Regulations made under s. 180X of the Public Health Act and section 23 of the Interpretation and General Clauses Act.

PUBLIC HEALTH (GENETICALLY MODIFIED MICRO-ORGANISMS) (CONTAINED USE) REGULATIONS 2001

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Transposing:
Directive 98/81/EC

Subsidiary 2001/038

PUBLIC HEALTH (GENETICALLY MODIFIED MICRO-ORGANISMS) (CONTAINED USE) REGULATIONS 2001

This version is out of date

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PUBLIC HEALTH (GENETICALLY MODIFIED MICRO-ORGANISMS) (CONTAINED USE) REGULATIONS 2001

This version is out of date

In exercise of the powers conferred on the Government by section 180X of the Public Health Act and section 23 of the Interpretation and General Clauses Act, and for the purpose of transposing into the law of Gibraltar Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC as amended by Commission Directive 94/51/EC on the contained use of genetically modified micro-organisms the Government has made the following regulations–

PART I

Citation and commencement.

1. These Regulations may be cited as the Public Health (Genetically Modified Organisms) (Contained Use) Regulations 2001.

Interpretation.

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

"accident" means an incident involving a significant and unintended release of genetically modified micro-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 the person or body designated as the Competent Authority by the Government from time to time by notice in the Gazette under section 180A of the principal Act;

"contained use" means an activity in which micro-organisms are genetically modified or in which genetically modified micro-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 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;

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

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

"genetic modification" in relation to a micro-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;

"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) or 11(1);

"working day" means any day other than a bank or public holiday within the meaning given to these terms by the Banking and Financial Dealings Act and the Interpretation and General Clauses Act respectively.

(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 sub-regulations 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 sub-regulation 3(i) and (j) of Part II of Schedule 3; and

(3) The provisions in–

(a) Part II of Schedule 7 shall be applied in accordance with Part I of that Schedule; and

(b) Tables 1a, 1b and 1c in Part II of Schedule 7 shall be applied in accordance with the notes set out at the end of the Table in question.

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 micro-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 micro-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 micro-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 competent authority under section 180F, or

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

(b) genetically modified micro-organisms are released or marketed in cases or circumstances in which the consent of the competent authority is required under section 180F.

(4) Regulations 8 to 15 shall not apply to the transport of genetically modified micro-organisms by land, sea or air.

(5) Regulation 6 shall apply to the transport of genetically modified micro-organisms by land, 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 sub-regulation 3(h) to (j) of Part II of Schedule 3.

Meaning of "product".

4. In these regulations and unless the context otherwise requires, "product" means a product consisting of or containing a genetically modified micro-organism or a combination of genetically modified organisms.

Meaning of "work" and "at work".

5. For the purpose of these Regulations and Part IVA of the principal 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.

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 sub-regulation (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.

Review of risk assessments.

7. 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.

Recording of risk assessments.

8.(1) 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.

(2) 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 4; and

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

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with sub-regulation (1), the competent authority 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 sub-regulations 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 5.

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with sub-regulation (1), the competent authority 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 sub-regulation (1) at the premises referred to in a notification submitted in accordance with that sub-regulation 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 sub-regulation (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 sub-regulation (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 sub-regulation (1) refers;

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

(5) Where a person submits a notification in accordance with sub-regulation (1) in respect of an activity referred to in that sub-regulation 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 sub-regulation (5) within 45 days of the date on which the acknowledgement was sent in accordance with sub-regulation (2).

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

11.(1) Subject to the following sub-regulations 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 5; 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 sub-regulation (1), the competent authority shall send to the notifier an acknowledgement of receipt.

(3) Where a person proposes to undertake an activity referred to in sub-regulation (1) for the first time at the premises referred to in a notification submitted in accordance with that sub-regulation, 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 sub-regulation (2).

(4) Where a person proposes to undertake an activity referred to in sub-regulation (1) for the second or subsequent times at the premises referred to in a notification submitted in accordance with that sub-regulation, 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 sub-regulation (2).

(5) Before granting a consent under either sub-regulation (3) or sub-regulation (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 sub-regulation (3) or sub-regulation (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 competent authority sent the acknowledgement of receipt in accordance with sub-regulation (2).

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

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

12.(1) Where a notification is required–

(a) under regulation 9(1) in respect of premises; or

(b) under regulation 10(1) or 11(1) in respect of an activity involving genetic modification,

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

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

Definitions for purposes of regulation 12.

13. In regulation 12–

(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) or 11(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) 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 sub-regulation (1), the competent authority 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

competent authority, the notifier shall not begin nor, subject to sub-regulation (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) or 10(1) has commenced the activity involving genetic modification before the competent authority requests additional information in accordance with sub-regulation (2)–

(a) the competent authority 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 micro-organisms resulting from the activity since its commencement.

(4) If requested to do so by the Government the competent authority shall request additional information under sub-regulation (2).

(5) Within 10 working days, the competent authority shall acknowledge receipt of all additional information provided in response to a request made by the competent authority under sub-regulation (2).

(6) The period of time between the date when the competent authority requests additional information in accordance with sub-regulation (2) and the date when the competent authority 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), or 11(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) or 11(1) has not commenced the activity relating to genetic modification to which his notification relates; and

(b) the competent authority requests additional information pursuant to sub-regulation (2); and

(c) the notifier in question does not provide that information within a period of six months of the date on which the competent authority 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 sub-regulations (a), (d) or (e) of Schedule 4 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) or 11(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 undersub-regulation (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) paragraph (b) and (c) of Schedule 4 and provided by him in accordance with regulation 9(1), or

(ii) paragraph 1(c) or (d) of Part I of Schedule 5 and provided by him in accordance with regulation 10(1).

(3) Subject to sub-regulations (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 sub-regulation (5), where a change referred to in sub-regulation (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) Sub-regulation (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 sub-regulation (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.

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 the exposure of humans and the environment to genetically modified 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 sub-regulation (1) shall include the general principles of good microbiological practice and of good occupational safety and hygiene set out in Schedule 6.

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

18.(1) Subject to sub-regulation (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 7, 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 7, 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.

Review of containment measures.

19.(1) A person who undertakes an activity involving genetic modification of micro-organisms shall review the containment measures applied by him in accordance with sub-regulation (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.

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

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) 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.

(3) 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 sub-regulation (2); 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 micro-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 sub-regulation (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 sub-regulation (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) Subject to sub-regulation (2), where, either in a notification submitted under regulation 9(1), 10(1) or 11(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 any ground–

(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.

(2) Subject to sub-regulation (7), sub-regulation (1) shall not apply to the following information, which shall not be kept confidential–

(a) the name and address of the notifier;

(b) the location of the activity,

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

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

(e) the containment measures, and

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

(3) 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 sub-regulation (1)(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.

(4) Where the competent authority has made a decision under sub-regulation (1)(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.

(5) A person who receives information by virtue of sub-regulation (3)(a) or (4)(a) shall not use that information except for the purposes of the competent authority.

(6) 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).

(7) Notwithstanding sub-regulation (2), 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 sub-regulation (2) 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 sub-regulation (9), where, pursuant to sub-regulation (1) or (7), 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 sub-regulation (1)(a) or the evidence submitted under sub-regulation (7), as the case may be.

(9) Sub-regulation (8) shall not apply if the competent authority has informed the notifier that the information in question is not to be kept confidential or withheld.

(10) Where–

(a) the competent authority has decided to keep information confidential pursuant to sub-regulation (1)(b) or has withheld information pursuant to sub-regulation (7); and

(b) the notifier has informed the competent authority of any change in circumstances pursuant to sub-regulation (8),

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.

(11) 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) Subject to sub-regulation (2), where a person indicates that information provided by him pursuant to regulation 21 should be kept confidential on any grounds set out in article 3(2) of Council Directive 90/313/EEC of 7 June 1990 on freedom of access to information on the environment–

(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.

(2) Subject to sub-regulation (6), sub-regulation (1) 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 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 actual and foreseeable effects, in particular any harmful effects on human health and the environment.

(3) 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 sub-regulation (1)(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).

(4) Where the competent authority has made a decision under sub-regulation (1)(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).

(5) A person who receives information by virtue of sub-regulation (3) or (4) shall not use that information except for the purposes of the competent authority.

(6) Notwithstanding sub-regulation (2), 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 sub-regulation (2) 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.

(7) Subject to sub-regulation (8), where, pursuant to sub-regulation (1) or (6), 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 sub-regulation (1)(a) or the evidence submitted under sub-regulation (6), as the case may be.

(8) Sub-regulation (7) shall not apply if the competent authority has informed the person providing the information that the information in question is not be kept confidential or withheld.

(9) Where–

(a) the competent authority has decided to keep information confidential pursuant to sub-regulation (1)(b) or has withheld information pursuant to sub-regulation (6); and

(b) the person who provided the information has informed the competent authority of a change in circumstances pursuant to sub-regulation (7),

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.

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

PART V
MISCELLANEOUS AND GENERAL

Enforcement and civil liability.

24.(1) It is an offence for a person other than the Competent Authority–

(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.

Schedules to have effect.

25. Schedule 1 to 7 shall have effect.

Revocation.

26.(1) The Public Health (Genetically Modified Organisms) (Contained Use) Regulations 1995 are revoked.

SCHEDULE 1

Regulation 25

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

Regulation 25

PART I

EXAMPLES OF TECHNIQUES CONSTITUTING GENETIC MODIFICATION

1. Examples of the techniques which constitute genetic modification which are referred to in sub-sub-regulation (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 a micro-organism of heritable genetic material prepared outside the micro-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 micro-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. The 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 micro-organisms other than those recombinant nucleic acid molecules or genetically modified micro-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 micro-organism is unlikely to cause disease or harm to humans, animals or plants.

4. In sub-paragraph 3–

(a) "self-cloning" means the removal of nucleic acid sequences from a cell of a micro-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 micro-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

Regulation 25

PART I

MATTERS TO BE TAKEN INTO ACCOUNT IN CARRYING OUT AN ASSESSMENT 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 sub-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 micro-organisms, plants or animals;

(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 as amended by Council Directive 93/88/EEC and Commission Directives 95/30/EC, 9759/EC and 97/65/EC 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-sub-paragraph (e) above;

(g) selection of the appropriate containment measures from those specified in the applicable Table in Schedule 7 on the basis of the provisional level of risk as adjusted in accordance with sub-sub-paragraph (f) above;

(h) assignment of the activity involving genetic modification of micro-organisms to the appropriate containment level, in accordance with sub-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 sub-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 7 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-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 sub-regulation 4, "selected containment measure" means an appropriate containment measure selected in accordance with sub-paragraph 3(g).

SCHEDULE 4

Regulation 25

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(2).

SCHEDULE 5

Regulation 25

PART I

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 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(2).

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).

SCHEDULE 6

Regulation 25

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 micro-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 7

Regulation 25

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					
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	Micro-biological 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
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 protect-ive 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
14	Efficient control of disease	required	required	required	required

	vectors (eg rodents and insects) which could disseminate GMMs	where and to extent the risk assessment shows they are required			
15	Specified disinfection procedures in place	required where and to extent the risk assesment shows they are required	required	required	required
Waste					
16	Inactivation of GMMs in effluent from hand washing 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 alternative is to be present so that occupants can be seen	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
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 sub-regulation 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 shows it is required	required	required	required	Modification
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	required so as to prevent run-off	required so as to prevent run-off	required so as to prevent run-off	Additional

		shows it is required				
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 dissemin-ation	required so as to prevent dissemina-tion	required so as to prevent dissemina-tion	Additional
6	Procedures for transfer of living material between the plant growth facilities, protective structure and laboratory shall control dissemina-tion of GMMs	required so as to minimise disseminati on	required so as to prevent dissemina-tion	required so as to prevent disseminati on	required so as to prevent disseminati on	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.

Table 1c:Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Animal Units (to be read with Table 1a as indicated in sub-regulation 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	Modification

		required				
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) designed to facilitate decontamin-ation (waterproof and easily washable material)	required where and to extent the risk assessment shows they are required	required where and to extent the risk assesment shows they are required	required	required	Additional
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, tanks or isolators	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 assess-ment shows it is required	required where and to extent the risk assess-ment 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.

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 closed system or transfer of material to another closed system	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
5	Inactivation of bulk culture fluids before removal from the closed system	required where and to extent the risk assessment	required by validated means	required by validated means	required by validated means

		shows it is required			
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, disinfectants and decontamination agents and easy to clean	required for any bench	required for any bench	required for floor and any bench	required for bench, floor, ceiling and walls
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	required

				assessment shows it is 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 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