STATUTORY INSTRUMENTS.

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GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS, 2001

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S.I. No. 73 of 2001

GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS, 2001

The Minister for the Environment and Local Government, in exercise of the powers conferred on him by sections 6 and 111 of the Environmental Protection Agency Act, 1992 (No. 7 of 1992), and for the purpose of giving effect to Council Directive 98/81/EC of 26 October 1998[1] amending Directive 90/219/EEC of 23 April 1990[2], hereby makes the following Regulations.

[2] OJ No L 117, 08.05.1990, as last amended by Commission Directive 97/35/EC, OJ No L 169, 27.6.1997.

[1] OJ No L 330, 05.12.1998.

PART I Preliminary and General

Citation.

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

Commencement.

2. The Regulations shall come into operation on the 15th day of March, 2001.

Interpretation.

3. (1) In these Regulations, unless the context otherwise requires -

"accident" means any incident involving a significant and unintended release of a genetically modified micro-organism, in the course of its contained use, which could present an immediate or delayed hazard to human health or the environment;

"the 1994 Regulations" means the Genetically Modified Organisms Regulations, 1994;

"the Act" means the Environmental Protection Agency Act, 1992;

"the Agency" means the Environmental Protection Agency established under section 19 of the Act;

"competent authority" has the meaning assigned to it in article 4;

"the Directive" means Council Directive 90/219/EEC, as amended by Council Directive 98/81/EC, on the contained use of genetically modified micro-organisms;

"first time use of a premises" means the first time use of a premises for an activity involving a contained use of a genetically modified micro-organism;

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

"genetically modified organism" means an organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination, or by a combination of both;

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

"the Minister" means the Minister for the Environment and Local Government;

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

"organism" has the meaning assigned to it in section 111 of the Act, and includes any biological entity capable of replication or of transferring genetic material;

"premises" means any facility, including a laboratory, in which an activity involving the contained use of a genetically modified micro-organism is carried out, or where it is proposed to carry out such an activity or operation;

"user" means any legal or natural person responsible for a contained use, or for giving notification of, or for meeting any other requirements in relation to, a proposed contained use.

(2) (a) In Parts I and V, unless the context otherwise requires,

"contained use" means any activity in which organisms are genetically modified or in which such organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which specific containment and other protective measures are used to limit their contact with the general public and the environment.

(b) In Parts II, IV and VI, unless the context otherwise requires,

"contained use" means any activity in which micro-organisms are genetically modified or in which such micro-organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which specific containment and other protective measures are used to limit their contact with the general public and the environment.

(c) In Part III, unless the context otherwise requires,

"contained use" means any activity in which organisms other than micro-organisms are genetically modified or in which such organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which specific containment and other protective measures are used to limit their contact with the general public and the environment.

(3) (a) Within the terms of the definition of "genetically modified organism" and the definition "genetically modified micro-organism", as set out in sub-article

(1) for the purposes of these Regulations, genetic modification occurs through use of the techniques listed in Part I of the First Schedule.

(b) For the purposes of these Regulations, the techniques listed in Part II of the First Schedule are not considered to result in genetic modification.

(4) (a) In these Regulations, any reference to a Schedule, Part or article which is not otherwise identified is a reference to a Schedule, Part or article of these Regulations.

(b) In these Regulations, any reference to a sub-article or paragraph which is not otherwise identified is a reference to the sub-article or paragraph of the provision in which the reference occurs.

Competent authority.

4. The Agency shall be the competent authority for the purposes of these Regulations.

Obligations, etc.

5. A user or any other person carrying out an activity involving a contained use shall ensure that all appropriate measures are taken to avoid adverse effects on human health or the environment.

Savings.

6. A person shall not be entitled solely by reason of compliance with these Regulations to carry out a contained use.

Calculation of time.

7. For the purposes of calculating periods within which the Agency may make a decision under these Regulations, a period of time during which the Agency is awaiting any further information on a notification or any modification to a proposed contained use or any amendment of a proposed classification, which it may have requested from the user under article 25, shall not be taken into account.

Register.

8. (1) Subject to article 9, the Agency shall maintain a register (in these Regulations referred to as the "register") which shall contain the following entries, as appropriate, for each notification or record -

(a) the name and address of the user,

(b) the location or postal address of the premises to which a record, notification or amended notification relates,

(c) a description of each genetically modified organism involved,

(d) the purpose of the contained use,

(e) the date of receipt of a record, notification or amended notification,

(f) the date and nature of any information provided under article 30(3),

(g) the date of any request by the Agency under article 10 or 25,

(h) the date of any response from the user to any request by the Agency under article 10 or 25,

(i) the date of publication of a notice pursuant to article 20 or 21,

(j) the date of withdrawal of a notification or an amended notification,

(k) the date and nature of the decision by the Agency on a notification or an amended notification, and

(l) the date and outcome of any review referred to in article 10, or carried out under article 10 or 29.

(2) The register shall be made available at the headquarters of the Agency for inspection by any person free of charge during office hours.

(3) The information referred to in sub-article (1) shall be entered in the register -

(a) in the case of a notification, an amended notification, a record or any other information given to the Agency by a user, within seven days of its receipt by the Agency,

(b) in the case of a request by the Agency referred to in sub-article (1)(g), within seven days of the making of the request, or

(c) in the case of a decision by the Agency on a notification or an amended notification or on a review of a contained use, within seven days of issuing the decision on the notification or on the amended notification or on the conclusion of the review.

Confidential information.

9. (1) Where, in pursuance of these Regulations, a user-

(a) gives a notification under Part II or an assessment under Part III, which includes, or

(b) otherwise provides,

information to which access may be refused under article 7 or 8(1) of the European Communities Act, 1972 (Access to Information on the Environment) Regulations, 1998, and requests that the said information should be treated by the Agency as confidential information, verifiable justification for that request shall be given by the user.

(2) (a) Where a request is made under sub-article (1), the Agency shall, following consultation with the user, decide which information (if any) shall be treated as confidential information and shall inform the user of its decision.

(b) In making a decision under paragraph (a), the Agency shall consider whether the public interest would, on balance, be better served by refusing to treat any or all of the information as confidential information.

(3) The Agency shall comply with the provisions of article 8 in respect of the first time use of a premises or the contained use, as the case may be, not less than fourteen days after informing the user of its decision on a request under sub-article (1), unless the user decides not to proceed with the contained use and informs the Agency accordingly within the said fourteen days.

(4) Without prejudice to sub-article (3) or (5), the Agency shall not decide that any of the following shall be confidential information -

(a) the name and address of the user and the location of the contained use,

(b) the purpose of the contained use and the general characteristics of the genetically modified organism involved,

(c) where appropriate, the class of the contained use, and the level of containment, and

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

(5) If, before the Agency has reached a decision as to whether information should be treated as confidential information or within fourteen days of such decision the user decides not to proceed with the contained use and informs the Agency accordingly, the Agency shall treat the information in respect of which the request was made as confidential information.

(6) The provisions of this article shall not prevent disclosure by the Agency of information to the Minister, the Commission of the European Communities or the competent authority of another Member State of the European Communities for the purposes of the Directive.

Transitional arrangements.

10. (1) (a) Where, immediately on commencement of these Regulations, a notification or an amended notification given to the Agency, or a review of a contained use of a genetically modified micro-organism initiated by the Agency, under Part II of the 1994 Regulations, has yet to be determined, the notification, amended notification or review shall, unless the notification or amended notification is withdrawn, in lieu of being further considered by the Agency under the 1994 Regulations, be determined by the Agency as if it had originally been given or initiated, as the case may be, under these Regulations.

(b) For the purposes of determining a notification, an amended notification or a review referred to in paragraph (a), the Agency may request the user to give a notification in accordance with the provisions of Part II of these Regulations or to provide such further information as the Agency may require, or to do both.

(2) (a) The Agency shall, in accordance with the provisions of Part II of these Regulations, review—

(i) each contained use of a genetically modified micro-organism in respect of which a record was forwarded to the Agency in accordance with article 14(1) of the 1994 Regulations, and

(ii) each contained use of a genetically modified micro-organism carried on in accordance with article 17 or 18, as the case may be, of the said Regulations.

(b) For the purposes of reviewing a contained use to which paragraph (a) applies, the Agency may request the user to give a notification in accordance with the provisions of Part II of these Regulations or to provide such further information as the Agency may require, or to do both.

(c) A review to which paragraph (a) refers shall be initiated by the Agency within two years of the commencement of these Regulations.

(d) Pending completion of a review in accordance with paragraph (a), the provisions of the 1994 Regulations replaced by these Regulations, and any consent granted under the said 1994 Regulations, shall continue in force and have full effect.

(e) As soon as may be after it has completed a review under this sub-article, the Agency shall give a decision in accordance with article 26.

(3) (a) Where a user fails to comply with a request by the Agency under paragraph (b) of sub-article (1) within such time as may be specified by the Agency, the notification or amended notification, as the case may be, shall be deemed to have been withdrawn by the user and any fee paid to the Agency in respect of the notification shall be forfeited to the Agency.

(b) Where a user fails to comply with a request by the Agency under paragraph (b) of sub-article (1) in relation to a review of a contained use referred to in paragraph (a) of sub-article (1), or a request under paragraph (b) of sub-article (2) in relation to a review initiated under paragraph (a) of sub-article (2), as the case may be, within such time as may be specified by the Agency, the Agency may require the user to suspend or terminate the contained use.

PART II Contained Use of Genetically Modified Micro-organisms

Exclusions

11. (1) Without prejudice to article 5, this Part shall not apply to the techniques or methods of genetic modification set out in the Second Schedule.

(2) Articles 14 to 29 shall not apply to the transport of genetically modified micro-organisms by road, rail, inland waterway, sea or air.

(3) This Part shall not apply to the storage, culture, transport, destruction, disposal or use of a genetically modified micro-organism which has been placed on the market in accordance with Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, as amended, or pursuant to other Community legislation which provides for a specific environmental risk assessment similar to that laid down in the said Directive, provided that any conditions attached to the consent to place the genetically modified micro-organism on the market have been complied with.

(4) Without prejudice to article 5, this Part shall not apply to a contained use involving a genetically modified micro-organism or a type of genetically modified micro-organism which meets any criteria which may be provided under Annex II, Part B of the Directive and which may be listed in Part C of the said Annex II.

Duty to comply with this Part

12. Subject to the exclusions in article 11, a contained use shall not be carried out save in compliance with the provisions of this Part.

General duty to conduct assessment of risks

13. (1) Without prejudice to any other provision of this Part, a user shall, before commencing a contained use, carry out an assessment of the risks to human health and the environment which may be associated with such use.

(2) In making an assessment in accordance with sub-article (1), a user shall, as a minimum, use the elements of assessment and the procedures set out in the Third Schedule, and take account, in particular, of issues related to the disposal of waste and effluent.

(3) Without prejudice to any other provision of these Regulations, a record of an assessment for the purposes of sub-article (1) shall be kept by the user and shall be made available to the Agency on request.

Classification of contained uses

14. (1) An assessment carried out in accordance with article 13 shall result in the classification of the contained use into one of the following classes —

Class 1: activities for which level one containment, as set out in the Fourth Schedule, is appropriate;
Class 2: activities for which level two containment, as set out in the Fourth Schedule, is appropriate;
Class 3: activities for which level three containment, as set out in the Fourth Schedule, is appropriate; and
Class 4: activities for which level four containment, as set out in the Fourth Schedule, is appropriate.

(2) In the event of doubt as to the appropriate class for a proposed contained use, the higher level of containment shall be applied by the user unless the Agency agrees in writing that there is sufficient evidence to justify application of the lower level.

Principles etc. to be applied by users

15. (1) The user shall apply —

(a) the general principles of good microbiological practice and of good occupational safety and hygiene set out in Part A of the Fourth Schedule, and

(b) except to the extent that Part B of the Fourth Schedule allows other measures to be applied, the containment measures set out in the tables in the said Part B which correspond to the class of the contained use,

in order to keep the exposure of humans and the environment to genetically modified micro-organisms to the lowest practicable level, and to ensure a high level of safety.

(2) The assessment referred to in article 13 and the containment measures applied shall be reviewed periodically by the user, and shall be reviewed forthwith if there is reason to consider that:

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

(b) in the light of new scientific or technical knowledge, the assessment is no longer appropriate.

(3) Where a user has reason to consider that containment measures applied to a contained use are no longer adequate or that a class assigned to a contained use is no longer correct or that an assessment carried out in accordance with article 13 is no longer appropriate, the user shall:

(a) immediately inform the Agency in writing of the proposed review to be carried out in accordance with sub-article (2), and

(b) immediately on the conclusion of the review, give the Agency a report on the outcome.

(4) If, following a review in accordance with sub-article (2) and consideration of the report referred to in sub-article (3), the Agency is not satisfied that the containment measures applied are adequate or that the class assigned is correct or that the assessment carried out in accordance with article 13 is appropriate, it shall:

(a) undertake a review of the contained use, in accordance with article 29, or

(b) require the user to give a new notification pursuant to article 16, 18 or 19, as the case may be.

First time use of a premises

16. (1) Notwithstanding any other provisions of these Regulations, a premises shall not be used for the first time for an activity involving a contained use of a genetically modified micro-organism unless a notification in respect of such first time use has been given by the user to the Agency, a consent for such use has been granted by the Agency, and the conditions, if any, attached to the consent have been complied with.

(2) The notification referred to in sub-article (1) shall contain, as a minimum, the information set out in Part A of the Fifth Schedule.

(3) Where a notification in respect of the first time use of a premises has been given to the Agency in accordance with sub-article (1), the Agency shall communicate its decision in writing to the user at the latest 45 days after receipt of the notification.

(4) For the purposes of this article, a consent granted for the first time use of a premises for a particular class of contained use shall be treated as a consent for the first time use of the premises for that class and for any lower class of contained use, and accordingly a further consent shall be required in respect of the first time use of the premises for any higher class of contained use.

(5) In the case of the first time use of a premises for a class 2 or a higher class of contained use, the provisions of article 18 or 19, as appropriate, in addition to the giving of a notification under sub-article (1), shall be complied with before the contained use may commence.

(6) A notification under sub-article (1) shall be accompanied by the fee payable in accordance with Part IV.

Class 1 contained use

17. (1) Where the conditions, if any, attached to a consent granted by the Agency under article 16 have been complied with, a class 1 contained use or a subsequent such contained use may proceed without further notification.

(2) A user of a class one contained use shall keep a written record, in such manner as may be specified by the Agency, of each assessment carried out in accordance with article 13 and of the work carried out on each contained use, and such records shall be—

(a) made available to the Agency on request, and

(b) submitted to the Agency within one month of the end of each calendar year.

Class 2 contained use

18. (1) Before commencing a class 2 contained use, the user shall give the Agency a notification containing the information set out in Part B of the Fifth Schedule.

(2) (a) Where a premises has been the subject of a previous notification to carry out a class 2 or higher class of contained use and any associated requirements have been complied with, the proposed class 2 contained use notified in accordance with sub-article (1) may proceed on the tenth day following receipt by the Agency of the notification.

(b) Where, in a case to which paragraph (a) refers, the user so requests, the Agency shall issue a decision in accordance with article 26 within 45 days of submission of the notification.

(3) In the case of a premises other than a premises referred to in sub-article (2), the proposed class 2 contained use notified in accordance with sub-article (1)

may, in the absence of any indication to the contrary from the Agency, proceed 45 days after submission of the notification, or earlier with the written agreement of the Agency.

(4) For the purposes of sub-articles (2) and (3), "submission of the notification" shall be interpreted as the date on which a notification under sub-article (1) is received by the Agency.

(5) A notification under sub-article (1) shall be accompanied by the fee payable in accordance with Part IV.

Class 3 or 4 contained use

19. (1) Before commencing a class 3 or 4 contained use, the user shall give the Agency a notification containing the information set out in Part C of the Fifth Schedule.

(2) A class 3 or 4 contained use notified in accordance with sub-article (1) may not proceed unless a consent has been granted by the Agency under this Part and the conditions, if any, attached to the consent have been complied with. The Agency shall communicate its decision in writing to the user at the latest:

(a) 45 days after receipt of the notification, in the case of a premises which has been the subject of a previous notification to carry out the same class or a higher class of contained use and where any associated consent requirements have been complied with, or

(b) 90 days after receipt of the notification in other cases.

(3) Should the Agency fail to issue a decision within a time period specified in sub-article (2), such failure shall not entitle a user to proceed with a class 3 or 4 contained use, as the case may be.

(4) A notification under sub-article (1) shall be accompanied by the fee payable in accordance with Part IV.

Notice of certain class 2 contained uses

20. (1) The Agency may, in its absolute discretion, in the case of a proposed activity involving a class 2 contained use to which article 18(3) relates, require the user to give notice of the notification in a newspaper in accordance with article 22.

(2) Where, in response to a notice required under sub-article (1), representations are made to the Agency in accordance with article 23, the Agency shall, notwithstanding article 18(3)—

(a) inform the user that the proposed contained use may not proceed prior to the Agency giving its decision on the notification, and

(b) communicate its decision in writing to the user not later than 45 days after receipt of the notification.

(3) For the purposes of calculating the period of 45 days referred to in sub-article (2)(b), the period of time between the date of issue of the request by the Agency to the user under sub-article (1) and the final date for the receipt of representations in accordance with article 23(1) shall not be taken into account.

Notice of class 3 and 4 contained uses

21. (1) Not later than seven days after the receipt by the Agency of a notification in accordance with article 19(1), the user shall give notice of the notification in a newspaper in accordance with article 22.

(2) For the purposes of calculating the period of 45 days referred to in article 19(2)(a) or the period of 90 days referred to in article 19(2)(b), the period of time between the date of submission of the notification and the final date for the receipt of representations in accordance with article 23(1) shall not be taken into account.

Form of notice

22. (1) A notice given pursuant to article 20 or 21 shall be published in a newspaper circulating in the district in which the proposed activity involving the contained use will be situate, shall contain as a heading "PROPOSED CONTAINED USE OF A GENETICALLY MODIFIED MICRO-ORGANISM" and shall state—

(a) the name and address of the user,

(b) the requirement under article 18 or 19, as appropriate, to notify the Agency of the proposed activity,

(c) the fact that a notification has been submitted to the Agency, and the address at which the proposed activity involving the contained use is proposed to be carried out,

(d) the general nature of the proposed activity, the purpose of the contained use involved and the proposed class of the said contained use,

(e) whether the notification relates to a proposed new activity or a proposed modification to an existing activity,

(f) the full title of the Agency and the full postal address of its headquarters, and

(g) that, in accordance with sub-article 23(1), any person may, within the period of 4 weeks beginning on the day of publication of the notice and subject to payment of the fee specified in Part II of the Eighth Schedule, make representations in writing to the Agency regarding the notification.

(2) Within fourteen days of the publication of a notice in accordance with sub-article (1), the user shall provide a copy of the notice to the Agency and to the local authority in whose functional area the proposed activity will be situate.

Representations

23. (1) Any person may, within the period of 4 weeks beginning on the day of publication of a notice pursuant to article 20 or 21, make representations to the Agency in relation to the notification.

(2) Representations under sub-article (1) shall be —

(a) made in writing,
(b) addressed to the Agency at its headquarters,
(c) forwarded so as to reach the Agency within the period of 4 weeks beginning on the day of publication of the notice, and
(d) accompanied by the fee specified in Part II of the Eighth Schedule.

(3) Representations which do not comply with the requirements of sub-article (2) shall be invalid and shall be returned by the Agency to the sender, if known, together with any accompanying fee.

(4) Where the Agency receives representations in accordance with sub-article (1), it shall—

(a) acknowledge the representations,
(b) consider the representations in determining the notification, and
(c) inform the person or body who made the representations of its decision on the notification.

Duty of the Agency

24. The Agency shall examine the conformity of a notification received under this Part with the requirements of this Part, including, as appropriate -

(a) the accuracy and completeness of the information provided,
(b) the correctness of the assessment carried out in accordance with article 13,
(c) the correctness of the proposed classification in accordance with article 14, and
(d) the suitability of the containment measures, and the waste management and emergency response measures.

Power of the Agency to request further information, etc.

25. (1) The Agency may, in the case of a notification under this Part, request the user to provide further information on the notification or, where appropriate, to modify the proposed contained use or to amend the proposed class of the contained use.

(2) Notwithstanding any other provision of this Part, where the Agency makes a request under sub-article (1), the user shall comply with the request and shall not proceed with the contained use unless the Agency has given its consent on the basis of the response by the user, and the conditions, if any, attached to the consent have been complied with.

Power of the Agency to grant or refuse consent and to impose conditions

26. (1) (a) Where —

(i) a notification has been given to the Agency in respect of the first time use of a premises for an activity involving a contained use in accordance with article 16, or in relation to a class three or four contained use in accordance with article 19, or

(ii) the Agency reviews a contained use in accordance with article 10,

the Agency shall give its consent with or without conditions, or refuse its consent.

(b) Without prejudice to article 18(2)(b), the Agency may, in the case of a notification other than a notification specified in paragraph (a), give its consent with or without conditions, or refuse its consent.

(2) Without prejudice to the generality of sub-article (1), conditions attached to a consent may, as appropriate -

(a) limit the period for which the contained use will be permitted,

(b) specify the periods during which the contained use may, or may not, be carried out,

(c) specify any matters relating to the design and construction of the premises in which the contained use is to be carried out,

(d) specify the means (including the provision, operation, maintenance and supervision of plant and other facilities, and the use of specified procedures or codes of practice) to be used to control the contained use,

(e) specify requirements, or limits, in relation to the amount or composition of any substance produced by or utilised in the contained use,

(f) require the provision, operation and maintenance of meters, gauges, manholes, inspection chambers and other apparatus, and other means for monitoring the nature, extent and effects of the contained use,

(g) require the taking and analysis of samples, the making of measurements, the keeping of records and the furnishing of information to the Agency or to any other person or body who may be specified, including submission by the user of reports on compliance with the conditions attached to the consent for the contained use and any breaches of such conditions,

(h) specify the measures to be taken in the event of a breakdown of any plant or other equipment, or procedures which may affect the contained use,

(i) specify the nature of any treatment to be applied to waste or effluent, and the manner in which it shall be held or disposed of,

(j) specify measures to be taken if a contained use, which is not in accordance with the conditions attached to the consent, has taken place,

(k) require the preparation of an emergency plan in accordance with article 30,

(l) require the making of payments to the Agency in relation to costs incurred in monitoring, or otherwise, in relation to emissions, or

(m) specify the latest date for complying with any conditions which are attached.

Duty to inform the Agency of new information, etc.

27. (1) Where a user becomes aware of new information which could have significant consequences for the risks posed by the contained use for human health or

the environment, the user shall discontinue the contained use and, as soon as practicable, inform the Agency.

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

(a) review the assessment carried out in accordance with article 13, and the class and level of containment applied in accordance with article 14, and

(b) submit an amended notification to the Agency.

(3) An amended notification under sub-article (2)(b) shall be accompanied by the fee payable in accordance with Part IV.

(4) For the purposes of sub-article (2) and without prejudice to sub-article (3), the provisions in relation to the submission of a notification by a user in accordance with articles 16, 18 or 19, and to the processing and determination of such a notification by the Agency in accordance with article 20 to 26, shall apply, as appropriate, to an amended notification as if it were a notification under article 16, 18 or 19.

Modifications

28. A user shall not modify an activity —

(a) in a way which could result in the classification of the contained use in accordance with article 14, which has been notified to or approved by the Agency in a consent under this Part, being amended to a higher class, or

(b) in any other way which could have significant consequences for the risks posed for human health or the environment,

without carrying out an assessment in accordance with article 13 and submitting a notification to the Agency pursuant to article 16, 18 or 19, as the case may be.

Review of contained use

29. (1) Without prejudice to article 15(4), the Agency may review a contained use at any time with the consent of the user or at a time not less than three years from the date the contained use commenced.

(2) Notwithstanding sub-article (1), the Agency may review a contained use at any time if, in the light of information which was not known to it previously, there is reason to consider that the risks posed by the contained use for human health or the environment are altered to a significant degree.

(3) As soon as may be after it has completed a review under this article, the Agency may —

(a) amend any consent granted under this Part or otherwise require the user to modify the contained use, or

(b) require the user to suspend or terminate the contained use.

(4) A contained use suspended in accordance with sub-article (3)(b) shall not be resumed unless the Agency agrees in writing and the conditions, if any, attached to the agreement of the Agency have been complied with.

Accident procedures

30. (1) Before a contained use commences, the user shall —

(a) where the assessment carried out in accordance with article 13 shows that a failure of the containment measures could lead to significant danger, whether immediate or delayed, to humans outside the premises or to the environment, or

(b) where the Agency requires it,

draw up, in consultation with the appropriate emergency services, and in such manner as may be specified by the Agency, an emergency plan for the contained use.

(2) An emergency plan drawn up by the user in accordance with Community legislation other than the Directive may be accepted by the Agency for the purposes of sub-article (1).

(3) (a) The user shall, with the agreement of the Agency and in a manner approved by the Agency, provide information on the emergency plan drawn up in accordance with sub-article (1), including the safety measures to be applied in the event of a failure of the containment measures, to persons or bodies liable to be affected by an accident.

(b) The information provided in accordance with paragraph (a) shall be updated at such periods, and made publicly available in such a manner, as the Agency may specify.

(4) In the event of an accident, the user shall -

(a) immediately inform the Agency and provide -

(i) full and detailed information on the circumstances of the accident,

(ii) full and detailed information on the identity and quantities of the genetically modified micro-organism concerned,

(iii) any information necessary to assess the effects of the accident on the health of the general public or on the environment,

(iv) full and detailed information on the measures taken,

(b) ensure that the relevant emergency services are informed of the accident,

(c) inform persons likely to be affected by the accident, and

(d) activate other relevant provisions of the emergency plan.

(5) Where, in accordance with sub-article (4), the Agency is notified of an accident, it shall -

(a) immediately alert any Member State of the European Communities 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 a similar accident in the future and to limit the effects of any such future accident, and

(c) ensure that any measures necessary are taken.

(6) In the event of an accident, the Agency may require the user to defray or contribute towards any or all of the costs incurred by it arising from such accident.

Consultation on emergency plans

31. (1) When emergency plans are proposed to be drawn up in accordance with article 30, the Agency shall consult with such other Member States of the European Communities as it considers are likely to be affected in the event of an accident involving a genetically modified micro-organism.

(2) Consultations under sub-article (1) shall have regard to any procedure for the exchange of information established by the Commission of the European Communities under the Directive.

(3) The Agency shall make available to such other Member States of the European Communities as it considers to be concerned, as a basis for all necessary consultation, the same information as is disseminated within the State in accordance with the provisions of article 30(3).

Informing the Commission of the European Communities

32. The Agency shall, as soon as is practicable and in the format set out in the Sixth Schedule, inform the Commission of the European Communities of any accident involving a genetically modified micro-organism, giving details of the circumstances of the accident, the identity and quantities of the genetically modified micro-organism concerned, the emergency measures taken and their effectiveness, and an analysis of the accident including recommendations to limit its effects and avoid similar accidents in the future.

PART III Contained Use of Genetically Modified Organisms other than Genetically Modified Micro-organisms

Exclusions

33. (1) Without prejudice to article 5, this Part shall not apply to -

(a) the techniques or methods of genetic modification set out in the Second Schedule, or

(b) the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(2) This Part shall not apply to the storage, culture, transport, destruction, disposal or use of a genetically modified organism which has been placed on the market in accordance with Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, as amended, or pursuant to other Community legislation which provides for a specific environmental risk assessment similar to that laid down in the said Directive, provided that any conditions attached to the consent to place the genetically modified organism on the market have been complied with.

Duty to comply with this Part

34. Subject to the exclusions in article 33, a contained use shall not be carried out save in compliance with the provisions of this Part.

Principles to be applied by users

35. A user shall, in carrying out an activity involving a contained use, apply principles of good greenhouse, growthroom or animal house practice, as appropriate, including such principles (if any) as may be specified or approved by the Agency.

General duty to conduct assessment of risks

36. (1) Without prejudice to any other provision of this Part, a user shall, before commencing a contained use —

(a) carry out an assessment of the risks to human health and the environment which may be associated with such use, and

(b) give the Agency a copy of the assessment together with the information set out in Part I of the Seventh Schedule.

(2) In making an assessment in accordance with sub-article (1), a user shall, as a minimum, use the elements of assessment and the procedures set out in Part II of the Seventh Schedule, and take account, in particular, of issues related to the disposal of waste and effluent.

(3) A copy of an assessment given to the Agency in accordance with sub-article (1)(b) shall be a record for the purposes of article 8.

Commencement of contained use

37. (1) A proposed contained use in respect of which an assessment has been given to the Agency in accordance with article 36(1) may proceed 45 days after submission of the assessment, or earlier with the written agreement of the Agency.

(2) For the purposes of sub-article (1), the date of submission of an assessment shall be interpreted as the date on which the assessment is received by the Agency.

Records

38. (1) A user shall keep a written record, in such manner as may be specified by the Agency, of the work carried out on each contained use, and such records shall be —

(a) made available to the Agency on request, and

(b) submitted to the Agency within one month of the end of each calendar year.

(2) Subject to article 9, the Agency shall, within seven days of their receipt, enter in the register provided for in article 8 the date of receipt of records provided in accordance with sub-article (1) and of the assessment provided under article 36(1)(b).

Duty to inform the Agency of new information, etc.

39. (1) Where a user becomes aware of new information which could have significant consequences for the risks posed by a contained use for human health or the environment, the user shall discontinue the contained use and, as soon as practicable, inform the Agency.

(2) Following examination of new information provided in accordance with sub-article (1), the Agency may require the user to modify, suspend or terminate the contained use.

Power of the Agency to require modification, suspension or termination

40. Where the Agency is not satisfied that a contained use is being carried out in accordance with this Part, it may require the user to modify, suspend or terminate the said contained use.

Transitional arrangements.

41. (1) The Agency shall, in accordance with the provisions of this Part, review each contained use of a genetically modified organism in respect of which, on the commencement of these Regulations, an entry appeared in the register provided for under article 8 of the 1994 Regulations.

(2) For the purposes of reviewing a contained use to which sub-article (1) applies, the Agency may request the user to undertake an assessment in accordance with article 36 or to provide such further information as the Agency may require, or to do both.

(3) A review to which sub-article (1) refers shall be initiated by the Agency within two years of the commencement of these Regulations.

(4) Pending completion of a review in accordance with sub-article (1), the provisions of the 1994 Regulations replaced by these Regulations, and any consent granted under the said 1994 Regulations, shall continue in force and have full effect.

(5) As soon as may be after it has completed a review under sub-article (1), the Agency shall give notice of the outcome to the user.

PART IV Fees and Charges

Fee for notification of first time use of a premises

42. (1) A fee shall be paid to the Agency in respect of a notification of a first time use of a premises given to the Agency under article 16.

(2) The fee payable under sub-article (1) shall be one of the amounts indicated in columns (2) to (5), whichever is appropriate, of the Eighth Schedule opposite the mention of a notification under article 16.

Fee for notification of a class 2 contained use

43. (1) A fee shall be paid to the Agency in respect of a notification of a class two contained use given to the Agency under article 18.

(2) The fee payable under sub-article (1) shall be the amount indicated in column (3) of the Eighth Schedule opposite the mention of a notification under article 18.

Fee for notification of a class 3 or 4 contained use

44. (1) A fee shall be paid to the Agency in respect of a notification of a class three or four contained use given to the Agency under article 19;

(2) The fee payable under sub-article (1) shall be either of the amounts indicated in columns (4) or (5), whichever is appropriate, of the Eighth Schedule opposite the mention of a notification under article 19.

Fee for an amended notification of a contained use

45. (1) A fee shall be paid to the Agency in respect of an amended notification of a contained use given to the Agency under article 27.

(2) The fee payable under sub-article (1) shall be one of the amounts indicated in columns (3), (4) or (5), whichever is appropriate, of the Eighth Schedule opposite the mention of an amended notification under article 27.

Refund of fee in case of certain repeat notifications

46. (1) Where a notification under article 16, 18 or 19 is withdrawn before a decision is made by the Agency and a subsequent such notification is made by or on behalf of the same user, the Agency shall, subject to article 47, refund three quarters of the fee paid to it in respect of the subsequent notification if each of the conditions mentioned in sub-article (2) is complied with.

(2) The conditions referred to in sub-article (1) are that -

(a) the Agency is satisfied that the subsequent notification relates to a contained use of the same nature and scale as the contained use to which the earlier notification related,

(b) a fee in respect of the same contained use to which the subsequent notification relates has been paid in respect of the earlier notification,

(c) the period between the withdrawal of the first notification and the date of receipt of the subsequent notification which complies with the requirements of these Regulations does not exceed twelve months,

(d) no previous refund under sub-article (1) has at any time been made to the same user in respect of a notification which related substantially to the same contained use as that to which the subsequent notification relates, and

(e) the case is not a case where a reduced fee has been paid under article 48.

Claim for refund to be in writing

47. A refund under article 46 shall be made on a claim in that behalf made in writing to the headquarters of the Agency and received by it within the period of two months beginning on the day of the giving of the decision by the Agency on a subsequent notification.

Discretionary power to refund or waive fee in certain limited circumstances

48. (1) Notwithstanding any other provision of these Regulations, the Agency shall have an absolute discretion to refund or waive up to half of the fee payable in respect of a particular notification where it is satisfied that the payment in full of the fee would not be just and reasonable having regard to any of the following —

(a) the limited scale of the contained use,

(b) the limited capital or operational costs, or both, as appropriate, of the contained use,

(c) the fee payable in respect of a notification for any other contained use of a similar character, extent or description.

(2) A decision under sub-article (1) shall contain a statement specifying the reasons for the decision.

Periodic charges for monitoring

49. The Agency may require a user to make periodic payments, not exceeding the costs incurred by the Agency, for the purpose of defraying or contributing towards the costs incurred by it in monitoring, carrying out inspections, or otherwise ensuring compliance of the contained use of a genetically modified organism with the

requirements of these Regulations and any consent, conditions or other requirements pursuant to these Regulations.

Agency investigations

50. The Agency may carry out, or arrange to have carried out, such additional investigations as it considers necessary, as part of its examination 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.

Recovery of costs or charges

51. The Agency may recover the amount of any payment due to it arising from a requirement under article 30(6), 49 or 50 as a simple contract debt in any court of competent jurisdiction.

PART V Enforcement and Regulation

Authorised persons

52. The Agency may appoint such of its officers to be authorised persons as it considers necessary for the purpose of these Regulations.

Prosecution of offences

53. An offence under these Regulations, or an offence arising from the exercise of powers under the Act by authorised persons appointed pursuant to article 52, may be prosecuted by the Agency.

High Court injunction

54. The High Court may, on the application of the Agency, by order, prohibit or restrict any activity involving a contained use where the court is satisfied that the commencement or continuation of the contained use would:

(a) constitute a contravention of these Regulations, or

(b) pose a real and substantial danger to human health or the environment.

Notice to take measures

55. (1) Where it appears to the Agency that it is necessary to do so in order to protect human health or the environment, it may serve a notice in writing under this article on any user in respect of a contained use.

(2) A notice pursuant to this article shall:

(a) specify the measures which appear to the Agency to be necessary in order to protect human health or the environment,

(b) direct the user on whom the notice is served to take such measures as may be specified in the notice, and

(c) specify a date by which such measures are to be taken.

(3) A notice under this article -

(a) may be served whether or not there has been a prosecution for an offence under these Regulations in relation to the particular contained use the subject of the notice, and

(b) shall not prejudice the initiation of a prosecution for an offence under these Regulations or under the Act.

(4) A person on whom a notice under this article has been served, may, within such period as may be specified in the notice, make representations in writing to the Agency concerning the terms of the notice and the Agency, having considered any such representations, may amend or revoke the notice.

(5) A person on whom notice under this article has been served shall, within the period specified, comply with the notice.

PART VI Miscellaneous

Monitoring

56. The Agency shall carry out, cause to be carried out, or arrange for such monitoring, inspections, or other measures as it considers necessary for the purposes of the performance of any of its functions under these Regulations.

Reporting on functions under these Regulations

57. The Agency shall provide to the Minister —

(1) as soon as may be after 31 December 2001 and each year thereafter, in such a manner as the Minister may specify, a summary report on class three and class four contained uses notified during the year in accordance with article 19, including, in respect of each notification, a description of the nature and purpose of the activity, the risks associated with the contained uses and, where relevant, the decision under article 26,

(2) not later than 30 April 2003 and every three years thereafter, in such a manner as the Minister may specify, a summary report on implementation of these Regulations, and

(3) any other information in relation to the performance of its functions under these Regulations as the Minister may specify from time to time.

Revocations and application of 1994 Regulations

58. (1) Part II, articles 43 to 46, the Second, Third, Fourth, Fifth and Sixth Schedules, and Parts I and II of the Eleventh Schedule, of the 1994 Regulations are hereby revoked and, subject to articles 10 and 41 of these Regulations, the 1994 Regulations shall cease to apply to the contained use of genetically modified organisms.

(2) The Genetically Modified Organisms (Amendment) Regulations, 1996 are hereby revoked.

Advisory Committee on Genetically Modified Organisms

59. (1) The Advisory Committee (hereinafter referred to as "the committee") provided for under Part VI of the 1994 Regulations shall also serve as the advisory committee for the purposes of consultation by the Agency on any aspect of its functions under these Regulations.

(2) Article 56 of the 1994 Regulations is hereby amended by:

(a) the insertion, after paragraph (g) of sub-article (1), of the following: "(gg) the Director of Consumer Affairs", and

(b) the insertion, after paragraph (i) of sub-article (1), of the following: "(j) organisations, other than the Office of the Director of Consumer Affairs, which in the opinion of the Agency are concerned with consumer affairs",

(c) the substitution, in sub-article (2), of "14" for "12".

Appointments to Advisory Committee

60. (1) The Agency shall, as soon as practicable after the commencement of these Regulations, appoint two new members to the committee in accordance with articles 56(1)(gg) and 56(1)(j) of the 1994 Regulations (as inserted by article 59 of these Regulations).

(2) Notwithstanding article 57 of the 1994 Regulations, the term of office of the two new members shall end when the term of office of the committee which is in place immediately prior to the commencement of these Regulations ends and such members shall not be precluded from reappointment under the said article.

FIRST SCHEDULE INTERPRETATION OF TECHNIQUES OF GENETIC MODIFICATION, FOR THE PURPOSES OF ARTICLE 3

Article 3

PART I

Techniques of genetic modification referred to in article 3(3)(a) 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 an organism of heritable material prepared outside the 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 II

Techniques referred to in article 3(3)(b) which are not considered to result in genetic modification, provided they do not involve the use of recombinant-nucleic acid molecules or genetically modified organisms made by techniques or methods other than techniques or methods excluded under articles 11(1) and 33(1) and set out in the Second Schedule:

(i) in vitro fertilisation;

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

(iii) polyploidy induction.

SECOND SCHEDULE INTERPRETATION OF TECHNIQUES OF GENETIC MODIFICATION, FOR THE PURPOSES OF ARTICLES 11 AND 33.

Articles 11 and 33

Techniques or methods of genetic modification yielding organisms excluded from the requirements of these Regulations, provided they do not involve the use of recombinant-nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques or methods listed below:

(a) mutagenesis,

(b) cell fusion (including protoplast fusion) of prokaryotic species that exchange genetic material by known physiological processes,

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

(d) self-cloning consisting of 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 organism is unlikely to cause disease to humans, animals or plants.

For the purposes of these Regulations, self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular organisms.

THIRD SCHEDULE PRINCIPLES TO BE FOLLOWED FOR THE ASSESSMENT REFERRED TO IN ARTICLE 13

Article 13

This Schedule describes in general terms the elements to be considered and the procedure to be followed in carrying out the assessment referred to in article 13. It is supplemented by, and shall be read in conjunction with, the guidance notes developed by the

Commission of the European Communities for the purposes of the Directive[3], and any subsequent amendment or additions to the said guidelines.

[3] Commission Decision 2000/608/EC of 27 September 2000 concerning the guidance notes for risk assessment outlined in Annex III of Directive 90/219/EEC on the contained use of genetically modified micro-organisms; OJ No. L 258, 12.10.2000

A ELEMENTS OF ASSESSMENT

1 The following shall 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 of the micro-organism in the environment,
- deleterious effects due to the natural transfer of inserted genetic material to other organisms.

2 The assessment referred to in article 13 shall 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 (where the donor micro-organism is used during the activity),

(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.

B PROCEDURE

3 The assessment shall involve —

(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 European Community legislation, including Council Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work[4], and other national or international classification schemes for genetically modified micro-organisms,

[4] OJ No. L374, 31.12.1990, as last amended by Commission Directive 97/59/EC: OJ No. L 282, 15.10.1997.

(d) following steps (a) to (c), identification of the level of risk associated with the genetically modified micro-organism,

(e) identification of the appropriate containment measures from those specified in the applicable table in Part B of the Fourth Schedule, on the basis of the level of risk identified and taking into consideration:

(i) the characteristics of the environment likely to be exposed (e.g. whether, in the environment likely to be exposed to the genetically modified micro-organism, there are known biota which could be adversely affected by the micro-organism),

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

(iii) any non-standard operations (e.g. the inoculation of animals with genetically modified micro-organisms, use of equipment likely to generate aerosols),

(f) in the light of the outcome of the procedures specified in paragraph (e), review and, where necessary, adjustment of the level of risk identified under paragraph (d),

(g) classification of the contained use into one of the classes specified in article 14,

(h) review and confirmation of the classification in the light of the completed assessment.

FOURTH SCHEDULE CONTAINMENT MEASURES FOR ACTIVITIES INVOLVING THE CONTAINED USE OF GENETICALLY MODIFIED MICRO-ORGANISMS

Articles 14 and 15

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

For the purposes of these Regulations, principles of good microbiological practice and good occupational safety and hygiene practice shall include:

(i) keeping the workplace and environmental exposure to any genetically modified micro-organism to the lowest practicable level,

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

(iii) testing and maintaining control measures and equipment,

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

(v) providing appropriate training of personnel,

(vi) establishing biological safety committees or subcommittees, where required,

(vii) formulating and implementing local codes of practice for the safety of personnel, where required,

(viii) where appropriate, displaying biohazard signs,

(ix) providing washing and decontamination facilities for personnel,

(x) keeping adequate records,

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

(xii) prohibiting mouth-pipetting,

(xiii) where appropriate, providing written standard operating procedures to ensure safety,

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

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

PART B CONTAINMENT MEASURES AND LEVELS

The following tables specify the minimum requirements and measures for each level of containment.

The title of each table is indicative:

- table IA specifies minimum requirements for a contained use carried out in a laboratory,

- table IB specifies additions to, and modifications of, table IA for the purpose of a contained use carried out in a plant growth facility,

- table IC specifies additions to, and modifications of, table IA for the purpose of a contained use involving animals and carried out in an animal unit, and

- table II specifies minimum requirements for a contained use in a facility other than a facility covered by tables IA, IB or IC.

For the purposes of the tables, "optional" means that the Agency may, in the case of any individual contained use, on foot of a notification or otherwise at the request of the user, having regard to the assessment carried out in accordance with article 13 and the class of the contained use identified in accordance with article 14, decide whether the relevant containment measures specified for the said class in the appropriate table or tables, as the case may be, shall be applied.

Where necessary, a combination of measures from table IA and table II, of the same level, shall be applied.

At the request of the user, the Agency may, having regard to the assessment carried out in accordance with article 13, in relation to the individual contained use -

(a) accept that the application of a particular measure specified under a particular level of containment is not necessary, or

(b) accept the application of measures from different levels.

Table IA

Containment measures for contained use of genetically modified micro-organisms in a laboratory

Measures	**Containment levels**			
	1	2	3	4
1	Laboratory suite: isolation			
	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 for bench

Required for bench

Required for bench and floor

Required for bench, floor, ceiling and walls

4

Entry to laboratory via airlock

Not required

Not required

Optional

Required

5

Negative pressure relative to the pressure of the immediate environment

Not required

Not required

Required

Required

6

Extract and input air from the laboratory should be HEPA-filtered

Not required

Not required

Required

Required for input and extract air

7

Microbiological safety cabinet

Not required

Optional

Required

Required

8

Autoclave

On site

In the building

En suite

Double-ended autoclave in laboratory

System of work

9

Restricted 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 to minimise

Required to prevent

Required to prevent

12

Shower

Not required

Not required

Optional

Required

13

Protective clothing

Suitable protective clothing

Suitable protective clothing; footwear optional

Suitable protective clothing and footwear

Complete change of clothing and footwear before entry and exit

14

Gloves

Not required

Optional

Required

Required

15

Efficient vector control (e.g. for rodents and insects)

Optional

Required

Required

Required

Waste

16

Inactivation of genetically modified micro-organisms in effluent from hand-washing sinks or drains and showers and similar effluents

Not required

Not required

Optional

Required

17

Inactivation of genetically modified micro-organisms in contaminated material and waste

Optional

Required

Required

Required

Other measures

18

Laboratory to contain its own equipment

Not required

Not required

Optional

Required

19

Observation window or alternative to enable occupants to be seen

Optional

Optional

Optional

Required

For the purposes of this Table:

(1) In measure 1, "isolation" means that the laboratory is separated from other areas in the same building or is in a separate building.

(2) In measure 4, "airlock" means that entry must be made through a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities, or by interlocking doors.

(3) In measure 5, "negative pressure relative to the pressure of the immediate environment" is only required for a class 3 contained use where airborne transmission can occur.

(4) "HEPA" means high efficiency particulate air.

(5) In measure 6, where viruses which are not capable of being retained by HEPA filters are used in a class 4 contained use, extra requirements shall be provided for extract air.

(6) In measure 8, "en suite" means that where the autoclave is located outside the laboratory in which the contained use is being carried out but within the laboratory suite, validated procedures shall be in place to ensure the safe transfer of material into the autoclave and to provide a level of protection equivalent to that which would be achieved if the autoclave were in the laboratory.

Table IB

Containment measures for contained use of genetically modified micro-organisms in plant growth facilities

In addition to the measures specified in Table 1 A, the following measures shall apply:

Measures

Containment levels

1

2

3

4

Building

1

Permanent structure

Not required

Required

Required

Required

Equipment

2

Entry via a separated room with two interlocking doors

Not required

Optional

Optional

Required

3

Control of contaminated run-off water

Optional

Required to minimise run-off

Required to prevent run-off

Required to prevent run-off

System of work

4

Measures to control undesired species such as insects, rodents, arthropods

Required

Required

Required

Required

5

Procedures for transfer of living material between the plant growth facility and laboratory to control dissemination of genetically modified micro-organisms

Required to minimise dissemination

Required to minimise dissemination

Required to prevent dissemination

Required to prevent dissemination

For the purposes of this Table:

(1) In measure 1, a permanent structure means a fixed structure with walls, a roof and a floor, designed and used principally for growing plants in a controlled and protected environment. Where the permanent structure is a greenhouse, it shall also have a continuous waterproofed covering and self-closing lockable outer doors, and be located on a site graded to prevent entry of surface-water run-off.

(2) In measure 3, control of contaminated run-off water is only required for containment level 2 where transmission can occur through the ground.

Table IC

Containment measures for contained use of genetically modified micro-organisms in animal units

In addition to the measures specified in Table 1 A, the following measures shall apply:

Measures	Containment levels
	1
	2
	3
	4
Facilities	
1	
Isolation of animal unit	

Optional

Required

Required

Required

2

Animal facilities separated by lockable doors

Optional

Required

Required

Required

3

Animal facilities designed to facilitate decontamination

Optional

Optional

Required

Required

4

Floor and walls easily washable

Optional

Required for floor

Required for floor and walls

Required for floor and walls

5	Animals kept in appropriate containment facilities	Optional	Optional	Optional
		Optional		
6	Filters on isolators or isolated room	Not required	Optional	Required
		Required		

For the purposes of this Table:

(1) In measure 1, an "animal unit" means a building or separate area within a building, containing an animal facility and other areas such as changing rooms, showers, autoclaves and food storage areas.

(2) In measures 2 and 3, an "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.

(3) In measure 3, "designed to facilitate decontamination" includes the use of waterproof and easily washable material.

(4) In measure 5, the keeping of animals in "appropriate containment facilities" includes cages, pens and tanks.

(5) In measure 6, "isolators" means transparent boxes where small animals are contained within or outside a cage.

Table II

Containment measures for contained use of genetically modified micro-organisms in facilities other than those covered by tables IA, IB or IC of this Schedule

Measures

Containment levels

1

2

3

4

General

1

Viable micro-organisms contained in a system which separates the process from the environment, i.e. a closed system

Optional

Required

Required

Required

2

Control of exhaust gases from the closed system

Not required

Required to minimise dissemination

Required to prevent dissemination

Required to 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 to minimise dissemination

Required to prevent dissemination

Required to 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 designed to minimise or prevent release

No specific requirement

Required to minimise dissemination

Required to prevent dissemination

Required to prevent dissemination

6

Designation of controlled area to contain spillage of the entire contents of the closed system

Optional

Optional

Required

Required

7

Controlled area 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, acid, alkalis, solvents, disinfectants, decontamination agents and easy to clean

Required for bench

Required for bench

Required for bench and floor

Required for bench, floor, ceiling and walls

10

Specific measures adequately to ventilate the controlled area in order to minimise air contamination

Optional

Optional

Optional

Required

11

Controlled area maintained at an air pressure negative to the immediate surroundings

Not required

Not required

Optional

Required

12

Extract and input air from the controlled area to be high efficiency particulate air filtered

Not required

Not required

Required for extract air and optional for input air

Required for input and extract air

System of work

13

Closed systems located within a controlled area

Not required

Optional

Required

Required

14

Access restricted to nominated personnel only

Not required

Required

Required

Required

15

Biohazard signs posted

Not required

Required

Required

Required

16

Personnel to shower before leaving the controlled area

Not required

Not required

Optional

Required

17

Personnel to wear protective clothing

Required (work clothing)

Required (work clothing)

Suitable protective clothing

Complete change before entry and exit

Waste

18

Inactivation of genetically modified micro-organisms in effluent from hand-washing sinks or showers or similar effluents

Not required

Not required

Optional

Required

19

Inactivation of genetically modified micro-organisms 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

For the purposes of this Table:
(1) In measure 8, "airlock" has the same meaning at that provided for the purposes of measure 4 in Table 1A.

:

FIFTH SCHEDULE INFORMATION REQUIRED IN THE NOTIFICATION OF A FIRST TIME USE OF A PREMISES OR OF A CONTAINED USE.

Articles 16, 18 and 19

PART A

Information required for the notification referred to in article 16:

- name of user, 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 use,

- in the case of a class 1 contained use, a summary of the assessment referred to in article 13 and information on waste management.

PART B

Information required for the notification referred to in article 18:

- date of submission of the notification under article 16,

- the names of the persons responsible for supervision and safety and information on their training and qualifications,

- 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 genetically modified micro-organism,

- the purpose of the contained use including the expected results,

- approximate culture volumes to be used,

- description of the containment 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 article 13,

- the information necessary for the competent authority to evaluate any emergency response plans if required under article 30.

PART C

Information required for the notification referred to in article 19:

- the date of submission of the notification under article 16,

- the names of the persons responsible for supervision and safety and information on their training and qualifications,

- the recipient or parental micro-organism to be used,

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

- the source and intended function of the genetic material involved in the modification,

- identity and characteristics of the genetically modified micro-organism,

- the culture volumes to be used,

- description of the containment 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 premises,

- information about accident prevention and emergency response plans, if any,

- any specific hazards arising from the location of the premises,

- 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 article 30, and

- a copy of the assessment referred to in article 13.

SIXTH SCHEDULE INFORMATION TO BE SUPPLIED TO THE COMMISSION OF THE EUROPEAN COMMUNITIES BY THE AGENCY WHERE AN ACCIDENT HAS OCCURRED

ARTICLE 32

PART 'A' — IMMEDIATE REPORT OF ACCIDENT

Member State:

Authority responsible for report:

Address:

1. General data

Date and time of the accident:

Name of company or institution:

Address:

Grid reference:

Principal activity on premises:

Class of contained use:

Class one

Class two

Class three

Class four

2. Type of accident

Failure of equipment, including breakage and leakage

Fire

Explosion

Maloperation of equipment, including human and mechanical

Other (specify)

_____
_____

3. Micro-organisms released

Identity:

Quantity:

Form or concentration of release:

4. Description of the circumstances of the accident

5. Whether an emergency plan had been drawn up in advance

Yes

No

If yes, by whom?

_____
_____

6. Emergency measures taken

(a) Inside premises

_____

_____
_____

(b) Outside premises

_____

_____
_____

7. Assumed or established cause of accident

Known (specify):

_____

Not known:

Information to be supplied as soon as possible

8. Nature and extent of exposure

(a) Within the installation

-

Persons exposed to the accident

-

Casualties

-

Damage to health

-

Material damage

-

Damage affecting the containment equipment

-

Danger still present

If yes, specify

-

Danger no longer present

(b) Outside the installation:

-

Persons exposed to the accident

-

Casualties

-

Damage to health

-

Type of environment exposure (water, sewerage systems, agricultural land, natural environment)

-

Material damage

-

Damage affecting the containment equipment

-

Damage to the environment

-

Danger still present

If yes, specify

-

Danger no longer present

9. Member States already informed bilaterally of the accident

PART 'B' - FURTHER REPORTING, ANALYSIS AND RECOMMENDATIONS

1. Analysis of the causes of the accident

2. Analysis of the efficiency of emergency plans

3. Experience gained

4. Results of any formal accident investigation (if relevant)

5. Medium and long-term measures, particularly those aimed at preventing the recurrence of similar accidents

6. Actions taken to inform the public of the accident

7. Monitoring within and outside premises following the accident

8. Final overall assessment of damage to health and the environment

9. Recommendations for avoiding similar accidents in future

SEVENTH SCHEDULE REQUIREMENTS IN RELATION TO CONTAINED USES OF GENETICALLY MODIFIED ORGANISMS OTHER THAN GENETICALLY MODIFIED MICRO-ORGANISMS

Article 36

PART I INFORMATION ON THE PREMISES TO BE USED FOR A CONTAINED USE OF A GENETICALLY MODIFIED ORGANISM OTHER THAN A GENETICALLY MODIFIED MICRO-ORGANISM

Information to be provided by the user in accordance with article 36(1)(b):

- name of user, 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 any work involving the contained use of a genetically modified organism, including a genetically modified micro-organism, already undertaken at the premises, and

- a description of the nature of the intended contained use in respect of which the information in this Part of this Schedule is being provided to the competent authority in accordance with article 36(1)(b).

PART II PRINCIPLES TO BE FOLLOWED FOR THE ASSESSMENT REFERRED TO IN ARTICLE 36

This Part of the Schedule describes in general terms the elements to be considered and the procedure to be followed for the purposes of performing the assessment referred to in article 36.

A ELEMENTS OF ASSESSMENT

1 The following shall be considered as potentially harmful effects:
- disease to humans, including allergenic or toxic effects,
- acting as a human disease vector or reservoir,
- adverse effects to humans arising from change in behaviour or in physical nature,

- adverse effects arising from the inability to treat human disease or offer effective prophylaxis.

2 The assessment referred to in article 36 shall be based on the following —

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

(i) the recipient organism;

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

(iii) the vector;

(iv) the donor organism (as long as the donor organism is used during the activity);

(v) the resulting genetically modified organism;

(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 — STAGES OF ASSESSMENT

3 (1) First Stage.

Identification of —

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

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

(2) Second Stage.

Identification of the level of risk associated with the genetically modified organism.

(3) Third Stage.

Selection of containment and other protective measures on the basis of -

(a) the level of risk associated with the genetically modified organism,

(b) the characteristics of the environment likely to be exposed, and

(c) the characteristics of the activity.

(4) Fourth Stage.

Review and reconsideration of the overall assessment, having regard to the outcome of each of the first three stages.

EIGHTH SCHEDULE FEES

ARTICLE 23 and PART IV

Table A

PART I

Fees payable to the Agency in respect of notifications or amended notifications given prior to 1 January 2002.

Notification or amended notification	Amount of Fee			
	Class one	Class two	Class three	Class four
	(1)	(2)	(3)	(4)	(5)
Notification of a first time use of a premises for a contained use under article 16	£196.89	£984.46	£2,362.69	£11,813.46
Notification of a class two contained use under article 18	Not applicable	£492.23	Not applicable	Not applicable

Notification of a class three or four contained use under article 19	
	Not applicable
	Not applicable
	£1,181.35
	£5,906.73
Amended notification of a contained use under article 27	
	Not applicable
	£374.09
	£886.01
	£4,430.05

PART II

Representations	Amount of fee
Making of representations under article 23	£7.88

Table B

PART I

Fees payable to the Agency in respect of notifications or amended notifications given on or after 1 January 2002.

Notification or amended notification	Amount of Fee
	Class one
	Class two
	Class three
	Class four
(1)	(2)
Notification of a first time use of a premises for a contained use under article 16	€250
	€1,250
	€3,000
	€15,000
Notification of a class two contained use under article 18	Not applicable

€625

Not applicable

Not applicable

Notification of a class three or four contained use under article 19

Not applicable

Not applicable

€1,500

€7,500

Amended notification of a contained use under article 27

Not applicable

€475

€1,125

€5,625

PART II

Representations

Amount of fee

Making of representations under article 23

€10

Given under the Official Seal of the

Minister for the Environment and Local Government

this 8th day of March, 2001.

Noel Dempsey

_____

Minister for the Environment and Local Government

EXPLANATORY NOTE.

(*This note is not part of the Instrument and does not purport to be a legal interpretation.*)

These Regulations give effect to Council Directive 90/219/EEC, as amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms. They replace Part II of the Genetically Modified Organisms Regulations, 1994, and all other provisions and Schedules of those Regulations which relate to contained use activities.

The Environmental Protection Agency (EPA) is the competent authority for the purposes of the Regulations and it may consult the Advisory Committee on Genetically Modified Organisms (provided for in Part VI of the 1994 Regulations) on any aspect of its functions.

The fundamental objective of the Regulations is to protect people and the environment from any adverse effects arising from the contained use of genetically modified organisms (GMOs). In this regard, they provide for the application of various procedural matters to contained use activities. Part II provides specifically for regulation of the contained use of genetically modified micro-organisms (GMMs) and gives full effect to the EU Directives. Part III provides an updated framework for the regulation of all contained uses involving GMOs other than GMMs covered under Part II.

Subject to limited exclusions in Parts II and III, all contained uses must comply with the Regulations. Proposed uses must be subjected to an environmental risk assessment which must be submitted, or otherwise made available, to the EPA for evaluation. Proposed contained uses of GMMs which fall into the moderate and high classes of risk (classes 3 and 4) may not proceed without explicit consent from the Agency. As well as applying specific containment measures in each case, users of GMMs are required to apply principles of good microbiological practice, and good occupational safety and hygiene, and users of GMOs are required, as appropriate, to apply good greenhouse, growthroom or animal-house practice. All users are required to keep appropriate records and to submit them, or otherwise make them available, to the EPA.

Subject to limited confidentiality requirements, a register of all contained uses must be maintained by the EPA and made available to the general public.

The Regulations include provision for their enforcement by the EPA, including powers in Part V to prosecute offences, to obtain a High Court order to prohibit or restrict an activity involving a contained use, or to serve a notice requiring a user to take specific measures which it regards as necessary for the protection of people and the environment.

The Regulations come into effect on 15th March 2001. Revocation and transitional arrangements are provided respectively in articles 58, and 10 and 41.