulations, the information specified in Part I of Schedule 6;

(b) in the case of an activity referred to in regulation 9(3) or regulation 9(4)(a) of the 1992 Regulations, the information specified in paragraphs (c), (d), (l), (m), (o) and (p) of Part I of Schedule 6; and

(c) in the case of an activity referred to in regulation 9(5) of the 1992 Regulations, the information specified in paragraphs (c), (d), (l)(ii) and (p) of Part I of Schedule 6,

in which case the provisions of these Regulations shall apply as if that person had submitted a notification pursuant to regulation 10(1) on the date he submitted the notification pursuant to this sub-paragraph, save that regulation 24 shall apply as modified in accordance with paragraph 10.

(2) Where a person had notified the Executive of his intention to undertake an activity involving genetic modification of micro-organisms in accordance with regulation 9(1) of the 1992 Regulations but immediately before the relevant date that person was not entitled under the 1992 Regulations to undertake that activity for any reason other than the reason mentioned in sub-paragraph (4), and where that activity involving genetic modification of micro-organisms is in class 3 or class 4, that person may submit a notification containing the information specified in Part II of Schedule 6, in which case the provisions of these Regulations shall apply as if that person had submitted a notification pursuant to regulation 11(1) on the date he submitted the notification pursuant to this sub-paragraph, save that regulation 24 shall apply as modified in accordance with paragraph 10.

(3) Where a person had notified the Executive of his intention to undertake an activity involving the genetic modification of organisms other than micro-organisms in accordance with regulation 9(1) of the 1992 Regulations but immediately before the relevant date that person was not entitled under the 1992 Regulations to undertake that activity for any reason other than the reason referred to in sub-paragraph (4), the provisions of these Regulations shall apply as if that person had submitted a

notification in accordance with regulation 12 on the relevant date, save that regulation 24 shall apply as modified in accordance with paragraph 10.

(4) The reason referred to in sub-paragraphs (1), (2) and (3) is that the Executive has informed the person who submitted the notification in question that he may not commence the activity involving genetic modification to which the notification relates.

(5) Where a person submits a notification in accordance with this paragraph, he shall at the same time provide the competent authority with a short description of the activity involving genetic modification to which the notification relates.

Duties on receiving notifications and additional information

6. Regulation 14(1) to (5) shall apply to a notification submitted pursuant to the 1992 Regulations which, by virtue of paragraph 4 of this Schedule, is treated as satisfying the requirements of these Regulations as it applies to a notification submitted pursuant to these Regulations.

Additional provisions relating to notification

7. Regulation 15 shall apply in cases where a notification has been submitted pursuant to regulation 8 or 9 of the 1992 Regulations as it applies where a notification has been submitted pursuant to these Regulations.

Emergency Plans

8. Where before the relevant date a person had ensured that a plan had been prepared in accordance with regulation 13 of the 1992 Regulations, that plan shall be treated as satisfying the requirements of regulation 20, provided that, immediately following the assessment to be carried out in accordance with paragraph 2, the plan is reviewed and, where necessary, revised pursuant to regulation 20(3).

Disclosure of information

9. Regulations 22 and 23 shall apply to information notified or provided under the 1992 Regulations as they apply to information provided under these Regulations.

Register of notifications

10.—(1) Subject to sub-paragraph (2), regulation 24 shall apply to a notification submitted in accordance with paragraphs 3, 4 and 5 as it applies to a notification submitted in accordance with regulations 9(1), 10(1), 11(1) and 12(1).

(2) Paragraphs (2), (3) and (4) of regulation 24 shall not apply to a notification submitted in accordance with paragraphs 3, 4 and 5 and shall be replaced by the following provisions, namely—

(a) in relation to a notification submitted in accordance with paragraph 3, the register shall contain the name and address of the person who submitted that notification, and the reference number given by the Executive to the notification under the 1992 Regulations of the premises in question;

(b) in relation to a notification submitted in accordance with paragraph 4, the register shall contain—

(i) the name and address of the person who submitted that notification,

(ii) a short description of the activity involving genetic modification to which the notification relates, and any reference number given by the Executive to the notification of that activity under the 1992 Regulations,

(iii) the date on which any information had been notified under regulation 10(4) of the 1992 Regulations, and

(iv) where appropriate, confirmation that a consent has been granted under paragraph 4(2)(b); and

(c) in relation to a notification submitted in accordance with paragraph 5, the register shall contain—

(i) the name and address of the person who submitted that notification,

(ii) a short description of the activity involving genetic modification to which the notification relates, and any reference number given by the Executive to the notification of that activity under the 1992 Regulations,

(iii) the date on which any information had been notified under regulation 10(4) of the 1992 Regulations, and

(iv) where appropriate, confirmation that a consent has been granted under regulation 11(3) or 11(4).

(3) The competent authority shall include in the register—

(a) by 15th March 2001, the information referred to in sub-paragraph (2)(a);

(b) by 15th April 2001, the information referred to in sub-paragraph (2)(b); and

(c) within fourteen days of the receipt of a notification submitted under paragraph 5, the information referred to in sub-paragraph 2(c).

Reference to previous notification

11. Where a person submits a notification in accordance with paragraph 3, 4 or 5, he shall at the same time provide the competent authority with the following information—

(a) his name, address and telephone number and any fax number and any e-mail address; and either

(b) in the case of a notification submitted in accordance with paragraph 3—

(i) the date of,

(ii) any reference number given by the Executive to, and

(iii) the date of any information notified to the Executive under regulation 10 of the 1992 Regulations relating to,

the notification in question submitted under regulation 8(1) of the 1992 Regulations; or

(c) in the case of a notification submitted in accordance with paragraph 4 or 5—

(i) the date of,

(ii) any reference number given by the Executive to, and

(iii) the date of any information notified to the Executive under regulation 10 of the 1992 Regulations relating to,

the notification in question submitted under regulation 9(1) of the 1992 Regulations.

SCHEDULE 11 Regulation 29

APPEALS

PART I

1. In this Schedule—

(a) "appeal" means an appeal under regulation 29;

"appellant" means a person who has brought an appeal;

"appointed person" means a person appointed in accordance with paragraph 2;

"appropriate person" has the same meaning as in regulation 29;

"authority" means the competent authority in the case of an appeal under regulation 29(1), (2)(c) or (3) and the Executive in the case of an appeal under regulation 29(2)(a) or (b);

"hearing" means a hearing to which Part II of this Schedule applies;

"the parties" means the appellant and the authority;

"site" means premises at which the activity involving genetic modification to which the appeal relates is, or is proposed to be, undertaken; and

(b) a reference to a numbered sub-paragraph is a reference to the sub-paragraph so numbered in the paragraph in which that reference occurs.

2. The appropriate person shall direct that an appeal shall be determined by a person appointed by him for the purpose and the appropriate person shall notify the parties in writing of the name of the appointed person.

3. Before the determination of an appeal, the appointed person shall ask the parties whether they wish to appear and be heard on the appeal and—

(a) the appeal may be determined without a hearing of the parties if both of them express a wish not to be heard as aforesaid;

(b) the appointed person shall, if either of the parties expresses a wish to appear and be heard, afford both of them an opportunity of so doing, in which case the provisions of Part II of this Schedule shall apply.

4. An appointed person may give such directions as he thinks appropriate to give effect to his determination.

5. The appropriate person may pay to an appointed person such remuneration and allowances as the appropriate person may, with the approval of the Minister for the Civil Service, determine.

PART II

6. An appeal brought pursuant to regulation 29(3) shall be heard in private.

7.—(1) Subject to the following sub-paragraphs of this paragraph, a date, time and place for the holding of the hearing shall be fixed, and may be varied, by the appointed person, who shall give not less than 42 days' notice in writing of such date, time and place to the parties.

(2) With the consent of the parties, the appointed person may give such lesser period of notice as shall be agreed with the parties and in that event he may specify a date for service of the statement referred to in paragraph 8(1) later than the date determined in accordance with that paragraph.

(3) Where it becomes necessary or advisable to vary the time or place fixed for the hearing, the appointed person shall give such notice of the variation as may appear to him to be reasonable in the circumstances.

(4) Without prejudice to the foregoing provisions of this paragraph, the appointed person may require the authority to take one or more of the following steps, namely:—

(a) to publish in one or more newspapers circulating in the locality in which the site is situated such notice of the hearing and in such form as he may direct;

(b) to serve such notice of the hearing, in such form and on such persons or classes of persons as he may direct;

(c) to give such other notice of the hearing and in such form as he may direct,

and the requirements as to the period of notice contained in sub-paragraph (1) shall not apply to any such notices.

8.—(1) Not later than 28 days before the date of the hearing, or such later date as the appointed person may specify in accordance with paragraph 7(2), the authority shall serve on the appellant a written statement of any submission which the authority proposes to put forward at the hearing and shall supply a copy of the statement to the appointed person.

(2) Where a government department has expressed in writing to the authority a view in support of the decision of the authority and the authority proposes to rely on such expression of view in its submission at the hearing, the authority shall include the expression of view in its statement and shall supply a copy of the statement to the government department concerned.

(3) Where the authority intends to refer to or put in evidence at the hearing, documents (including photographs, maps and plans), the statement of the authority shall be accompanied by a list of such documents, together with a written notice stating the times and place at which the documents may be inspected by the appellant; and the authority shall afford the appellant a reasonable opportunity to inspect and, where practicable, to take copies of the documents.

(4) If so required by the appointed person, the appellant shall—

(a) serve on the authority and on the appointed person, within such time before the hearing as the appointed person may specify, a written statement of the submissions which he proposes to put forward at the hearing; and such statement shall be accompanied by a list of any documents (including photographs, maps and plans) which the appellant intends to refer to or put in evidence at the hearing; and

(b) afford the authority a reasonable opportunity to inspect and, where practicable, to take copies of such documents as are referred to in the foregoing provision.

9.—(1) The parties shall be entitled to appear at the hearing.

(2) Any other person may appear at the discretion of the appointed person provided that he has, not later than 7 days before the date of the hearing, served on the authority a statement of his proposed submissions.

(3) The authority shall send a copy of every statement served on it in accordance with sub-paragraph (2) to the appointed person and to the appellant.

(4) A body corporate may appear by its clerk or secretary or by any other officer appointed for the purpose by that body, or by counsel or a solicitor.

(5) A person may appear on his own behalf or be represented by counsel, a solicitor or any other person.

(6) Where there are two or more persons having a similar interest in the subject matter of the hearing, the appointed person may allow one or more persons to appear for the benefit of some or all persons so interested.

10.—(1) Where a government department has expressed in writing to the authority a view in support of the decision of the authority and the authority has included this view in the statement referred to in paragraph 8(1), the appellant may apply in writing to the appointed person, not later than 14 days before the date of the hearing, for a representative of the government department concerned to be made available at the hearing.

(2) The appointed person shall send any application made to him under sub-paragraph (1) to the government department concerned who shall make a representative of the department available to attend the hearing.

(3) A representative of a government department who, in pursuance of this paragraph, attends a hearing shall be called as a witness by the authority and shall state the reasons for the view expressed by his department and included in the statement of the authority under paragraph 8(1) and shall give evidence and be subject to cross-examination to the same extent as any other witness.

(4) Nothing in the last foregoing paragraph shall require a representative of a government department to answer any question which in the opinion of the appointed person is directed to the merits of government policy or to matters which affect the safety of the State and the appointed person shall disallow any such question.

11.—(1) Except as otherwise provided in this Part of this Schedule, the procedure at the hearing shall be such as the appointed person shall in his discretion determine and the appointed person shall—

(a) state at the commencement of the hearing the procedure which, subject to consideration of any submission by the parties, he proposes to adopt; and

(b) shall inform the parties what he proposes as regards any site inspection arising out of the hearing.

(2) Unless in any particular case the appointed person with the consent of the appellant otherwise determines—

(a) in the case of an appeal to the Secretary of State, the appellant shall be heard first and shall have the right of final reply; and

(b) in the case of an appeal to the Secretary of State and the Scottish Ministers acting jointly—

(i) the appellant shall be heard first,

(ii) the other persons entitled or permitted to appear shall be heard in such order as the appointed person may determine, and

(iii) any closing statements shall be made in the same order, unless the appointed person otherwise determines.

(3) The parties shall be entitled to make an opening statement, to call evidence and to cross-examine persons giving evidence, but any other person appearing at the hearing may do so only to the extent permitted by the appointed person.

(4) Subject to sub-paragraph (5), any evidence may be admitted at the discretion of the appointed person, who may direct that documents tendered in evidence may be inspected by any person entitled or permitted to appear at the hearing and that facilities be afforded him to take or obtain copies thereof.

(5) The appointed person shall not require or permit the giving or production of any evidence, whether written or oral, which would be contrary to the public interest.

(6) The appointed person may allow the authority or the appellant, or both of them, to alter or add to the submissions contained in any statement served under paragraph 8(1) or (4), or to any list of documents which accompanied such statement, so far as may be necessary for the purpose of determining the questions in controversy between the parties, but shall (if necessary by adjourning

the hearing) give the appellant or the authority, as the case may be, an adequate opportunity of considering any such fresh submission or document.

(7) If any person entitled to appear at the hearing fails to appear, the appointed person may proceed with the hearing at his discretion.

(8) The appointed person shall be entitled (subject to disclosure thereof at the hearing) to take into account any written representations or statements received by him before the hearing from any person.

(9) The appointed person may from time to time adjourn the hearing, and where he does so, shall give reasonable notice to every person entitled or permitted to appear at the hearing of the date, time and place of the adjourned hearing.

12.—(1) The appointed person may make an inspection of the site before or during the hearing after having given notice to the parties of the date and time at which he proposes to do so.

(2) The appointed person may, and shall if so requested by either party before or during the hearing, inspect the site after the close of the hearing and, in all cases where he intends to make such an inspection, shall announce during the hearing the date and time at which he proposes to do so.

(3) The parties shall be entitled to accompany the appointed person on any inspection under this paragraph, but the appointed person shall not be bound to defer his inspection if any person entitled to accompany him is not present at the time appointed.

13.—(1) Where, after the close of the hearing, the appointed person proposes to take into consideration—

(a) any new evidence, including expert opinion on a matter of fact; or

(b) any new issue of fact, not being a matter of government policy or a matter affecting the safety of the State,

which was not raised at the hearing and which he considers to be material to his decision, he shall not come to a decision without first notifying the parties of the substance of the new evidence or of the new issue of fact and affording them an opportunity of making representations thereon in writing within 21 days or of asking within that time for the re-opening of the hearing.

(2) If he thinks fit, the appointed person may cause the hearing to be re-opened and shall cause it to be re-opened if asked to do so in accordance with sub-paragraph (1).

(3) Where the hearing is re-opened, paragraphs 7(1) and 7(4) shall apply as they applied to the original hearing with the substitution in paragraph 7(1) of "28" for "42".

14. The appointed person shall notify the decision on the appeal, and the reasons therefor, in writing to the parties and to any person who, having appeared at the hearing, has asked to be notified of the decision.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. 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 micro-organisms

and protecting persons from risks arising from activities involving the contained use of genetically modified organisms which are not micro-organisms.

2. Save as regards the matters referred to in regulations 7, 12, 17(1)(b), 17(3), 19, 20(2), 24, 25, 27 and 29, Schedule 4, Part III of Schedule 6, Schedule 9 and Schedule 11, these Regulations implement as respects Great Britain Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (O.J. No. L117, 8.5.90, p. 1), as amended by Commission Directive 94/51/EC of 7 November 1994 (O.J. L297, 18.11.94, p. 29) and Council Directive 98/81/EC of 26 October 1998 (O.J. No. L330, 5.12.98, p. 13).

3. The Regulations revoke and replace the Genetically Modified Organisms (Contained Use) Regulations 1992, as amended. The principal provisions are as follows.

4. Any activity involving genetic modification of micro-organisms is prohibited unless the person intending to undertake the activity in question has ensured that an assessment of the risks created by that activity to human health and the environment has been carried out. Any activity involving genetic modification of organisms other than micro-organisms is prohibited unless the person intending to undertake the activity in question has ensured that an assessment of the risks created by that activity to human health has been carried out. A person who carries out such an assessment is required to establish a safety committee to advise him. (Regulations 6, 7 and 16.) (The terms "activity involving genetic modification", "micro-organism" and "organism" are defined in regulation 2(1).)

5. No person shall use premises for the first time for the purpose of undertaking an activity involving genetic modification unless he has notified the competent authority (also defined in regulation 2(1)) of his intention to do so and provided to the competent authority certain information. (Regulation 9 and Schedule 5.)

6. The Regulations prohibit the undertaking of certain types of activity involving the genetic modification of micro-organisms and the genetic modification of organisms other than micro-organisms unless the competent authority has been given prior notification together with certain information and, in specified circumstances, the competent authority has given its consent. (Regulations 10, 11 and 12 and Schedule 6.)

7. The competent authority is placed under a duty to examine a notification submitted to it under regulations 9, 10, 11 and 12 and the Health and Safety Executive may ask the notifier for additional information. (Regulation 14.)

8. The competent authority has power to vary or revoke any consent under regulation 11, and a notifier is required to inform the competent authority of changes in the information supplied with the notification submitted by him or other changes in circumstances relating to the undertaking of the activity involving genetic modification. (Regulation 15.)

9. The Regulations impose on a person who undertakes an activity involving genetic modification a requirement to ensure that safety principles are observed. (Regulation 17.)

10. A person who undertakes an activity involving genetic modification of micro-organisms is required to apply the containment measures which are appropriate to that activity as set out in the relevant table in Schedule 8. (Regulation 18.)

11. A person who undertakes an activity involving genetic modification of organisms other than micro-organisms is required to apply the containment measures selected in accordance with the assessment made under regulation 7. (Regulation 19.)

12. In certain circumstances, before a person undertakes an activity involving genetic modification of micro-organisms, he must prepare an emergency plan to secure the health of persons and the protection of the environment. In certain circumstances, before a person undertakes an activity involving genetic modification of genetically modified organisms other than micro-organisms, he must prepare an emergency plan to secure the health of persons. (Regulation 20.)

13. A person who undertakes an activity involving genetic modification of organisms must report to the competent authority every accident and provide that authority with information about the accident. (Regulation 21.) (The term "accident" is defined in regulation 2(1).)

14. The Regulations contain provisions relating to the confidentiality of information provided to the competent authority. (Regulations 22 and 23.)

15. The competent authority is to maintain a register of the notifications made under regulations 9 to 12 and copies of the register are to be kept at certain offices of the Health and Safety Executive. The register is to be open to public inspection at any reasonable time and is to contain certain information. (Regulation 24.)

16. The competent authority may grant an exemption from the requirements of the Regulations but only if it is satisfied that the health and safety of persons and the environment are not prejudiced by the granting of such an exemption. (Regulation 25.)

17. Provision is made for the enforcement of the Regulations, for the payment of fees and for transitional measures. (Regulations 26, 27 and 28 and Schedules 9 and 10.)

18. There is a right of appeal for any person who is aggrieved by certain decisions of the competent authority, a request for information or an instruction given to him by the Health and Safety Executive. (Regulation 29 and Schedule 11.)

19. A copy of the regulatory impact assessment prepared in respect of these Regulations can be obtained from the Health and Safety Executive, Economic Adviser's Unit, Rose Court, 2, Southwark Bridge, London SE1 9HS. A copy has been placed in the Library of each House of Parliament.