SUBSIDIARY LEGISLATION 549.49

CONTAINED USE OF GENETICALLY MODIFIED MICRO-ORGANISMS REGULATIONS

29th April, 2008

LEGAL NOTICE 127 of 2008, as amended by Legal Notice 265 of 2010.

1. The title of these regulations is the Contained Use of Genetically Modified Micro-Organisms Regulations. Citation.

2. (1) The objective of these regulations is to lay down measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment. Objectives. *Amended by: L.N. 265 of 2010.*

(2) These regulations provide the provisions required for the implementation in Malta of the European Council Directive 2009/41/EC of 6th May 2009 on the contained use of genetically modified micro-organisms (recast) and shall be read and construed as one with such legal instrument.

(3) These regulations are to be read and construed with the Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations, in relation to issues in connection with occupational health and safety. S.L. 424.25

PART I: DEFINITIONS AND EXEMPTIONS

3. In these regulations, unless the context otherwise requires: Interpretation.

"accident" means any incident involving a significant and unintended release of GMMs in the course of their contained use which could present an immediate or delayed hazard to human health or the environment;

"the competent authority" means the Environment and Resources Authority as prescribed by the Nomination of the Competent Authority Order, and such other body or person as the Minister responsible for the environment may by order in the Gazette prescribe and different bodies or persons may be designated as the competent authority for different provisions and different purposes of these regulations; S.L. 549.19

"contained use" means any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment;

"genetically modified micro-organism" or "GMM" means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and, or natural recombination.

Within the terms of this definition:

(*a*) genetic modification occurs at least through the use of the techniques listed in Schedule I, Part A;

(*b*) the techniques listed in Schedule I, Part B, are not considered to result in genetic modification;

"micro-organism" means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture;

"the Minister" means the Minister responsible for the environment;

"notification" means the presentation of the requisite information to the competent authority;

"user" means any natural or legal person responsible for the contained use of GMMs.

PART II: ASSESSMENT

Assessment.

4. (1) In order to ensure that the contained use of GMMs does not produce adverse effects on human health and the environment the user shall carry out an assessment of the contained uses as regards the risks to human health and the environment that these contained uses may incur, using as a minimum the elements of assessment and the procedure set out in Schedule III, sections A and B.

(2) The assessment referred to in sub-regulation (1) shall result in the final classification of the contained uses in four classes applying the procedure set out in Schedule III, which will result in the assignment of containment levels in accordance with sub-regulations (6) and (7):

Class 1: activities of no or negligible risk, for which level 1 containment is appropriate.

Class 2: activities of low risk, for which level 2 containment is appropriate.

Class 3: activities of moderate risk, for which level 3 containment is appropriate.

Class 4: activities of high risk, for which level 4 containment is appropriate.

(3) Where there is doubt as to which class is appropriate for the proposed contained use, the more stringent protective measures shall be applied unless sufficient evidence, in agreement with the Competent Authority, justifies the application of less stringent measures.

(4) The assessment referred to in sub-regulation (1) shall especially take into account the question of disposal of waste and effluents. Where appropriate, the necessary safety measures shall be implemented in order to protect human health and the environment.

(5) A record of the assessment referred to in sub-regulation (1)

shall be kept by the user and made available in an appropriate form to the Competent Authority as part of the notification pursuant to regulations 6, 8 and 9 or on request.

(6) The user shall apply, except to the extent that paragraph 2 of Schedule IV allows other measures to be applied, the general principles and the appropriate containment and other protective measures set out in Schedule IV corresponding to the class of the contained use, so as to keep workplace and environmental exposure to any GMMs to the lowest reasonably practicable level, and so that a high level of safety is ensured.

(7) The assessment referred to in sub-regulation (1) and the containment and other protective measures applied shall be reviewed periodically, and forthwith if:

(*a*) the containment measures applied are no longer adequate or the class assigned to the contained uses is no longer correct, or

(*b*) there is reason to suspect that the assessment is no longer appropriately judged in the light of new scientific or technical knowledge.

Exemptions.

5. (1) Without prejudice to regulation 4(1), these regulations shall not apply:

(*a*) where genetic modification is obtained through the use of the techniques or methods listed in Schedule II, Part A, or

(*b*) for contained uses involving only types of GMMs meeting the criteria listed in Schedule II, Part B which establish their safety to human health and the environment. These types of GMMs are listed in Schedule II, Part C.

(2) Regulation 4(2), 4(5), 4(6), 4(7) and regulations 6 to 11 shall not apply to the transport of GMMs by road, sea or air.

(3) These regulations shall not apply to the storage, culture, transport, destruction, disposal or use of GMMs which have been placed on the market in accordance with the Deliberate Release into the Environment of Genetically Modified Organisms Regulations, or pursuant to other relevant legislation, which provides for a specific environmental risk assessment similar to that laid down in the said regulations, provided that the contained use is in accordance with the conditions, if any, of the consent for placing on the market.

S.L. 549.60

PART III: PERMITTING AND PENALTIES

Premises used for the first time.

6. When premises are to be used for the first time for contained uses, the user shall be required to submit to the competent authority, before commencing such use, a notification containing at least the information listed in Schedule V, Part A.

Contained use of Class 1.

7. (1) For the first time or subsequent Class 1 contained uses to be carried out in premises notified in accordance with regulation 6, a notification containing the information listed in Schedule V,

Part B (excluding the summary of assessment referred to in regulation 4(1)), shall be submitted to the competent authority. The Class 1 contained use may proceed immediately following notification.

(2) Users of GMMs in Class 1 contained use shall be required to keep a record of each assessment referred to in regulation 4(5), which shall be made available to the competent authority on request.

Contained use of Class 2.

8. (1) For the first and subsequent Class 2 contained uses to be carried out in premises notified in accordance with regulation 6, a notification containing the information listed in Schedule V, Part B shall be submitted to the competent authority.

(2) If the premises have been the subject of a previous notification to carry out Class 2 or a higher class of contained uses and any associated consent requirements have been satisfied, the Class 2 contained use may proceed immediately following the new notification:

Provided that the applicant can, however, himself request a decision on a formal authorisation from the competent authority. The decision must be made within a maximum of forty-five days from the notification.

(3) If the premises have not been the subject of a previous notification to carry out Class 2 or a higher class of contained uses, the Class 2 contained use may, in the absence of any indication to the contrary from the competent authority, proceed forty-five days after submission of the notification referred to in sub-regulation (1), or earlier with the agreement of the competent authority.

Contained use of Class 3 and Class 4.

9. (1) For the first and subsequent Class 3 or Class 4 contained uses to be carried out in premises notified in accordance with regulation 6, a notification containing the information listed in Schedule V, Part C shall be submitted to the competent authority.

(2) A Class 3 or higher class of contained use may not proceed without the prior consent of the competent authority which shall communicate its decision in writing:

(*a*) at the latest forty-five days after submission of the new notification, in the case of premises which have been the subject of a previous notification to carry out Class 3 or a higher class of contained uses and where any associated consent requirements have been satisfied for the same or a higher class than the contained use with which it is intended to proceed;

(*b*) at the latest ninety days after submission of the notification, in other cases.

Notifications to the competent authority.
Amended by: L.N. 265 of 2010.

10. (1) The person submitting a notification in order to obtain a permit for activities referred to in regulations 6, 7, 8 and 9, hereinafter referred to as the applicant, shall submit his request in writing to the competent authority prior to carrying out such activities.

(2) In order to enable the competent authority to adequately assess a notification and issue a permit, the application shall be accompanied by the relevant documents and any other requisite information as specified and required by the competent authority. The applicant shall clearly indicate whether the application prejudices any enforcement case, court case or other causes currently *sub-judice*.

(3) The competent authority shall examine the conformity of the notifications with the requirements of these regulations, the accuracy and completeness of the information given, the correctness of the assessment referred to in regulation 4(1) and the class of contained uses and, where appropriate, the suitability of the containment and other protective measures, the waste management, and emergency response measures.

(4) If necessary, the competent authority may:

(*a*) ask the user to provide further information or to modify the conditions of the proposed contained use or to amend the class assigned to any contained use;

Provided that in this case the competent authority may require that the contained use, if proposed, does not begin, or, if in progress, is suspended or terminated, until the competent authority has given its approval on the basis of the further information obtained or of the modified conditions of the contained use;

(*b*) limit the time for which the contained use should be permitted or subject it to certain specific conditions.

(5) For the purpose of calculating the periods referred to in regulations 8 and 9, any period of time during which the competent authority:

(*a*) is awaiting any further information which it may have requested from the notifier in accordance with sub-regulation (4)(*a*), or

(*b*) is carrying out a public inquiry or consultation in accordance with regulation 15,

shall not be taken into account.

(6) Whenever the competent authority issues a permit, it may impose such conditions as it may deem fit and appropriate.

(7) Whenever the competent authority refuses such permit, it shall inform the applicant of the reasons for such refusal.

(8) The period of validity of such permit shall also be established at the discretion of the competent authority.

(9) The applicant shall provide a copy of any published results and other publications relevant to this permit to the competent authority within three months from the date of publication.

(10) The competent authority shall not issue or renew any permit if the applicant in question has not fulfilled or honoured any of the conditions or obligations arising from any other permit issued by the competent authority under these regulations and, or the related

regulations.

New information on risks of contained use.

11.(1)(*a*) If new information subsequently becomes available to the competent authority which could have significant consequences for the risks posed by the contained use, the competent authority may require the user to modify the conditions of, or suspend or terminate, the contained use.

(*b*) Where a user becomes aware of new information or modifies the contained use in a way which could have significant consequences for the risks posed by it, the user shall discontinue the contained use and, as soon as practicable, inform the competent authority.

(2) Prior to resuming a contained use discontinued in accordance with sub-regulation (1), the user shall -

(*a*) review the assessment carried out in accordance with regulation 4, and the class and level of containment applied in accordance with regulation 4(2); and

(*b*) submit an amended notification to the competent authority.

(3) For the purposes of sub-regulation (2) the provisions in relation to the submission of a notification by a user in accordance with regulations 6, 8 or 9, and to the processing and determination of such a notification by the competent authority in accordance with regulation 10, shall apply, as appropriate, to an amended notification as if it were a notification under regulations 6, 8 or 9.

Offences.

12. (1) Any person shall be guilty of an offence under these regulations if:

(*a*) he fails to comply with any provision of these regulations or fails to comply with permit conditions or with any order lawfully given in terms of any provision of these regulations; or

(*b*) he contravenes any restriction, prohibition or requirement imposed by or under these regulations; or

(*c*) he acts in contravention of any of the provisions of these regulations; or

(*d*) he makes a statement or presents information or documentation, which such person knows to be false for the purpose of obtaining the approval or continuation of a permit in line with regulations 6, 8, 9 or 11(2)(*b*); or

(*e*) he conspires or attempts to conspire, aids or attempts to aid, abets or attempts to abet, counsel or attempt to counsel, procures or attempt to procure any other person to contravene the provisions of these regulations or to fail to comply with any such provisions, including any order lawfully given in terms of any of the provision of these regulations, or to contravene any restriction, prohibition or requirement

imposed by or under the said regulations or by virtue thereof.

(2) Any person who commits, or attempts to commit an offence against these regulations shall, on conviction, be liable to the following range of penalties: Penalties.

(*a*) on first conviction for an offence under Class 1 a fine (*multa*) of not less than five hundred euro (€500) but not exceeding one thousand euro (€1,000); on a second or subsequent convictions for an offence under Class 1, a fine (*multa*) of not less than one thousand euro (€1,000), but not exceeding two thousand five hundred euro (€2,500) or to imprisonment for a term not exceeding two years or to both such fine and imprisonment;

(*b*) on first conviction for an offence under Class 2 a fine (*multa*) of not less than one thousand euro (€1,000) but not exceeding two thousand euro (€2,000); on a second or subsequent convictions for an offence under Class 2, a fine (*multa*) of not less than two thousand euro (€2,000), but not exceeding three thousand five hundred euro (€3,500) or to imprisonment for a term not exceeding two years or to both such fine and imprisonment;

(*c*) on first conviction for an offence under Class 3 a fine (*multa*) of not less than two thousand five hundred euro (€2,500) but not exceeding six thousand euro (€6,000); on a second or subsequent convictions for an offence under Class 3, a fine (*multa*) of not less than four thousand five hundred euro (€4,500), but not exceeding twenty-five thousand euro (€25,000) or to imprisonment for a term not exceeding two years or to both such fine and imprisonment;

(*d*) on first conviction for an offence under Class 4 a fine (*multa*) of not less than twelve thousand euro (€12,000) but not exceeding twenty-five thousand euro (€25,000); on a second or subsequent convictions for an offence under Class 4, a fine (*multa*) of not less than twenty-five thousand euro (€25,000), but not exceeding thirty-five thousand euro (€35,000) or to imprisonment for a term not exceeding two years or to both such fine and imprisonment:

Provided that the Court shall order any person who has been found guilty of committing an offence against these regulations to pay for the expenses incurred by the competent authority as a result of the said offence, including any remedying action for any damage caused by the said offence, the revocation of the permit issued by the competent authority and the confiscation of the *corpus delicti*, including any expenses incurred for the keeping and transport of the said *corpus delicti*.

(3) The Court shall order the offender to remove the causes of the offence and to undo anything which was done without a permit

within a time sufficient for the purpose to be fixed by the Court; and, if the offender fails to comply with any such order within the time so fixed, he shall be liable to a fine (*multa*) of not less than sixty euro (€60) and not more than five hundred euro (€500), as the Court may fix, for every day that the default continues after the expiration of the said time.

Applicability of the Criminal Code. Cap. 9.

(4) The provisions of articles 23 and 30 of the Criminal Code shall apply, *mutatis mutandis*, to proceedings in respect of offences against these regulations, so however that the disqualification from holding or obtaining a licence or permit from the competent authority shall in no case be for less than one year.

Cap. 9.

(5) Notwithstanding the provisions of article 370 of the Criminal Code, proceedings for an offence against these regulations shall be held before the Court of Magistrates (Malta) or the Court of Magistrates (Gozo), as the case may be, and shall be in accordance with the provisions of the Criminal Code regulating the procedure before the said courts as courts of criminal judicature.

Cap. 9.

(6) Notwithstanding the provisions of the Criminal Code, the Attorney General shall always have a right of appeal to the Court of Criminal Appeal from any judgement given by the Court of Magistrates (Malta) or the Court of Magistrates (Gozo) in respect of proceedings for any offence against these regulations.

Inspections and control measures.

13. The competent authority may organise inspections and other control measures to ensure user compliance with these regulations.

PART IV: PUBLIC CONSULTATION AND CONFIDENTIALITY

Disclosure of confidential data.

14. (1) Where disclosure of data related to these regulations, affects one or more of the following -

(*a*) the confidentiality of the proceedings of public authorities, international relations and national defence,

(*b*) public security,

(*c*) matters which are, or have been, *sub judice*, or under enquiry (including disciplinary enquiries), or which are the subject of preliminary investigation proceedings,

(*d*) commercial and industrial confidentiality, including intellectual property,

(*e*) the confidentiality of personal data and, or files,

(*f*) material supplied by a third party without that party being under a legal obligation to do so,

(*g*) material, the disclosure of which would make it more likely that the environment to which such material is related would be damaged,

the notifier may indicate the information in the notifications submitted pursuant to these regulations that should be treated as confidential:

Provided that a verifiable justification must be given in such cases.

(2) The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decision.

(3) In no case may the following information, when submitted according to regulations 6, 8 or 9, be kept confidential:

(*a*) the general characteristics of the GMMs, name and address of the notifier, and location of use,

(*b*) class of contained use and measures of containment,

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

(4) The competent authority shall not divulge to third parties any information decided to be confidential according to subregulation (2) and notified or otherwise provided pursuant to these regulations, and shall protect intellectual property rights relating to the data received.

(5) If, for whatever reasons, the notifier withdraws the notification, the competent authority must respect the confidentiality of the information supplied.

Public consultation.

15. Without prejudice to regulation 14, the competent authority may hold public consultations on aspects of the proposed contained use where it considers to be appropriate.

PART V: ACCIDENTS AND EMERGENCY PLANS

Emergency plans.

16. (1) The competent authority shall ensure that before a contained use commences:

(*a*) an emergency plan is drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and, or to the environment, except where such an emergency plan has been drawn up under other relevant legislation;

(*b*) information on such emergency plans, including the relevant safetymeasures to be applied, is supplied in an appropriate manner, and without them having to request it, to bodies and authorities liable to be affected by the accident. The information shall be updated at appropriate intervals. It shall also be made publicly available.

(2) The competent authority shall at the same time make available to other Member States concerned, the same information as that which is disseminated to their nationals.

Occurrences of accidents.

17. (1) In the event of an accident, the user shall be required to inform immediately the competent authority and provide the following information:

(*a*) the circumstances of the accident,

(*b*) the identity and quantities of the GMMs concerned,

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

(*d*) the measures taken.

S.L. 424.25

(2) The user shall also inform the competent authority, cited in the Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations, of such accident.

(3) Where information is given pursuant to sub-regulation (1), the competent authority, in collaboration with the competent authority cited in sub-regulation (2), shall be required to:

(*a*) ensure that any measures necessary are taken, and immediately alert other Member States which could be affected by the accident,

(*b*) 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 the effects thereof.

(4) In the event of an accident, the competent authority, in collaboration with the competent authority cited in sub-regulation (2), may require the user to defray or contribute towards any or all of the costs incurred by it arising from such accident.

Communication with other Member States.

18. The competent authority shall consult with other Member States, likely to be affected in the event of an accident, on the proposed implementation of emergency plans.

PART VI: FEES

Fee for notification of use of a premises.

19. (1) A fee shall be paid to the competent authority in respect of:

Fee for notification of first time use of a premises.

(*a*) a notification of a first time use of a premises given to the competent authority under regulation 6, in accordance with the applicable fees indicated in Part A of Schedule VI, whichever is appropriate;

Fee for notification of any individual contained use.

(*b*) a notification of an individual contained use given to the competent authority under regulations 7, 8 and 9, in accordance with the applicable fees indicated in Part B of Schedule VI, whichever is appropriate;

Fee for an amended notification of a contained use.

(*c*) an amended notification of a contained use given to the competent authority under regulation 11, in accordance with the applicable fees indicated in Part C of Schedule VI, whichever is appropriate.

Agency investigations.

(2) The competent authority may carry out, or arrange to have carried out, such additional investigations as it considers necessary, as part of its examination or monitoring of a notification of a contained use to enable it properly to assess the notification and may require the user to defray or contribute towards the cost of any such investigations.

(3) The competent authority may recover the amount of any payment due to it arising from a requirement under regulation 17(4). Recovery of costs or charges.

PART VII: OTHER PROVISIONS

20. Schedules I to VI are being published in the English language with the English text of these regulations. Schedules I to VI published in English only.

SCHEDULE I

PART A

Techniques of genetic modification referred to in regulation 3 are, *inter alia*:

1. 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.

2. Techniques involving the direct introduction into a micro-organism of heritable material prepared outside the micro-organism including micro-injection, macro-injection and micro-encapsulation.

3. Cell fusion or hybridisation 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 B

Techniques referred to in regulation 3 which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs made by techniques/methods other than techniques/ methods excluded by Schedule II, Part A:

(1) in vitro fertilisation;

(2) natural processes such as: conjugation, transduction, transformation;

(3) polyploidy induction.

SCHEDULE II

PART A

Techniques or methods of genetic modification yielding micro-organisms to be excluded from the Regulation on the condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs other than those produced by one or more of the techniques/methods listed below

1. Mutagenesis.

2. Cell fusion (including protoplast fusion) of prokaryotic species that exchange genetic material by known physiological processes.

3. Cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions.

4. Self-cloning consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent) with or without prior enzymic or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants.

Self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular micro-organisms.

PART B

Criteria establishing the safety of GMMs for human health and the environment

This Schedule describes in general terms the criteria to be met when establishing the safety of types of GMMs for human health and the environment.

1. GENERAL CRITERIA

2.1. Strain verification/authentication

Identity of the strain must be precisely established. Modification must be known and verified.

2.2. Documented and established evidence of safety

Documented evidence of the safety of the organism must be provided.

2.3. Genetic stability

Where any instability could adversely affect safety, evidence of stability is required.

3. SPECIFIC CRITERIA

3.1. Non-pathogenic

The GMM should not be capable of causing disease or harm to a healthy human, plant or animal. Since pathogenicity includes both toxigenicity and allergenicity, the GMM should therefore be:

3.1.1. Non-toxigenic

The GMM should not produce increased toxigenicity as a result of the genetic modification nor be noted for its toxigenic properties.

3.1.2. Non-allergenic

The GMM should not produce increased allergenicity as a result of the genetic modification nor be a noted allergen, having, for example, allergenicity comparable in particular with that of the micro-organisms identified in the Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations.

3.2. No harmful adventitious agents

The GMM should not harbour known harmful adventitious agents such as other micro-organisms, active or latent, existing alongside or inside the GMM that could cause harm to human health and the environment.

3.3. Transfer of genetic material

The modified genetic material must not give rise to harm if transferred nor should it be self-transmissible or transferable at a frequency greater than other genes of the recipient or parental micro-organism.

3.4. Safety for the environment in the event of a significant and unintended release GMMs must not produce adverse effects on the environment, immediate or delayed, should any incident involving a significant and unintended release occur.

PART C

Types of GMMs which meet the criteria listed in Part B can be referred to Schedule III of the Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations.

SCHEDULE III

PRINCIPLES TO BE FOLLOWED FOR THE ASSESSMENT REFERRED TO IN REGULATION 4(1)

This Schedule describes in general terms the elements to be considered and the procedure to be followed to perform the assessment referred to in regulation 4(1). It may be supplemented, as regards in particular section B, by guidance notes which may be issued by the competent authority.

A. ELEMENTS OF ASSESSMENT

1. The following should be considered as potentially harmful effects:

- disease to humans including allergenic or toxic effects,
- disease to animals or plants,
- deleterious effects due to the impossibility of treating a disease or providing an effective prophylaxis,
- deleterious effects due to establishment or dissemination in the environment,
- deleterious effects due to the natural transfer of inserted genetic material to other organisms.

2. The assessment referred to in regulation 4(1) should be based on the following:

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

(i) the recipient micro-organism;

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

(iii) the vector;

(iv) the donor micro-organism (as long as the donor micro-organism is used during the operation);

(v) the resulting GMM;

(*b*) the characteristics of the activity;

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

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

B. PROCEDURE

3. The first stage in the assessment process should be to identify the harmful properties of the recipient and, where appropriate, the donor micro-organism, any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties.

4. In general, only GMMs which show the following characteristics would be considered appropriate for inclusion in Class 1 as defined in regulation 4:

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

(ii) the nature of the vector and the insert is such that they do not endow the GMM with a phenotype likely to cause disease to humans, animals or

*This would only apply to animals and plants in the environment likely to be exposed.

plants (*), or likely to cause deleterious effects in the environment;

(iii) the GMM is unlikely to cause disease to humans, animals or plants (*) and is unlikely to have deleterious effects on the environment.

5. In order to obtain the necessary information to implement this process the user may firstly take into account relevant Community legislation (in particular Council Directive 90/679/EEC). International or national classification schemes (e.g. WHO, NIH, etc.) and their revisions due to new scientific knowledge and technical progress may also be considered.

These schemes concern natural micro-organisms and as such are usually based on the ability of micro-organisms to cause disease to humans, animals or plants and on the severity and transmissibility of the disease likely to be caused. Directive 90/679/EEC classifies micro-organisms, as biological agents, into four classes of risk on the basis of potential effects on a healthy human adult. These classes of risk can be used as guidance to the categorisation of the contained use activities in the four classes of risk referred to in regulation 4(2). The user may also take into consideration classification schemes referring to plant and animal pathogens (which are usually established on a national basis). The abovementioned classification schemes give only a provisional indication of the risk class of the activity and the corresponding set of containment and control measures.

6. The hazard identification process carried out in accordance with paragraphs 3 to 5, should lead to the identification of the level of risk associated with the GMM.

7. Selection of the containment and other protective measures should then be made on the basis of the level or risk associated with the GMMs together with consideration of:

(i) the characteristics of the environment likely to be exposed (e.g. whether in the environment likely to be exposed to the GMMs there are known biota which can be adversely affected by the micro-organisms used in the contained use activity);

(ii) the characteristics of the activity (e.g. its scale; nature);

(iii) any non-standard operations (e.g. the inoculation of animals with GMMs; equipment likely to generate aerosols).

Consideration of items (i) to (iii) for the particular activity may increase, reduce or leave unaltered the level of risk associated with the GMM as identified under paragraph 6.

8. The analysis carried out as described above will finally lead to the assignment of the activity to one of the classes described in regulation 4(2).

9. The final classification of the contained use should be confirmed by reviewing the completed assessment referred to in regulation 4(2).

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*This would only apply to animals and plants in the environment likely to be exposed.

SCHEDULE IV

CONTAINMENT AND OTHER PROTECTIVE MEASURES

General principles

1. These tables present the normal minimum requirements and measures necessary for each level of containment.

Containment is also achieved through the use of good work practices, training, containment equipment and special installation design. For all activities involving GMMs the principles of good microbiological practice and the following principles of good occupational safety and hygiene, shall apply:

(i) to keep workplace and environmental exposure to any GMM to the lowest practicable level;

(ii) to exercise engineering control measures at source and to supplement these with appropriate personal protective clothing and equipment when necessary;

(iii) to test adequately and maintain control measures and equipment;

(iv) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;

(v) to provide appropriate training of personnel;

(vi) to establish biological safety committees or subcommittees, if required;

(vii) to formulate and implement local codes of practice for the safety of personnel, as required;

(viii) where appropriate to display biohazard signs;

(ix) to provide washing and decontamination facilities for personnel;

(x) to keep adequate records;

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

(xii) to prohibit mouth pipetting;

(xiii) to provide written standard operating procedures where appropriate to ensure safety;

(xiv) to have effective disinfectants and specified disinfection procedures available in case of spillage of GMMs;

(xv) to provide safe storage for contaminated laboratory equipment and materials, when appropriate.

2. The titles of the tables are indicative:

Table I A presents minimum requirements for laboratory activities.

Table I B presents additions to and modifications of Table I A for glasshouse/ growth-room activities involving GMMs.

Table I C presents additions to and modifications of Table I A for activities with animals involving GMMs.

Table II presents minimum requirements for activities other than laboratory activities.

In some particular cases, it might be necessary to apply a combination of measures, from Table I A and Table II, of the same level. In some cases users may,

with the agreement of the competent authority, not apply a specification under a particular containment level or combine specifications from two different levels.

In these tables "optional" means that the user may apply these measures on a case-by-case basis, subject to the assessment referred to in regulation 4(1).

Table I A

Containment and other protective measures for laboratory activities

Specifications		Containment levels			
		1	2	3	4
1	Laboratory suite: isolation ([1])	Not required	Not required	Required	Required
2	Laboratory: sealable for fumigation	Not required	Not required	Required	Required
Equipment					
3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required (bench)	Required (bench)	Required (bench, floor)	Required (bench, floor, ceiling, walls)
4	Entry to lab via airlock ([2])	Not required	Not required	Optional	Required
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required	Required except for ([1])	Required
6	Extract and input air from the laboratory should be HEPA-filtered	Not required	Not required	Required (HEPA) ([4]) - extract air except for ([3])	Required (HEPA) ([5]) - input and extract air
7	Microbiological safety post	Not required	Optional	Required	Required
8	Autoclave	On site	In the building	En suite ([6])	In lab = double-ended
System of work					
9	Restritted access	Not required	Required	Required	Required
10	Biohazard sign on the door	Not required	Required	Required	Required
11	Specific measures to control aerosol dissemination	Not required	Required minimise	Required prevent	Required prevent
13	Shower	Not required	Not required	Optional	Required
14	Protective clothing	Suitable protective clothing	Suitable protective clothing and (optional) footwear	Suitable protective clothing	Complete change of clothing and footwear before entry and exit
15	Gloves	Not required	Optional	Required	Required

	Specifications	Containment levels			
		1	2	3	4
18	Efficient vector control (e.g. for rodents and insects)	Optional	Required	Required	Required
Waste					
19	Inactivation of GMMs in effluent from hand-washing sinks or drains and showers and similar effluents	Not required	Not required	Optional	Required
20	Inactivation of GMMs in contaminated material and waste	Optional	Required	Required	Required
Other measures					
21	Laboratory to contain its own equipment	Not required	Not required	Optional	Required
23	An observation window or alternative is to be present so that occupants can be seen	Optional	Optional	Optional	Required

([1]) Isolation = the laboratory is separated from other areas in the same building or is in a separated building.

([2]) Airlock = 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]) Activities where transmission does not occur via airborne route.

([4]) HEPA = High efficiency particulate air.

([5]) Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.

([6]) With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.

Table I B

Containment and other protective measures for glasshouses and growth-rooms

The terms "glasshouse" and "growth-room" refer to a structure with walls, a roof and a floor designed and used principally for growing plants in a controlled and protected environment.

All provisions of Table I A shall apply with the following additions/modifications:

Specifications		Containment levels			
		1	2	3	4
Building					
1	Greenhouse: permanent structure ([1])	Not required	Required	Required	Required
Equipment					
3	Entry via a separated room with two interlocking doors	Not required	Optional	Optional	Required
4	Control of contaminated run-off water	Optional	Minimise run-off ([2])	Prevent run-off	Prevent run-off
System of work					
6	Measures to control undesired species such as insects, rodents, anthropods	Required	Required	Required	Required
7	Procedures for transfer of living material between the glasshouse/growth-room, protective structure and laboratory shall control dissemination of genetically modified micro-organisms	Minimise dissemina-tion	Minimise dissemina-tion	Prevent dissemina-tion	Prevent dissemina-tion

([1]) The glasshouse shall consist of a permanent structure with a continuous waterproofed covering, located on a site graded to prevent entry of surface-water run-off having self-closing lockable doors.

([2]) Where transmission can occur through the ground.

Table I C

Containment and other protective measures for activities in animal units

All provisions of Table I A shall apply with the following additions/modifications:

Specifications		Containment levels			
		1	2	3	4
Facilities					
1	Isolation of animal unit ([1])	Optional	Required	Required	Required
2	Animal facilities ([2]) separated by lockable doors	Optional	Required	Required	Required
3	Animal facilities designed to facilitate decontamination (waterproof and easily washable material (cages, etc.))	Optional	Optional	Required	Required
4	Floor and/or walls easily washable	Optional	Required (floor)	Required (floor and walls)	Required (floor and walls)
5	Animals kept in appropriate containment facilities such as cages, pens or tanks	Optional	Optional	Optional	Optional
6	Filters on isolators or isolated room ([3])	Not required	Optional	Required	Required

([1]) Animal unit: a building, or separate area within a building containing facilities and other areas such as changing rooms, showers, autoclaves, food storage areas, etc..

([2]) Animal facility: a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures.

([3]) Isolators: transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

Table II

Containment and other protective measures for other activities

Specifications		Containment levels			
		1	2	3	4
General					
1	Viable micro-organisms should be contained in a system which separates the process from the environment (closed system)	Optional	Required	Required	Required
2	Control of exhaust gases from the closed system	Not required	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
3	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	Optional	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
4	Inactivation of bulk culture fluids before removal from the closed system	Optional	Required, by validated means	Required, by validated means	Required, by validated means
5	Seals should be designed so as to minimise or prevent release	Minimise dissemination	Minimise dissemination	Prevent dissemination	Prevent dissemination
6	The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Optional	Required	Required
7	The controlled area should be sealable to permit fumigation	Not required	Optional	Optional	Required
Equipment					
8	Entry via airlock	Not required	Not required	Optional	Required
9	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required (bench if any)	Required (bench if any)	Required (bench if any, floor)	Required (bench, floor, ceiling, walls)
10	Specific measures to adequately ventilate the controlled area in order to minimise air ventilation	Optional	Optional	Optional	Required
11	The controlled area should be maintained at an air pressure negative to the immediate surroundings	Not required	Not required	Optional	Required

	Specifications	Containment levels			
		1	2	3	4
12	Extract and input air from the controlled area should be HEPA filtered	Not required	Not required	Required (extract air, optional for input air)	Required (input and extract air)
System of work					
13	Closed systems should be located within a controlled area	Not required	Optional	Required	Required
14	Access should be restricted to nominated personnel only	Not required	Required	Required	Required
15	Biohazard signs should be posted	Not required	Required	Required	Required
17	Personnel should shower before leaving the controlled area	Not required	Not required	Optional	Required
18	Personnel should wear protective clothing	Required (work clothing)	Required (work clothing)	Required	Complete change before exit and entry
Waste					
22	Inactivation of GMMs in effluent from hand-washing sinks and showers or similar effluents	Not required	Not required	Optional	Required
23	Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	Optional	Required, by validated means	Required, by validated means	Required, by validated means

SCHEDULE V

PART A

Information required for the notification referred to in regulation 6:

- name of user(s) including those responsible for supervision and safety,
- information on the training and qualifications of the persons responsible for supervision and safety,
- details of any biological committees or subcommittees,
- address and general description of the premises,
- a description of the nature of the work which will be undertaken,
- the class of the contained uses,
- only for Class 1 contained uses, a summary of the assessment referred to in regulation 4(1) and information on waste management.

PART B

Information required for the notification referred to in regulation 8:

- the date of submission of the notification referred to in regulation 6,
- the name of the persons responsible for supervision and safety and information on the training and qualification,
- the recipient, donor and/or parental micro-organism(s) used and, where applicable, the host-vector system(s) used,
- the source(s) and the intended function(s) of the genetic material(s) involved in the modification(s),
- identity and characteristics of the GMM,
- the purpose of the contained use including the expected results,
- approximate culture volumes to be used,
- description of the containment and other protective measures to be applied, including information about waste management including the wastes to be generated, their treatment, final form and destination,
- a summary of the assessment referred to in regulation 4(1),
- the information necessary for the competent authority to evaluate any emergency response plans if required under regulation 16.

PART C

Information required for the notification referred to in regulation 9:

(*a*) - the date of submission of the notification referred to in regulation 6,
- the name of the persons responsible for supervision and safety and information on the training and qualification;

(*b*) - the recipient or parental micro-organism(s) to be used,
- the host-vector system(s) to be used (where applicable),
- the source(s) and intended functions(s) of the genetic material(s) involved in the modification(s),
- identity and characteristics of the GMM,
- the culture volumes to be used;

(*c*) - description of the containment and other protective measures to be

applied, including information about waste management including the type and form of wastes to be generated, their treatment, final form and destination,

- the purpose of the contained use including the expected results,
- description of the parts of the installation;

(d) information about accident prevention and emergency response plans, if any:

- any specific hazards arising from the location of the installation,
- the preventive measures applied such as safety equipment, alarm systems and containment methods,
- procedures and plans for verifying the continuing effectiveness of the containment measures,
- a description of information provided to workers,
- the information necessary for the competent authority to evaluate any emergency response plans if required under regulation 16;

(*e*) a copy of the assessment referred to in regulation 4(1).

SCHEDULE VI

Fees

Part A: First time use of facility

Class 1 - €500

Class 2 - €1,200

Class 3 - €4,700

Class 4 - €15,000

Part B: Individual contained use activities

Class 1 - €30

Class 2 - €800

Class 3 - €4,500

Class 4 - €10,000

Part C: Amended Notification

Class 1 - €30

Class 2 - €500

Class 3 - €1,500

Class 4 - €7,000