Regulations made under s.180X.

PUBLIC HEALTH (GENETICALLY MODIFIED ORGANISMS) (CONTAINED USE) REGULATIONS 1995

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Title and commencement.

1. (1) These Regulations may be cited as the Public Health (Genetically Modified Organisms) (Contained Use) Regulations 1995 and, subject to sub-regulation (2), shall come into effect on 8th day of January 1996.

(2) Where a person is carrying out an activity to which these Regulations apply at the coming into effect of these Regulations the provisions of these Regulations shall not apply to such person for a period of 90 days commencing on the day on which these Regulations shall have come into effect.

PART I
GENERAL

Interpretation.

2. (1) In these Regulations, unless the context shall otherwise require–

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

"approved" means approved in writing for the time being by the Competent Authority;

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

"Competent Authority" means the person or body designated as the Competent Authority by the Government from time to time by notice in the Gazette under section 180A;

"a competent authority of a member State" means a competent authority of the United Kingdom or of another member State appointed by the United Kingdom or that State, as the case may be, for the purposes of the Contained Use Directive;

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

"the Contained Use Directive" means Council Directive 90/219/EEC, as amended by Council Directive 94/51/EEC, on the contained use of genetically modified micro-organisms and includes any changes made to that Directive under Article 20 thereof to reflect technical or scientific change and any further Directives made for that purpose;

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

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

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

"genetically modified" shall be construed accordingly;

"member State" means a member State of the European Union and shall include states that are members of the European Economic Area;

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

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

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

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

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

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

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

(2) Genetically modified organisms shall be classified–

(a) in the case of micro-organisms–

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

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

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

Application.

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

(2) Regulations 7 to 11 shall not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

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

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

(5) Nothing in these Regulations shall prejudice any requirement imposed by or under any enactment which relates to public health or the protection of the environment.

Meaning of "work" and "at work".

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

PART II
NOTIFICATION OF AND CONSENT FOR ACTIVITIES INVOLVING GENETIC MODIFICATION

Prohibition of certain work with genetically modified organisms outside containment.

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

(2) Sub-regulation (1) shall not apply to any operation in which–

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

(i) a consent granted by the Competent Authority under section 180F; or

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

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

(b) genetically modified organisms are released or marketed in circumstances in which the consent of the Competent Authority is required under section 180F.

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

Risk assessment.

6. (1) A person shall not–

(a) use any premises for activities involving genetic modification for the first time; or

(b) undertake any activity involving genetic modification,

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

(2) Without prejudice to the generality of sub-regulation (1), the purposes of the assessment undertaken under that sub-regulation shall include–

(a) classifying any genetically modified organisms involved in the activity in accordance with the provisions of Schedule 2; and

(b) where appropriate, making decisions about the levels of containment required for the activity concerned.

(3) In making the assessment required by sub-regulation (1) the person undertaking that assessment shall–

(a) in particular, take due account of the parameters set out in Schedule 3 in as far as they are relevant; and

(b) in a case in which the Competent Authority has approved a method in relation to the activity involving genetic modification concerned or in relation to a particular element of that assessment, undertake the assessment in accordance with that method.

(4) The assessment shall be reviewed forthwith if–

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

(b) there has been a significant change in the activity to which the assessment relates.

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

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

7. (1) Subject to sub-regulations (2) to (6) and regulation 9, no person shall undertake any activity involving genetic modification at any premises for the first time, unless he has notified the Competent Authority of his intention to do so at least 90 days in advance or before such shorter time as the Competent Authority may approve and with that notification has furnished the particulars specified in Schedule 4.

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

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

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

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

(6) Nothing in this regulation shall prevent a person from notifying under regulation 8 an individual activity which he intends to undertake in the premises at the same time as making a notification under this regulation and in such a case he shall not commence the activity except in accordance with the time periods specified in this regulation.

Notification of individual activities involving genetic modification.

8. (1) Subject to sub-regulations (2) to (7) and regulation 9, no person shall undertake any activity involving genetic modification unless he has notified the Competent Authority of his intention to do so at least 60 days in advance or before such shorter time as the Competent Authority may approve and has furnished the particulars specified in sub-regulations

(2) to (7) and, except in the case of an activity to which sub-regulation (5) applies, the activity may be commenced after the expiry of the relevant period if by then the Competent Authority has not objected in writing.

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

(a) a Type A operation involving only micro-organisms classified as Group I; or

(b) an activity involving genetically modified organisms other than micro-organisms and which satisfy the criteria set out in Part III of Schedule 2,

it shall be a sufficient compliance with sub-regulation (1) if the person undertaking the activity keeps a record of such activities and forthwith after the end of each calendar year notifies the Competent Authority–

(c) of the total number of risk assessments under regulation 6 undertaken during that year;

(d) where appropriate, that he is intending to continue to undertake such activities; and

(e) that the information notified to the Competent Authority in accordance with regulation 7 remains correct.

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

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

(a) a Type A operation involving genetically modified micro-organisms classified as Group II; or

(b) an activity involving genetically modified organisms other than micro-organisms and which do not satisfy the criteria set out in Part III of Schedule 2,

the specified particulars for the purposes of sub-regulation (1) shall be those specified in Parts I and II of Schedule 5.

(5) In the case of an activity which is a Type B operation involving genetically modified micro-organisms classified as Group II, the specified particulars for the purposes of sub-regulation (1) shall be those specified in

Parts I, II and III of Schedule 5 and the activity shall only be commenced with the consent of the Competent Authority.

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

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

Additional provisions relating to notifications and consents.

9.(1) Where necessary for the purpose of evaluating a notification made under regulation 7 or 8, the Competent Authority may require in writing the person making the notification to give such additional information relating to the proposal as it may specify and, in such a case, the person making the notification shall not proceed with the activity involving genetic modification, until the Competent Authority gives its approval, and the period between the time when the Competent Authority requires the information and the notifier responds to the satisfaction of the Competent Authority shall not be taken into account in calculating the periods of days referred to in the provisions concerned.

(2) Any consent granted by the Competent Authority under regulation 7 or 8 may be granted subject to conditions or to a limit of time and may be revoked or varied at any time and in such a case the person undertaking the activity shall comply with those conditions.

(3) Where a person making a notification in pursuance of regulation 7 or 8 subsequently makes a significant change in any premises or activity to which the notification relates or becomes aware of any new information which would affect the particulars previously notified, he shall forthwith notify the Competent Authority thereof.

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

(5) Notifications made in pursuance of regulations 7 and 8 shall be in a form approved by the Competent Authority.

Advisory power of Competent Authority.

10. The Competent Authority shall advise any person or body that undertakes an assessment made for the purposes of regulation 6(1) in relation to that assessment.

PART III
CONDUCT OF ACTIVITIES INVOLVING GENETIC MODIFICATION

Standards of occupational and environmental safety and containment.

11.(1) For any activity involving genetically modified micro-organisms of Group I, the principles of good microbiological practice and the following principles of good occupational safety and hygiene shall apply, that is to say–

(a) keeping workplace and environmental exposure to any physical, chemical and biological agent adequately controlled;

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

(c) testing and maintaining control measures and equipment;

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

(e) providing training of personnel; and

(f) formulating and implementing local rules for the safety of personnel.

(2) For the purpose of sub-regulation (1) "adequate" in relation to the control of an agent means adequate having regard only to the nature of the agent and the nature and degree of exposure to such an agent and "adequately" shall be construed accordingly.

(3) For any activities involving genetically modified micro-organisms of Group II in Type A operations, in addition to the principles set out in sub-regulation (1) the containment measures shall be determined by a method approved by the Competent Authority.

(4) For any activities involving genetically modified micro-organisms of Group II in Type B operations, in addition to the principles set out in sub-regulation (1) the containment measures set out in Schedule 6 shall be

applied at an appropriate level so as to ensure a high level of health and safety and environmental protection.

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

Emergency plans.

12. (1) Where the assessment made in accordance with regulation 6(1) shows that as a result of any reasonably foreseeable accident the health or safety of persons outside the premises in which an activity involving genetic modification is carried on is liable to be affected or there is a risk of damage to the environment, the person undertaking the activity shall ensure that a suitable emergency plan is prepared with a view to securing the health and safety of those persons and the protection of the environment.

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

(3) The person undertaking the activity involving genetic modification which is the subject of the emergency plan shall take appropriate measures to inform persons who are liable to be affected by an accident of the safety measures and the correct behaviour to adopt in the event of an accident.

(4) The information required to be given in pursuance of sub-regulation (3) shall be repeated and brought up to date at appropriate intervals and shall be made publicly available.

Notification of accidents.

13. (1) Where an accident occurs, the person undertaking the activity involving genetically modified organisms shall forthwith notify the Competent Authority of it and shall provide the following information–

(a) the circumstances of the accident;

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

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

(d) the emergency measures taken.

(2) Where the Competent Authority receives a notification in pursuance of sub-regulation (1), the Competent Authority shall–

(a) ensure that any emergency, medium and long term measures are taken;

(b) immediately inform any member State that could be affected by the accident;

(c) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit their effects; and

(d) send to the European Commission the information provided for under sub-regulation (1), together with an analysis of the accident and details of any recommendations made to avoid similar accidents in the future and to limit their effects.

PART IV
DISCLOSURE OF INFORMATION NOTIFIED AND PUBLICITY

Disclosure of information notified.

14. (1) Where a person making a notification in pursuance of regulations 7, 8 and 9 indicates that it contains certain information the disclosure of which might harm his competitive position and should be kept confidential, full justification for that indication shall be given and in such a case after consulting the notifier the Competent Authority shall decide which information shall be kept confidential and shall inform the notifier of its decision.

(2) Nothing in sub-regulation (1) shall apply to the following information which shall not be kept confidential–

(a) the name and address of the notifier and the location of the activity involving genetic modification;

(b) the purpose of the activity;

(c) the description of the genetically modified organism involved;

(d) methods and plans for monitoring the genetically modified organism and for emergency response; and

(e) the evaluation of foreseeable effects and in particular pathogenic effects and ecologically disruptive effects.

(3) Notwithstanding sub-regulation (2), where the Competent Authority is satisfied on the basis of detailed evidence submitted to it by the notifier and where appropriate, after consultation with the notifier, that it is necessary to withhold, for the time being, certain of the information specified in sub-regulation (2) in order to protect his intellectual property rights, the Competent Authority shall withhold that information to the extent and for so long as it is necessary to protect those rights.

(4) Information which is kept confidential in accordance with sub-regulation (1) or withheld in accordance with sub-regulation (3) shall be disclosed only–

(a) to the Government;

(b) to the European Commission or the competent authority of a member State;

(c) for the purpose of any legal proceedings;

(d) with the consent of the notifier; or

(e) to the extent necessary to evaluate the notification.

(5) A person who receives information in accordance with sub-regulation (4)(e) shall not use that information except for a purpose of the Competent Authority or the Government.

(6) Where the notifier has requested that certain information in the notification shall be kept confidential in accordance with sub-regulation (1) or withheld in accordance with sub-regulation (3), the Competent Authority shall not disclose any of that information (except in accordance with sub-regulation (4)) until at least 14 days after it has reached a decision under the relevant sub-regulation.

(7) After consulting the notifier, the Competent Authority may review any decision made under sub-regulation (1) or (3) and shall inform the notifier of the result of that review.

(8) Where, for whatever reason, the notifier withdraws the notification, the Competent Authority shall not thereafter disclose any of the information supplied.

Register of notifications.

15. (1) The Competent Authority shall maintain a register of notifications to which regulation 7(3) or 8(5) relates (for which the consent of the Competent Authority is required) and that register shall be open to inspection by members of the public at any reasonable time.

(2) The register referred to in sub-regulation (1) shall contain in relation to each such notification–

(a) such of the information referred to in sub-regulation (3) of regulation 14 as has not been withheld in accordance with sub-regulation (4) of that regulation; and

(b) a statement as to whether or not the consent of the Competent Authority has been granted.

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

PART V
ADDITIONAL DUTIES PLACED ON THE COMPETENT AUTHORITY

Duties on receiving notifications.

16. The Competent Authority shall examine a notification under regulations 7 or 8 for–

(a) the conformity with the requirements of these Regulations;

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

(c) the correctness of the classification of the organisms to which the notification relates in accordance with Schedule 2; and

(d) where appropriate, the adequacy of the waste management, safety and emergency response measures.

Information to be sent to the Government.

17 Forthwith after receipt, the Competent Authority shall send to the Government a copy in each case of–

(a) any notification received under regulations 7 or 8;

(b) any requirement for further information under regulation 9(1) and the response thereto; and

(c) any notification relating to an accident under regulation 13, and if requested to do so by the Government shall require additional information under regulation 9(1).

Reports to the European Commission.

18. The Competent Authority shall send to the European Commission reports of notifications for which a consent is required under regulation 8(5) and summary reports of the application of these Regulations in accordance with Article 18 of the Contained Use Directive.

PART VI
MISCELLANEOUS AND GENERAL

Exemption certificates.

19.(1) Subject to sub-regulation (2) and to any provisions imposed by the Communities in respect of the control and regulation of genetically modified organisms, the Competent Authority may, with the agreement of the Government in so far as the exemption relates to the environment, by a certificate in writing, exempt any person or class of persons, genetically modified organism or class of genetically modified organisms from all or any of the requirements or prohibitions imposed by these Regulations and any such exemption may be granted subject to conditions and to a time limit and may be revoked by a certificate in writing at any time.

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

(a) the conditions, if any, that it proposes to attach to the exemption; and

(b) any requirements imposed by or under any enactments which apply to the case, likely to be affected by the exemption,

the protection of the environment will not be prejudiced in consequence of it.

Enforcement and civil liability.

20.(1) It is an offence for a person —

(a) to fail to discharge a duty to which he is subject by virtue of the provisions of these Regulations;

(b) to contravene any requirement or prohibition imposed by these Regulations;

(2) In the event of a breach of duty imposed by regulations 5 to 13 the Competent Authority shall have a right of action in civil proceedings if that breach of duty causes damages.

Fees for notifications.

21. (1) Fees shall be payable in accordance with sub-regulation (2) by a notifier to the Competent Authority in relation to any matter referred to in that sub-regulation.

(2) The fees referred to in sub-regulation (1) shall be–

(a) subject to paragraph (b), on each notification of the intention to use premises for activities involving genetic modification for the first time under regulation 7;

(b) on each notification of the intention to use premises for activities involving genetic modification for the first time where a consent is required under regulation 7(3);

(c) subject to paragraph (d), on each notification of individual activities involving genetic modification under regulation 8;

(d) on each of the paragraphs of this sub-regulation, such fee as would not reasonably exceed the sum of the costs incurred in dealing with the notification concerned.; and on each notification of individual activities involving genetic modification for which a consent is required under regulation 8(5).

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PUBLIC HEALTH (GENETICALLY MODIFIED ORGANISMS) (CONTAINED USE) REGULATIONS 1995
SCHEDULE 1

Regulations 2(1) and 3(3)

DEFINITION OF GENETIC MODIFICATION

PART I

Examples of techniques constituting genetic modification

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

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

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

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

PART II

Techniques which are not considered to result in genetic modification

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

(a) in vitro fertilisation;

(b) conjugation, transduction, transformation or any other natural process; and

(c) polyploidy induction.

PART III

Techniques to which these Regulations do not apply

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

(a) mutagenesis;

(b) the construction and use of somatic hybridoma cells (for example for the production of monoclonal antibodies);

(c) cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods;

(d) self-cloning of non-pathogenic naturally occurring micro-organisms which fulfil the criteria of Group I for recipient micro-organisms; and

(e) self-cloning of non-pathogenic naturally occurring organisms other than micro-organisms which fulfil the criteria of Part III of Schedule 2.

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PUBLIC HEALTH (GENETICALLY MODIFIED ORGANISMS) (CONTAINED USE) REGULATIONS 1995

SCHEDULE 2

Regulation 2(2)

CRITERIA FOR THE CLASSIFICATION OF ORGANISMS

PART I

Criteria for classifying genetically modified micro-organisms into Group I

4. A genetically modified micro-organism is classified as falling within Group I when all the following criteria are fulfilled —

(a) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants;

(b) the nature of the vector and the insert is such that they do not endow the genetically modified micro-organism with a phenotype likely to cause disease to humans, anmilas or plants, or likely to cause adverse effects in the environment;

(c) the genetically micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to cause adverse effects in the environment.

PART II

Guidelines as applicable for classification of micro-organisms in Group I

For classification into Group I the following guidelines should be used to further interpret Part I of this Schedule

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

(1) Non-pathogenic

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

(a) the recipient or parental strain should have an established record of safety in the laboratory and/or industry, with no adverse effects on human health and the environment;

(b) the recipient or parental strain does not meet the conditions of clause (a) but it belongs to a species for which there is a long record of biological work including safety in the laboratory and/or industry, showing no adverse effects on human health and the environment;

(c) if the recipient or parental organism is a strain which does not satisfy the conditions of clause (a) and belongs to a species for which there is no record of biological work including safe use in the laboratory and/or industry, appropriate testing (including, if necessary, animals) shall be carried out, in order to establish non-pathogenicity and safety in the environment;

(d) if a non-virulent strain of an acknowledged pathogenic species is used, the strain should be as deficient as possible in genetic material that determines virulence so as to ensure no reversion to pathogenicity. In the case of bacteria, special attention should be given to plasmid or phage-borne virulence determinants.

(2) No adventitious agents; the recipient or parental strain/cell line should be free of known biological contaminating agents (symbionts, mycoplasms, viruses, viroids, etc.), which are potentially harmful.

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

6.Characteristics of the vector

(1) The vector should be well characterised. For this purpose the following characteristics should be taken into account–

(a) information on composition and construction–

(i) the type of the vector should be defined (virus, plasmid, cosmid, phasmid, transposable element, minichromosome, etc.);

(ii) the following information on the constituent fragments of the vector should be available–

(aa) the origin of each fragment (progenitor genetic element, strain of organism in which the progenitor genetic element naturally occurred),

(bb) if some fragments are synthetic, their functions should be known;

(iii) the methods used for construction should be known;

(b) information on vector structure–

(i) the size of the vector should be known and expressed in basepairs or D;

(ii) the function and relative positions of the following should be known–

(aa) structural genes,

(bb) marker genes for selection (antibiotic resistance, heavy metal resistance, phage immunity, genes coding for degradation of xenobiotics, etc.),

(cc) regulatory elements,

(dd) target sites (nic-sites, restriction endonuclease sites, Tinkers, etc.),

(ee) transposable elements (including provirus sequences),

(ff) genes related to transfer and mobilisation function (e.g. with respect to conjugation, transduction or chromosomal integration),

(gg) replicon(s).

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

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

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

(5) The vector should be poorly mobilisable–

(a) if the vector is a plasmid–

(i) it should have a restricted host-range;

(ii) it should be defective in transfer-mobilisation factors e.g. Tra, MobS. 036, for Type A operations or Tra, Mob, for Type B operations;

(b) if the vector is a virus, cosmid or phasmid–

(i) it should have a restricted host-range;

(ii) it should be rendered non-lysogenic when used as a cloning vector (e.g. defective in the ci-lambda repressor).

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

7. Required characteristics of the insert

(1) The insert should be well characterised. For this purpose, the following characteristics should be taken into account–

(a) the origin of the insert should be known (genus, species, strain);

(b) the following information on the library from which the insert originated, should be known–

(i) the source and method for obtaining the nucleic acid of interest (CDNA, chromosomal, mitochondrial, etc.);

(ii) the vector in which the library was constructed (e.g. lambda gt 11, pBR372, etc.) and the site in which the DNA was inserted;

(iii) the method used for identification (colony, hybridization, immuno-blot, etc.);

(iv) the strain used for library construction;

(c) if the insert is synthetic, its intended function should be identified;

(d) the following information on the structure of the insert is required–

(i) information on structural genes, regulatory elements;

(ii) size of the insert;

(iii) restriction endonuclease sites flanking the insert;

(iv) information on transposable elements and provirus sequences.

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

(a) the function of each genetic unit in the insert should be defined (not applicable for Type A operations);

(b) the insert should not contain genes coding for potentially harmful or pathogenic traits (e.g. virulence determinants, toxins, etc.), (unless for Type A operations, such genes constitute an essential part of the insert without, under any circumstances, resulting in a harmful or pathogenic phenotype of the genetically modified micro-organism).

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

(4) The insert should not increase the stability of the construct in the environment (unless that is a requirement of intended function).

(5) The insert should be poorly mobilisable. For instance, it should not contain transposing or transferable provirus sequences and other functional transposing sequences.

8. Required characteristics of the genetically modified micro-organism

(1) The genetically modified micro-organism should be non-pathogenic. This requirement is reasonably assured by compliance with all the requirements above.

(2) The genetically modified micro-organisms should be as safe–

(a) to man and the environment as the recipient or parental strains (applicable only for Type A operations);

(b) in the reactor or fermentor as the recipient or parental strains, but with limited survivability and/or replicability outside the reactor or fermenter without adverse consequences in the environment (applicable only for Type B operations).

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

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

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

PART III

Criteria for the classification of organisms other than micro-organisms

10. An organism which satisfies the criteria of this Part is a genetically modified organism–

(a) which is not a genetically modified micro-organism; and

(b) which is as safe in the containment facility as any recipient or parental organism.

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PUBLIC HEALTH (GENETICALLY MODIFIED ORGANISMS) (CONTAINED USE) REGULATIONS 1995

SCHEDULE 3

Regulation 6(3)

PARAMETERS TO BE TAKEN INTO ACCOUNT IN RISK ASSESSMENTS, AS FAR AS THEY ARE RELEVANT, UNDER REGULATION 6

Characteristics of the donor, recipient or (where appropriate) parental organism

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

(a) the name, species, subspecies and strain of the organism;

(b) the degree of relatedness between the donor, recipient (and where appropriate the parental) organism in relation to which the assessment is being carried out;

(c) the sources of the organism;

(d) the reproductive cycle of the organism;

(e) history of prior genetic modifications to the organism;

(f) the stability of the genetic traits of the organism;

(g) the nature of the pathogenicity, virulence, infectivity, toxicity, and vectors of disease transmission of the organism;

(h) the base sequence, frequency of mobilisation and specificity of the organisms indigenous vectors;

(j) the presence in the organism of genes which confer resistance;

(k) the host range of an organism which is a parasite or pathogen;

(l) the organisms other potentially significant physiological traits, and the stability of those traits;

(m) the organisms natural habitat and geographic distribution;

(n) the climatic characteristics of the organisms natural habitat;

(p) the significant involvement of the organism in environmental processes, including nitrogen fixation and pH rule;

(q) the interaction of the organism with other organisms in the environment and its effect on those organisms, including its likely competitive or symbiotic properties;

(r) the ability of the organism to form survival structures, including seeds, spores or sclerotia.

2. Characteristics of the modified organism

The following matters shall be investigated and assessed in relation to an organism in relation to which a risk assessment under regulation 6 is carried out–

(a) the description of the modification, including the technique used or proposed to be used to introduce a vector or insert into the organism;

(b) the nature and source of the vector introduced into the organism;

(c) the function of the genetic modification and/or of the new nucleic acid;

(d) the structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organism;

(e) the stability of the genetic traits introduced into the organism;

(f) the frequency of mobilisation of inserted vector or genetic transfer capability;

(g) the rate and level of expression of the new genetic material in .the organism, and the method and sensitivity of measurement of that rate and level;

(h) the activity of the expressed protein.

3. Health considerations

The following matters shall be investigated and assessed in relation to an organism in relation to which a risk assessment under regulation 6 is carried out–

(a) toxic or allergenic effects of non-viable organisms and/or their metabolic products;

(b) product hazards;

(c) comparison of the modified micro-organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(d) capacity for colonisation;

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

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

(ii) communicability,

(iii) infective dose,

(iv) host range, possibility of alteration,

(v) possibility of survival outside of human host,

(vi) presence of vectors or means of dissemination,

(vii) biological stability,

(viii) antibiotic-resistance patterns,

(ix) allergenicity,

(x) availability of appropriate therapies.

4. Environmental considerations

The following matters shall also be investigated and assessed in relation to an organism in relation to which a risk assessment under regulation 6 is carried out–

(a) the factors affecting survival, multiplication and dissemination of the modified organism in the environment;

(b) the available techniques for detection, identification, and monitoring of the modified organism in the environment;

(c) the available techniques for detecting transfer of the new genetic material to other organisms;

(d) the known and predicted habitats of the modified organism;

(e) the ecosystems to which the modified organism could be disseminated as a result of an escape;

(f) the anticipated mechanism and result of interaction between the modified organism and the organisms which might be exposed in case of the escape of the organism;

(g) the known or predicted effects of the organism on plants and animals, including pathogenicity, infectivity, toxicity virulence, vector or pathogen allergenicity colonisation, predation, parasitism, symbiosis and competition;

(h) the known or predicted involvement of the organism in biogeochemical processes, including nitrogen fixation and pH rule;

(j) the availability of methods for decontamination of the area in case of release to the environment.

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SCHEDULE 4

Regulation 7(1)

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 7(1)

A notification required for the purposes of regulation 7(1) shall include the following information–

(a) the name and address of the person responsible for carrying out the activity and the names of persons responsible for supervision, monitoring and safety together with details of their training and qualifications;

(b) address of the premises where the activity is to be carried on and its grid reference and, where appropriate, a description of the sections of the installation;

(c) a description of the nature of the activity to be undertaken, the likely scale of the operation and in particular, in the case of micro-organisms, their classification (whether in Group I or Group II);

(d) a summary of the risk assessment undertaken in accordance with regulation 6;

(e) the names and capacities of the members of the genetic modification safety committee;

(f) comments made by the genetic modification safety committee on the local arrangements for risk assessment;

(g) the names of the biological and deputy biological safety officers concerned with the intended activities (if any);

(h) the name of the supervisory medical officer (if any);

(j) the arrangements for health surveillance (if any); and

(k) any other information the Competent Authority needs for the purpose of maintaining the register referred to in regulation 15.

SCHEDULE 5

Regulation 8

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 9

PART I

1.Information required under regulation 8(3)

A notification required for the purposes of regulation 8(3) shall include the following information–

(a) the name and address of the person responsible for carrying out the activity;

(b) address of the premises where the activity is to be carried out;

(c) the date of the notification referred to in regulation 7(1);

(d) the parental organism used, or where applicable the host-vector system used;

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

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

(g) the purpose of the activity including the expected results;

(h) where appropriate the culture volumes to be used or the scale of the activity;

(j) details of waste treatment including levels of live genetically modified micro-organisms in the waste; and

(k) a summary of the risk assessment required in accordance with regulation 6 and of the comments of the genetic modification safety committee on it.

PART II

2.Additional information required under regulation 8(4)

In addition to the information required under Part I a notification made for the purposes of regulation 8(4) shall contain the following information–

(a) a description of the sections of the installation involved and the methods for handling the organisms;

(b) a description of the predominant meteorological conditions and the potential sources of danger arising from the location of the installation;

(c) a description of the protective and supervisory methods to be applied throughout the duration of the activity; and

(d) in the case of micro-organisms, the containment level to which the micro-organism has been allocated in accordance with the risk assessment made in accordance with regulation 6(1) and in any case the safety precautions to be observed.

PART III

Additional information required under regulation 8(5)

3.In addition to the information required under Parts I and II a notification made for the purposes of regulation 8(5) shall contain the information specified in paragraph 5.

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

5.The additional information required is–

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

(i) the identity and characteristics of the genetically modified micro-organisms,

(ii) the purpose of the contained use or the nature of the product,

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

(iv) the culture volume to be used,

(v) behaviour and characteristics of the micro-organisms in the case of changes in the conditions of containment or release into the environment,

(vi) overview of the potential hazards associated with the release of the micro-organisms into the environment, and

(vii) substances which are or may be produced in the course of use of the micro-organisms other than the intended product;

(b) information about personnel–

(i) the maximum number of persons working in the installation, and

(ii) the number of persons who will work directly with the micro-organisms;

(c) information about the installation–

(i) the activity in which the micro-organisms are to be used,

(ii) the technological processes used,

(iii) a description of the sections of the installation involved, and

(iv) the predominant meteorological conditions and specific hazards arising from the location of the installation;

(d) information about waste management–

(i) types, quantities and potential hazards arising from the use of the micro-organisms,

(ii) waste management techniques used including recovery of liquid or solid wastes and the inactivation techniques used, and

(iii) ultimate form and destination of inactivated wastes;

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

(i) the sources of hazards and conditions under which accidents might occur,

(ii) the preventive measures applied such as safety equipment, alarm systems, containment methods and procedures and available resources,

(iii) a description of information given to workers, and

(iv) the information necessary for the Competent Authority to evaluate any emergency plan prepared in accordance with regulation 12;

(f) the full risk assessment referred to in regulation 6; and

(g) any other information the Competent Authority needs for the purpose of maintaining the register referred to in regulation 15.

PUBLIC HEALTH (GENETICALLY MODIFIED ORGANISMS) (CONTAINED USE) REGULATIONS 1995
SCHEDULE 6

Subsidiary 1995/155

Regulation 11(4)

CONTAINMENT MEASURES FOR MICRO-ORGANISMS OF GROUP II

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

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

		Containmen t Level	Containm ent Level	Containment Level
	Specification s	B2	B3	B4
1	Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system)	Yes	Yes	Yes
2	Exhaust gases from the closed system should be	Minimise release	Prevent release	Prevent release

	treated so as to -			
3	Sample collection, addition of materials to a closed system and transfer of viable micro-organisms to another closed system, should be performed so as to -	Minimise release	Prevent release	Prevent release
4	Bulk culture fluids should not be removed from the closed system unless the viable micro-organisms have been -	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5	Seals should be designed to -	Minimise release	Prevent release	Prevent release

6	Closed systems should be located within a controlled area,	Optional	Optional	Yes, and purpose built
	(a) Biohazard signs should be posted	Optional	Yes	Yes
	(b) Access should be restricted to nominated personnel only,	Optional	Yes	Yes, via airlock
	(c) Personnel should wear protective clothing,	Yes, work clothing	Yes	Yes, a complete change
	(d)Decontam--ination and washing facilities should be provided for personnel	Yes	Yes	Yes
	(e)Personnel should shower before leaving the controlled area	No	Optional	Yes
	(f) Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes
	(g) The controlled area should be adequately ventilated to minimise air contamination	Optional	Optional	Yes
	(h) The	No	Optional	Yes

	controlled areas should be maintained at an air pressure negative to atmosphere (i) Input air and extract air to the controlled area should be HEPA filtered (j) The controlled area should be designed to contain spillage of the entire contents of the closed system (k) The controlled area should be sealable to permit fumigation	No Optional No	Yes Yes Optional	Optional Yes Yes
7	Effluent treatment before final discharge	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated physical means