GENETICALLY MODIFIED ORGANISMS REGULATIONS 1994

S.I. No. 345 of 1994.

GENETICALLY MODIFIED ORGANISMS REGULATIONS, 1994.

In exercise of the powers conferred on the Minister for the Environment by sections 6 and 111 on the Environmental Protection Agency Act, 1992 (No. 7 of 1992), which said powers are delegated to me by the Environment (Delegation of Ministerial Functions) Order, 1993 (S.I. No. 127 of 1993), I, JOHN BROWNE, Minister of State at the Department of the Environment, hereby make the following Regulations.

PART I

PRELIMINARY AND GENERAL

REG 1

Citation.
1. These Regulations may be cited as the Genetically Modified Organisms Regulations, 1994.

REG 2

Commencement.
2. The Regulations shall come into operation on the 1st day of January, 1995.

REG 3

Interpretation.
3. (1) In these Regulations, unless the context otherwise requires—
"accident" means any incident involving a significant and unintended release of genetically modified organisms in the course of their contained use which could present an immediate or delayed hazard to human health or the environment;
"the Act" means the Environmental Protection Agency Act, 1992;
"the Agency" means the Environmental Protection Agency established under section 19 of the Act;
"confidential information" includes information the disclosure of which might harm the competitive position of the notifier or the intellectual property rights relating to any data received;
"competent authority" has the meaning assigned to it in article 4;
"contained use" means any operation in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers, or a combination of physical barriers, together with chemical and/or biological barriers, are used to limit their contact with the general population and the environment;
"deliberate release" means any intentional introduction into the environment of a genetically modified organism or a combination of

genetically modified organisms without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment, and cognate words and expressions shall be construed accordingly;
"first time use of an installation" means the first time use of an installation for an operation involving the contained use of a genetically modified organism;
"Group I genetically modified micro-organisms" means genetically modified micro-organisms which satisfy such of the criteria of Part I of the Second Schedule as are applicable in the particular case in accordance with the guidelines set out in Part II of that Schedule. For Type A operations, where any of the criteria in Part I of the Second Schedule may not be applicable in determining the classification of a particular genetically modified micro-organism, the matter shall be referred to the Agency, which shall, as far as possible, determine the classification having regard to the relevant criteria and the guidelines set out in Part II of that Schedule;
"Group II genetically modified micro-organisms" means genetically modified micro-organisms other than those in Group I;
"genetically modified micro-organism" means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material in which the genetic material has been altered in a way that does not occur naturally by mating and/or by natural recombination;
"Type A operation" means any activity involving genetically modified micro-organisms for the purposes of teaching, research or development, or for non-industrial or non-commercial purposes on a scale at which the practices and conditions of the activity relative to the culture, volume and numbers of organisms are such that—
(a) the system used to keep the organisms under containment reflects good microbiological practice and good occupational safety and hygiene, and
(b) it is practicable to render the organisms inactive by standard laboratory decontamination techniques;
"Type B operation" means any activity involving the genetic modification of micro-organisms other a Type A operation;
"higher plant" has the meaning assigned to it in the Seventh Schedule;
"notifier" means a person or body who submits a notification or a record to the competent authority under these Regulations;
"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;
"placing on the market" means supplying or making available to third parties, and cognate words and expressions shall be construed accordingly;
"product" means a preparation consisting of, or containing, a genetically modified organism or a combination of genetically modified organisms, which is placed on the market;
"use" means the deliberate release of a product which has been placed on the market;
"user" shall mean any legal or natural person responsible for the contained use of a genetically modified organism, or a person carrying out a use as defined above, whichever is appropriate.

(2) (a) Within the terms of the definition of "genetically modified organism" as set out in section 111 of the Act, and "genetically modified micro-organism" as set out in subarticle (1), genetic modification occurs at least through the use of the techniques listed in Part I of the First Schedule.
(b) The techniques listed in Part II of the First Schedule are not considered to result in genetic modification.
(3) (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.

REG 4

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

REG 5

Obligations. etc.
5. A person who carries out a contained use, deliberate release or a placing on the market, or any other user, shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment.

REG 6

Savings.
6. A person shall not be entitled solely by reason of compliance with these Regulations to—
(a) carry out a contained use of,
(b) deliberately release, or
(c) place on the market
a genetically modified organism.

REG 7

Calculation of time.
7. For the purposes of calculating periods within which the Agency may make a decision, a period of time during which the Agency is awaiting any further information or revised conditions which it may have requested from the notifier in accordance with these Regulations shall not be taken into account.

REG 8

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 notifier,
(b) the location or postal address of the installation to which a record, notification or amended notification relates,
(c) the location (including, where necessary, the name of the townland or townlands) of a deliberate release,
(d) the date or dates of a deliberate release,
(e) the date or dates of a placing on the market,
(f) the description of each genetically modified organism involved,
(g) the purpose of the contained use, deliberate release or placing on the market,
(h) the date of receipt of a record, notification or amended notification,
(i) the date of any publication of information under article 25 (1) (b) (v),
(j) the date of publication of a notice under article 31 (1),
(k) the number of objections received, if any, under article 31 (4),
(l) the date of any request for additional information or revised conditions,
(m) the date of receipt of any additional information or revised conditions,
(n) the date and nature of any waiver or modification under article 38,
(o) the date and nature of any reasoned objection of another Member State of the European Communities under article 42 (5),
(p) the date and nature of any decision by the Commission of the European Communities under Article 13 (3) of Council Directive 90/220/EEC1,
1O.J L 117, 8.5.90.
(q) the date of withdrawal of a notification or an amended notification,
(r) the date and nature of the decision by the Agency on a notification or an amended notification, and
(s) the date and outcome of any review under article 24.
(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 within seven days of its receipt by the Agency, or in the case of a consent or the attachment of conditions, within seven days of the decision to consent or attach conditions being made.

REG 9

Confidential information.
9. (1) Where a person gives a notification or otherwise provides information in pursuance of these Regulations and requests that certain information should be treated by the Agency as confidential information, full justification for that request shall be given with the notification.
(2) Where a request is made under sub-article (1), the Agency shall, following consultation with the notifier, decide which information (if any) shall be treated as confidential information and

shall inform the notifier of its decision.
(3) The Agency shall comply with the provisions of article 8 in respect of the first time use of an installation, contained use, deliberate release or placing on the market of a genetically modified organism, not less than fourteen days after informing the notifier of its decision on a request under sub-article (1), unless the notifier decides not to proceed with the contained use, deliberate release or placing on the market and informs the Agency accordingly within the said fourteen days.
(4) Without prejudice to sub-articles (3) or (5) the Agency shall not decide that any of the following shall be confidential information—
(a) the name and address of the notifier and the location of the contained use, deliberate release or placing on the market,
(b) the purpose of the contained use, deliberate release or placing on the market,
(c) the description of the genetically modified organism involved,
(d) methods and plans for monitoring the genetically modified organism and for emergency response, or
(e) the evaluation of foreseeable effects and in particular pathogenic effects and ecologically disruptive effects.
(5) If, before the Agency has reached a decision as to whether information in respect of which the notifier has requested that it should be treated as confidential information, or within fourteen days of such decision, the notifier decides not to prpoceed with the contained use, deliberate release or placing on the market and informs the Agency accordingly, the Agency shall treat the information in respect of which the request was made as confidential.
(6) The provision of this article shall not prevent disclosure of information to the Minister, the Commission of the European Communities or the competent authority of another Member State of the European Communities.

REG 10

Transitional arrangements.
10. (1) Articles 16 (1), 17 (2), 18, 30 (1) and 41 (1) shall not apply to the respective notifiers where such notifiers have already given a notification to which sub-article (2) applies.
(2) Where immediately before the commencement of these Regulations a notification referred to in sub-article (1) had been given to the Minister, the said articles 16 (1), 17 (2), 18, 30 (1) and 41 (1) shall apply in relation to the notification which, in lieu of being further considered by the Minister, shall, unless it is withdrawn, be decided by the Agency as if it had originally been submitted to the Agency under these Regulations.

PART II
CONTAINED USE

REG 11

Exclusions.
11. (1) This Part shall not apply to micro-organisms obtained through—
(a) mutagenesis,
(b) the construction and use of somatic animal hybridoma cells,
(c) cell fusion (including protoplast fusion) of cells from plants which can be produced by traditional breeding methods, or
(d) self-cloning on non-pathogenic naturally occurring micro-organisms which fulfil the criteria of Group I genetically modified micro-organisms for recipient micro-organisms,
on condition that they do not involve the use of genetically modified micro-organisms as recipient or parental organisms.
(2) Articles 14 to 24 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, transport, destruction or disposal of genetically modified micro-organisms which have been placed on the market pursuant to legislation of the European Community, which includes a specific risk assessment similar to that provided for in this Part.

REG 12

Duty to comply with this Part.
12. Subject to the exclusions contained in article 11, no contained use of a genetically modified organism shall be carried out save in compliance with the provisions of this Part.

REG 13

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 of a genetically modified organism, carry out an assessment of the risks to human health and the environment (if any) which may be associated with such use.
(2) In making an assessment under sub-article (1), the user shall have regard to the parameters set out in the Third Schedule in so far as they are relevant to the genetically modified organism which is the subject of the contained use.
(3) A record of any assessment carried out under sub-article (1) shall be kept by the user in such manner (if any), as may be specified by the Agency.

REG 14

Record of existing uses.
14. (1). A record in respect of each operation involving the contained use of a genetically modified organism and carried out on the day immediately prior to the day of the coming into operation of these Regulations, or at any time between the 23rd day of October, 1991 and the day immediately prior to the day of the coming into operation of these Regulations, shall be forwarded by the user to the Agency within three months of such date.
(2) A record under sub-article (1) shall, in so far as possible, contain the following—
(a) the name and address of the user and the location of the contained use,
(b) the purpose of the contained use,
(c) a description of the genetically modified organism used,
(d) information on accident prevention and containment measures,
(e) the methods and arrangements for monitoring the presence of viable genetically modified organisms outside the primary physical containment,
(f) the evaluation of effects, in particular any pathogenic or ecologically disruptive effects, and
(g) a description of the emergency response measures.

REG 15

Principles to be applied by users.
15. (1) A user of Group I genetically modified micro-organism shall—
(a) apply principles of good microbiological practice, including such principles (if any) as may be specified or approved by the Agency,
(b) keep the workplace and environmental exposure to any physical, chemical or biological agent to the lowest practicable level,
(c) exercise engineering control measures at source and supplement these with appropriate personal protective clothing and equipment where necessary,
(d) test and maintain control measures and equipment,
(e) test, when necessary, for the presence of viable process genetically modified micro-organisms outside the primary physical containment,
(f) provide training of personnel,
(g) establish biological safety committees or subcommittees, as necessary or as may be required by the Agency, having regard to the nature of the genetically modified micro-organism and the degree of exposure to that micro-organism, and
(h) formulate and implement rules and procedures to ensure the safety of personnel who may be affected by the contained use.
(2) A user of a Group II genetically modified micro-organism shall, in addition to complying with sub-article (1), apply the containment measures set out in the Fourth Schedule, where relevant, in order to ensure a high level of safety.
(3) A user of a Group I or Group II genetically modified micro-organism shall, from time to time and in any event at least

once every two years, review the containment measures applied so as to take account of scientific or technical knowledge relative to risk management and the treatment and disposal of wastes.
(4) A user of a Group I or Group II genetically modified micro-organism shall keep a written record, in such manner (if any) as may be specified by the Agency, of a review carried out in accordance with sub-article (3) and shall provide a copy of such written record to the Agency within one month of the completion of the review.

REG 16

Notification of first-time use of an installation for the contained use of genetically modified organisms.
16. (1) Notwithstanding any other provisions of these provisions of these Regulations, an installation shall not be used for the first time for an operation involving the contained use of a genetically modified organism unless a notification in respect of such first time use has been given to the Agency, and the conditions, if any, attached to a consent or agreement of the Agency have been complied with.
(2) In the case of the first time use of an installation for an operation involving the contained use of a Group I genetically modified micro-organism in a Type B operation or a Group II genetically modified micro-organism, the provisions of articles 17 (2) or 18, as appropriate, in addition to the giving of a notification under sub-article (1), shall be complied with before the use may commence.
(3) The notification referred to in sub-article (1) shall contain the information listed in Part I of the Fifth Schedule, as appropriate.
(4) For the purposes of this article the first time use of an installation for an operation involving the contained use of a Group I genetically modified micro-organism shall be treated as a first time use of the installation notwithstanding that the installation has been used previously for an operation involving the contained use of a Group II genetically modified micro-organism.
(5) For the purposes of this article the first time use of an installation for an operation involving the contained use of a Group II genetically modified micro-organism shall be treated as a first time use of the installation notwithstanding that the installation has been used previously for an operation involving the contained use of a Group I genetically modified micro-organism.
(6) Separate notifications must be given in respect of the first time use of an installation for an operation or operations involving the contained use of both a Group I genetically modified micro-organism and a Group II genetically modified micro-organism.
(7) A notification under sub-article (1) shall be accompanied by the fee payable in accordance with Part V.

REG 17

Contained use of Group I genetically modified micro-organisms.
17. (1) A user of a Group I genetically modified micro-organism in a Type A operation shall keep written records, in such manner (if

any) as may be specified by the Agency, of the work carried out which shall—
(a) be made available to the Agency on request, and
(b) be submitted to the Agency within one month of the end of each calendar year.
(2) A user of a Group I genetically modified micro-organism in a Type B operation shall, before commencing the contained use, give to the Agency a notification containing the information listed in Part II of the Fifth Schedule.
(3) A user of a genetically modified organism not covered by sub-articles (1) or (2), or article 18, shall keep written records of the work carried out which shall be made available to the Agency on request.
(4) A notification under sub-article (2) shall be accompanied by the fee payable in accordance with Part V.

REG 18

Contained use of Group II genetically modified micro-organisms.
18. (1) A user of a Group II genetically modified micro-organism in a Type A operation shall, before commencing the contained use, give to the Agency a notification containing the information listed in Part III of the Fifth Schedule.
(2) A user of a Group II genetically modified micro-organism in a Type B operation shall, before commencing the contained use, give to the Agency a notification containing the information listed in Part IV of the Fifth Schedule.
(3) A notification under sub-article (1) or (2) shall be accompanied by the fee payable in accordance with Part V.

REG 19

Effect of notifications.
19. (1) Where a notification in relation to the first time use of an installation for an operation involving the contained use of a Group I genetically modified micro-organism has been given in accordance with article 16, the installation may, in the absence of an indication from the Agency to the contrary, be so used ninety days after the receipt by the Agency of the notification, or at such earlier date as may be agreed with the Agency.
(2) Where a notification in relation to the first time use of an installation for an operation involving the contained use of a Group II genetically modified micro-organism has been given in accordance with article 16, the installation shall not be used without the consent of the Agency.
(3) Where a notification in relation to the first time use of an installation for an operation involving the contained use of a genetically modified organism, other than a genetically modified micro-organism covered by article 17 (1) or (2), or article 18, has been given in accordance with article 16, the installation may, in the absence of an indication from the Agency to the contrary, be so used ninety days after the receipt by the Agency of the notification, or at such earlier date as may be agreed with the Agency.
(4) A contained use of a Group I genetically modified micro-organism

in a Type B operation notified in accordance with article 17 (2), and a contained use of a Group II genetically modified micro-organism in a Type A operation notified in accordance with article 18 (1)—

(a) may, in the absence of any indication to the contrary from the Agency, proceed sixty days after the receipt by the Agency of the notification, or at such earlier date as may be agreed with the Agency, or

(b) where any conditions or requirements have been indicated by the Agency within sixty days of the receipt by it of the notification, may not proceed unless the said conditions or requirements have been complied with.

(5) A contained use of a Group II genetically modified micro-organism in a Type B operation notified in accordance with article 18 (2) may not proceed unless the consent of the Agency has been received under this Part and the conditions, if any, attached to the consent have been complied with.

(6) Where a notification has been received by the Agency in respect of the first time use of an installation for an operation involving the contained use of a Group II genetically modified micro-organism in accordance with article 16, or in respect of the contained use of a Group II genetically modified micro-organism in a Type B operation in accordance with article 18 (2), the Agency shall communicate its decision in writing to the notifier within ninety days of the receipt by the Agency of the notification.

(7) Should the Agency fail to issue a decision within ninety days as required by sub-article (6), such failure will not entitle the notifier to proceed with the first time use of an installation for an operation involving the contained use of a Group II genetically modified micro-organism, or a contained use of a Group II genetically modified micro-organism in a Type B operation, as the case may be.

REG 20

Duty of the Agency under this Part.

20. The Agency shall examine the conformity of a notification received under this Part with the requirements of this Part, the accuracy and completeness of the information given, the correctness of the classification and, where appropriate, the adequacy of the waste management, safety and emergency response measures.

REG 21

Power of the Agency to request further information or modifications.

21. (1) The Agency may, in the case of a notification under this Part, request the user or notifier to provide further information, or to submit revised conditions for a proposed contained use.

(2) Where the Agency makes a request under sub-article (1), the user or notifier shall comply with the request and shall not proceed with a first time use of an installation or a contained use unless the Agency has given its consent on the basis of the further information obtained, or of the modified conditions of the contained use, and the conditions of the consent on the basis of

the further information or the modified conditions have been complied with.

REG 22

Power of the Agency to grant or refuse consent.

22. (1) (a) Where a notification has been given to the Agency in respect of the first time use of an installation for an operation involving the contained use of a Group II genetically modified micro-organism in accordance with article 16, or in relation to the contained use of a Group II genetically modified micro-organism in a Type B operation in accordance with article 18 (2), the Agency shall give its consent with or without conditions, or refuse its consent.

(b) In the case of a notification, other than a notification specified in paragraph (a), the Agency may 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 installation 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 for controlling 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 confirmation by the user of compliance with the conditions attached to the use of a genetically modified organism and indicating any breaches of such conditions,

(h) specify the measures to be taken if there is 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 and the manner in which it shall be held or disposed of,

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

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

(l) specify the latest date for complying with any conditions

which are attached.

REG 23

Duty of user to inform the Agency of new information etc.
23. (1) 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 the contained use, the user shall as soon as is practicable—
(a) review the containment measures drawn up in respect of the risk, and
(b) submit an amended notification to the Agency,
(2) Where the contained use changes from Group or Type of operation as defined in article 3, an amended notification or notifications, in accordance with the appropriate article or articles, shall be submitted and the contained use shall be discontinued until such time as these Regulations have been complied with.
(3) An amended notification or notifications under sub-article (1) (b) or (2) shall be accompanied by the fee payable in accordance with Part V.

REG 24

Review of contained uses.
24. (1) 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 where information becomes available to it which was not available at the time of notification, inspection or review, and the risks posed by the contained use are altered to a material degree.
(3) As soon as may be after it has completed a review under this article, the Agency may require the user to modify the conditions of, suspend or terminate the contained use.

REG 25

Accident procedures.
25. (1) Before a contained use commences a user shall—
(a) where the risk assessment shows that an accident would create a significant risk to human health or the environment, or
(b) where the Agency requires it,
(i) draw up, in consultation with the appropriate emergency services, and such other persons, and in such manner as may be specified by the Agency, an emergency plan for the protection of human health and the environment outside the installation in the event of an accident,
(ii) inform the appropriate emergency services of the hazards and the proposed emergency plan in writing,
(iii) supply information in writing on safety measures, and on the correct behaviour to adopt in the case of an accident, to persons liable to be affected by the accident, and to such other persons within or without the State as may be specified by the Agency,
(iv) repeat and update the information specified in subparagraph

(iii) at such periods as the Agency may specify, and
(v) make public the information supplied in accordance with subparagraph (iii) in such manner as the Agency may specify.
(2) 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 organisms released,
(iii) any information necessary to assess the effects of the accident on the health of the general population and the environment,
(iv) full and detailed information on the emergency measures taken,
(b) ensure that the relevant emergency services are fully informed of the accident,
(c) inform persons likely to be affected by the accident, and
(d) activate other relevant provisions of the emergency plan.
(3) Where the Agency is notified of an accident under sub-article (2) it shall—
(a) immediately alert any Member State of the European Communities which could be affected by an accident involving a Group I or Group II genetically modified micro-organism,
(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, and
(c) ensure that any emergency, medium and long-term measures necessary are taken.
(4) 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.

REG 26

Consultation concerning emergency plans.
26. (1) When emergency plans are being drawn up under article 25 (1) or implemented under article 25 (2), the Agency shall consult with such other Member States of the European Communities as it considers are liable to be affected in the event of an accident involving a Group I or Group II 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.
(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 that which is disseminated within the State.

REG 27

Informing the Commission of the European Communities.
27. 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 Group I or Group II genetically modified micro-organism, giving details of the

circumstances of the accident, the identity and quantities of the genetically modified micro-organisms released, the emergency response measures employed and their effectiveness, and an analysis of the accident including recommendations to limit its effects and avoid similar accidents in the future.

PART III

DELIBERATE RELEASE INTO THE ENVIRONMENT FOR PURPOSES OTHER THAN FOR PLACING ON THE MARKET

REG 28

Exclusions.
28. Parts III and IV shall not apply to—
(a) organisms obtained through the techniques of—
(i) mutagenesis,
(ii) cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods,
on condition that the techniques do not involve the use of genetically modified organisms as recipient or parental organisms, or
(b) the carriage of genetically modified organisms by road, rail, inland waterway, sea or air.

REG 29

Prohibition of a deliberate release in the absence of consent.
29. Subject to the provisions of article 5, a person shall not deliberately release a genetically modified organism, or a combination of genetically modified organisms, for the purpose of research and development, or for any purpose other than for placing on the market, unless the written consent of the Agency has been received and the conditions attached to the consent have been complied with in respect of that release.

REG 30

Notification of intent to make a deliberate release.
30. (1) A person proposing to make a deliberate release of a genetically modified organism, or a combination of genetically modified organisms, for the purpose of research and development, or for any purpose other than for placing on the market, shall give a notification to the Agency.
(2) A notification under sub-article (1) shall include—
(a) a technical description of the proposed deliberate release containing the information specified in the Seventh Schedule insofar as that Schedule may apply to the particular deliberate release and sufficient to enable the Agency to evaluate the foreseeable risks, whether immediate or delayed, which the deliberate release of the genetically modified organism, or a combination of genetically modified organisms, may pose to human health or the environment, together with the methods used and the bibliographic reference to them,

(b) a statement evaluating the impacts and risks posed by the genetically modified organism, or a combination of genetically modified organisms, to human health or the environment, from the uses envisaged,
(c) information on data or results from a deliberate release of the same genetically modified organism, or the same combination of genetically modified organisms, previously or currently notified and/or carried out by the notifier either inside or outside the territory of the European Communities.
(3) (a) The notifier may refer to data or results from a notification previously given by another notifier, provided that the latter has agreed in writing and a copy of this agreement is included in the notification.
(b) Where appropriate, the notifier may refer to data from previous notifications, or results from previous releases, in respect of the same genetically modified organism, or combination of genetically modified organisms, previously notified as part of the same research programme.
(4) Notwithstanding sub-article (1), the Agency may accept that a deliberate release of a combination of genetically modified organisms on the same site or of the same genetically modified organism on different sites for the same purpose and within a limited period, may be included in a single notification.
(5) A notification under sub-article (1) shall be accompanied by the fee payable in accordance with Part V.

REG 31

Advertisement of notification for consent to a deliberate release.
31. (1) Subject to sub-article (2), a person who gives a notification in connection with the deliberate release of a genetically modified organism, or a combination of genetically modified organisms, shall, not more than fourteen days after the date of acknowledgement of receipt of that notification by the Agency, cause to be published in a newspaper circulating in the area of the proposed deliberate release a notice containing the following information—
(a) the name and address of the notifier,
(b) the description of the organism to be released,
(c) the location and purpose of the deliberate release, and
(d) the date or dates of the deliberate release.
(2) The information on the location of the deliberate release published pursuant to sub-article (1) shall be the same as the information on its location which is placed on the register kept by the Agency under article 8.
(3) A person who gives a notification in connection with the deliberate release of a genetically modified organism, or a combination of genetically modified organisms, shall, not more than fourteen days after the date of acknowledgement of receipt of that notification by the Agency, send a notice containing the information set out in sub-article (1) (a) to (d) above to—
(a) the owner of the site of the proposed deliberate release, if a person other than the notifier, and
(b) the local authority in whose functional area the proposed deliberate release is intended to take place.

(4) Any person or body may, within twenty one days of the publication of a notice under subarticle (1), make representations in writing to the Agency in relation to a notification under article 30.

REG 32

Modification of notifications.

32. If, after the receipt of a notification but before the giving of consent by the Agency to the deliberate release, there is a modification of the deliberate release of a genetically modified organism, or a combination of genetically modified organisms, which could have consequences for the risks to human health or the environment, or new information on such risks becomes available—

(a) the notifier shall submit an amended notification, and

(b) the Agency shall deal with the amended notification as if it were the original notification in relation to the deliberate release and the provisions of this Part shall apply to the amended notification as if it were the original notification.

REG 33

Duty of the Agency under this Part.

33. (1) On receipt of a notification under this Part the Agency shall—

(a) acknowledge such receipt in writing,

(b) send a copy of a summary of the notification, in the format set out in the Ninth Schedule, to the Commission of the European Communities within thirty days of the receipt of the notification,

(c) examine it for compliance with these Regulations,

(d) evaluate the risks posed by the deliberate release,

(e) consider, where appropriate, any observations presented by another Member State of the European Communities either directly or through the Commission of the European Communities,

(f) consider any representations received by it under article 31 (4), and

(g) record its conclusions in writing.

(2) In addition to the matters specified in sub-article (1), the Agency may carry out such tests or inspections as may be necessary for its consideration of the notification.

(3) The Agency shall respond in writing to the notifier within ninety days of receipt of the notification by indicating either—

(a) that it consents to the deliberate release subject to, or without conditions, or

(b) that consent to the release is refused and the reasons for the refusal.

(4) The Agency shall not consent to a deliberate release unless it is satisfied that the deliberate release will not result in adverse effects on human health or the environment.

REG 34

Power of the Agency to modify consent.
34. If information becomes available to the Agency, subsequent to giving its consent, which could have significant consequences for the risks posed by the deliberate release, the Agency may require the notifier to modify the conditions of, suspend or terminate the deliberate release.

REG 35

Duty to inform Agency of new information, etc.
35. (1) If, after the Agency has given its written consent to a deliberate release, there is a modification of the deliberate release of a genetically modified organism or a combination of genetically modified organisms which could have consequences for the risks to human health or the environment, or new information on such risks becomes available, the notifier shall immediately—
(i) revise the measures specified in the notification,
(ii) inform the Agency in advance of any modification or as soon as the new information is available, and
(iii) take all measures necessary to protect human health and the environment.
(2) The Agency may, having examined any modification or new information under sub-article (1) for compliance with these Regulations and evaluated the risks, require the notifier to modify the conditions of, suspend or terminate the deliberate release.

REG 36

Post release procedures.
36. After completion of a deliberate release, the notifier shall send to the Agency the result of the deliberate release and, in particular, shall submit an assessment of any risk to human health or the environment involved in the deliberate release, with particular reference to any product that the notifier intends to notify at a later stage which may contain the genetically modified organism which was deliberately released.

REG 37

Notification of decision.
37. The Agency shall, as soon as is practicable, inform in writing—
(a) any person or body referred to in article 31 (3),
(b) each Member State of the European Communities,
(c) the Commission of the European Communities, and
(d) any person or body who made representations to the Agency under article 31 (4),
of its decision under article 33 in relation to a notification.

REG 38

Waiver or modification.
38. Any provision of this Part of these Regulations may be waived or modified by the Agency in respect of the deliberate release of specified genetically modified organisms, or combinations of genetically modified organisms, provided that the Agency has requested and obtained the approval of the Commission of the European Communities for such waiver or modification.

PART IV

PLACING ON THE MARKET OF PRODUCTS CONTAINING GENETICALLY MODIFIED ORGANISMS

REG 39

Consent to market products.
39. A person shall not place on the market any product containing or consisting of genetically modified organisms, unless
(a) consent in writing has been received under this Part, or
(b) consent in writing has been received from the competent authority of another Member State of the European Communities in accordance with Part C of Council Directive 90/220/EEC,
and the conditions attached to the relevant consent have been complied with.

REG 40

Power of the Agency to prohibit placing on the market.
40. (1) Notwithstanding the provisions of article 39, the Agency may by notice in writing provisionally restrict or prohibit the use or placing on the market of a product containing or consisting of genetically modified organisms where there are reasonable grounds to believe that the product constitutes a risk to human health or the environment.
(2) Where the Agency decides provisionally to restrict or prohibit the placing on the market of a product containing genetically modified organisms, that has received a written consent under these Regulations or from the competent authority of another Member State of the European Communities which satisfies the provisions of Part C of Council Directive 90/220/EEC, it shall, as soon as is practicable, inform the Commission of the European Communities and the other Member States of the European Communities of its decision and the reasons therefor.
(3) It shall be an offence to contravene a provision of any notice in writing made under sub-article (1).
(4) A decision taken under article 16 (2) of Council Directive 90/220/EEC shall be accepted by the Agency in respect of any notice in writing given by it under sub-article (1).

REG 41

Information to be contained in a notification.

41. (1) Before a genetically modified organism is, or a combination of genetically modified organisms are, placed on the market for the first time as or in a product, the manufacturer or the importer, whichever is appropriate, shall give a notification to the Agency containing—

(a) the information specified in the Seventh Schedule to the extent that such information is appropriate to the nature and scale of the release which may result from the marketing,

(b) information on data or results from any previous release of the organism, or of organisms of the same description, which have been carried out by the notifier whether inside or outside the European Community, and information from any previous notification in connection with a release of the organisms, or of organisms of the same description, which the notifier has made to the Agency in accordance with these Regulations or to the competent authority of another Member State of the European Communities which satisfies the provisions of Part C of Council Directive 90/220/EEC, and

(c) subject to sub-article (5), the information specified in the Eighth Schedule.

(2) The Agency shall be given a separate notification in accordance with sub-article (1) in respect of each new product which, containing or consisting of the same genetically modified organism or combination of genetically modified organisms, is intended for a different use.

(3) The information specified in the Seventh Schedule shall be included in the notification at the level of detail which is appropriate to the nature and scale of the release which may result from the marketing, and shall take into account the diversity of sites of use of the product, including—

(a) information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product, and

(b) an assessment of any risks for human health or the environment related to the genetically modified organism contained in the product, including information obtained from the research and development stage on the impact of the release on human health and the environment.

(4) The notification shall contain the description of the methods used to obtain the information presented in the notification or, where internationally recognised methods are used, a reference to which method was used to obtain the information and its bibliographic references together with the neme of the body responsible for carrying out the studies.

(5) Where the notifier considers, on the basis of the results of any release in pursuance of a consent granted under Part III or this Part, or a written consent given by the competent authority of another Member State of the European Communities which is in accordance with the provisions of Part B of Council Directive 90/220/EEC, or on substantive, reasoned scientific grounds, that the placing on the market and use of the product do not pose a risk to human health or the environment, the notifier may propose to the

Agency not to supply the information specified in Part II of the Eighth Schedule.
(6) A notification may contain data or results from a notification previously given by another notifier provided that the latter has agreed in writing, and that a copy of that agreement is attached to the notification.
(7) A notification under sub-article (1) shall be accompanied by the fee specified in Part V.

REG 42

Duty of the Agency under this Part.
42. (1) On receipt of a notification given under article 41, the Agency shall—
(a) acknowledge such receipt in writing, and
(b) examine the notification for its compliance with these Regulations, giving particular attention to the environmental risk assessment and the precautions related to the safe use of the product.
(2) Within ninety days of the receipt of a notification under article 41, the Agency shall either—
(a) send to the Commission of the European Communities,
(i) a copy of the notification,
(ii) a summary of the notification in the format specified in the Tenth Schedule,
(iii) a statement of the conditions which it proposes to attach to the consent to the marketing of the product,
(iv) any agreement to a proposal of a notifier under article 41
(5) not to supply any of the information specified in Part II of the Eighth Schedule, and
(v) its favourable opinion on the notification, or
(b) inform the notifier that the consent is refused and the reasons for the refusal.
(3) The Agency shall, as soon as is practicable, inform the competent authority of each Member State of the European Communities and the Commission of the European Communities of any other information it receives from the notifier before or after the granting of the consent.
(4) In the absence of a reasoned objection by another Member State of the European Communities, or where an objection has been raised and that objection has subsequently been withdrawn in writing, within a period of sixty days beginning with the day on which the documents referred to in sub-article (2) (a) were forwarded to each Member State by the Commission of the European Communities, the Agency shall give consent in writing, with or without conditions, to the notification and inform each other Member State and the Commission of the European Communities that it has done so.
(5) Where the competent authority of another Member State of the European Communities has made a reasoned objection and the Agency has not reached an agreement with such other competent authority within the period specified in sub-article (4), a decision taken by the Commission of the European Communities under Article 13 (3) of Council Directive 90/220/EEC shall be accepted by the Agency.
(6) Where the Commission of the European Communities has taken a favourable decision under Article 13 (3) of Council Directive

90/220/EEC on a notification received by the Agency, the Agency shall give its consent in writing with any necessary conditions, to the notification and inform each Member State of the European Communities and the Commission that it has done so.
(7) A consent in respect of a product containing, or consisting of, genetically modified organisms shall include conditions relating to the labelling and packaging of the product.

PART V

FEES AND CHARGES

REG 43

Fee for notification of a first time use of an installation.
43. (1) A fee shall be paid to the Agency in respect of a notification of a first time use of an installation given to the Agency under article 16.
(2) The fee payable under sub-article (1) shall be—
(a) one of the amounts indicated in columns 2 to 5, whichever is appropriate, of Part I of the Eleventh Schedule opposite the mention of a notification under article 16, or
(b) the amount indicated in column 2 of Part II of the Eleventh Schedule opposite the mention of a notification under article 16.

REG 44

Fee for notification of a Group I contained use.
44. (1) A fee shall be paid to the Agency in respect of a notification of a contained use of a Group I genetically modified micro-organism given to the Agency under article 17.
(2) The fee payable under sub-article (1) shall be the amount indicated in column 3 of Part I of the Eleventh Schedule opposite the mention of a notification under article 17.

REG 45

Fee for notification of a Group II contained use.
45. (1) A fee shall be paid to the Agency in respect of a notification of a contained use of a Group II genetically modified micro-organism given to the Agency under article 18.
(2) The fee payable under sub-article (1) shall be either of the amounts indicated in columns 4 or 5, whichever is appropriate, of Part I of the Eleventh Schedule opposite the mention of a notification under article 18.

REG 46

Fee for an amended notification of a contained use.
46. (1) A fee shall be paid to the Agency in respect of an amended notification of a contained use of a Group I or Group II genetically modified micro-organism given to the Agency under article 23.

(2) The fee payable under sub-article (1) shall be one of the amounts indicated in columns 3 to 5, whichever is appropriate, of Part I of the Eleventh Schedule opposite the mention of an amended notification under article 23.

REG 47

Fee for notification of a deliberate release.
47. (1) A fee shall be paid to the Agency in respect of a notification of a deliberate release given to the Agency under article 30.
(2) The fee payable under sub-article (1) shall be the amount indicated in column 2 of Part III of the Eleventh Schedule opposite the mention of a notification under article 30.

REG 48

Fee for notification of the placing of a product on the market.
48. (1) A fee shall be paid to the Agency in respect of a notification in connection with the placing of a product on the market given to the Agency under article 41.
(2) The fee payable under sub-article (1) shall be the amount indicated in column 2 of Part IV of the eleventh Schedule opposite the mention of a notification under article 41.

REG 49

Refund of fee in case of certain repeat notifications.
49. (1) Where a notification under articles 16, 17, 18, 30 or 41 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 50, refund three quarters of the fee paid to it in respect of the subsequent notification if, and only 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 use or a contained use of the same nature and scale as the use or contained use to which the earlier notification related,
(b) a fee in respect of the same use or 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 subarticle (1) has at any time been made to the same user in respect of a notification which related substantially to the same use or 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 51.

REG 50

Claim for refund to be in writing.
50. A refund under article 49 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 the subsequent notification.

REG 51

Discretionary power to refund or waive fee in certain limited circumstances.
51. (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 use or contained use,
(b) the limited capital or operational costs, or both, as appropriate, of the use or contained use,
(c) the fee payable in respect of a notification for any other use or 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.

REG 52

Periodic charges for monitoring.
52. The Agency may require a user to make periodic payments, not exceeding the costs incurred by the Agency, for the purposes of defraying or contributing towards the costs incurred by it in monitoring, carrying out inspections, or otherwise ensuring compliance of the use or contained use with the requirements of these Regulations and any consent, conditions or other requirements pursuant to these Regulations.

REG 53

Agency investigations.
53. 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 use or a contained use, to enable it properly to assess the notification and may require the notifier to defray or contribute towards the cost of any such investigations.

REG 54

Recovery of costs or charges.
54. The Agency may recover the amount of any payment due to it arising from a requirement under article 25 (4), 52 or 53 as a simple contract debt in any Court of competent jurisdiction.

PART VI

ADVISORY COMMITTEE ON GENETICALLY MODIFIED ORGANISMS

REG 55

Advisory Committee.
55. The Agency shall appoint a committee to be known as the "Advisory Committee on Genetically Modified Organisms" for the purposes of consultation on any aspect of its functions under these Regulations.

REG 56

Membership of Advisory Committee.
56. (1) The Membership of the Committee shall include persons nominated by the following:
(a) the Agency,
(b) the Minister for the Environment,
(c) the Minister for Agriculture, Food and Forestry,
(d) the Minister for Health,
(e) the Minister for Enterprise and Employment,
(f) the Commissioners of Public Works in Ireland,
(g) the National Authority for Occupational Safety and Health,
(h) organisations which in the opinion of the Agency are representative of persons whose professions or occupations relate to biotechnology research or the bio-technology industry,
(i) organisations which in the opinion of the Agency are concerned with environmental protection.
(2) The number of members of the Committee, including the person appointed under article 58 to chair the meetings, shall not exceed 12.

REG 57

Term of appointment of members of Advisory Committee.
57. A member shall be appointed to the Committee for such term (not exceeding three years) as shall be specified by the Agency and a member whose term of office expires by the effluxion of time shall be eligible for reappointment.

REG 58

Appointment of person to chair meetings.
58. The Agency shall appoint a person to chair the meetings of the committee and a person to act in the absence of the person appointed.

REG 59

Regulation of procedure or business.
59. The committee may regulate, by standing orders or otherwise, its procedure or business.

PART VII

ENFORCEMENT AND REGULATION

REG 60

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

REG 61

Prosecution of offences.
61. An offence under these Regulations or an offence arising from the exercise of powers under the Act by authorised persons appointed pursuant to article 60, may be prosecuted by the Agency.

REG 62

High Court injunction.
62. The High Court may, on the application of the Agency, by order, prohibit or restrict any process or action involving a genetically modified organism where the court is satisfied that:
(a) the continuance of the process or action would constitute a contravention of these Regulations, or
(b) the continuance of the process or action would pose a real and substantial danger to human health or the environment.

REG 63

Notice to take measures.
63. (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.
(2) A notice under 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 process or action 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 VIII

MONITORING AND REPORTING

REG 64

Monitoring.
64. 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.

REG 65

Reporting on functions under these Regulations.
65. The Agency shall, if so directed by the Minister, supply to the Minister or to any other person specified by the Minister, at such intervals and in such manner as the Minister may direct, records of any monitoring carried out under these Regulations or any other information in relation to the performance of functions under these Regulations, as the Minister may specify.

FIRST SCHEDULE

Article 3
TECHNIQUES OF GENETIC MODIFICATION
PART I
Techniques of genetic modification are, inter alia:
(1) recombinant DNA techniques using vector systems as previously covered by Council Recommendation 82/472/EEC(1);
(1)Official Journal of the European Communities No. 213/15 of 21 July 1982.
(2) techniques involving the direct introduction into a micro-organism, or other organism as the case may be, of heritable material prepared outside the micro-organism, or other organism as the case may be, including micro-injection, macro-injection and micro-encapsulation;
(3) cell fusion or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.
PART II
Techniques which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant-DNA molecules or genetically modified organisms:
(1) in vitro fertilisation;
(2) conjugation, transduction, transformation or any other natural process;
(3) polyploidy induction.

SECOND SCHEDULE

Article 3
CLASSIFICATION OF GENETICALLY MODIFIED MICRO-ORGANISMS
PART I
CRITERIA FOR CLASSIFYING GENETICALLY MODIFIED MICRO ORGANISMS IN GROUP I
A. Recipient or parental organism
— non-pathogenic;
— no adventitious agents;
— proven and extended history of safe use or built-in biological barriers, which, without interfering with optimal growth in the reactor or fermenter, confer limited survivability and replaceability, without adverse consequences in the environment.
B. Vector/insert
— well characterised and free from known harmful sequences;
— limited in size as much as possible to the genetic sequences required to perform the intended function;
— should not increase the stability of the construct in the environment (unless that is a requirement of intended function);
— should be poorly mobilisable;
— should not transfer any resistance markers to micro-organisms not known to acquire them naturally (if such acquisition could compromise use of drug to control disease agents).
C. Genetically modified micro-organisms
— non-pathogenic;
— as safe in the reactor or fermenter as recipient or parental organism, but with limited survivability and/or replaceability without adverse consequences in the environment.
D. Other genetically modified micro-organisms that could be included in Group I if they meet the conditions in C above
— those constructed entirely from a single prokaryotic recipient (including its indigenous plasmids and viruses) or from a single eukaryotic recipient (including its chloroplasts, mitochondria, plasmids, but excluding viruses);
— those that consist entirely of genetic sequences from different species that exchange these sequences by known physiological processes.
PART II
GUIDELINES FOR THE CLASSIFICATION OF GENETICALLY MODIFIED MICRO-ORGANISMS INTO GROUP I
For classification into Group I, the following guidelines should be used to further interpret Part I of this Schedule.
A: Characteristics of the recipient or parental organism(s)
1. Non-pathogenic
The recipient or parental organisms can be classified as non-pathogenic if they satisfy the conditions of one of the following paragraphs:
(i) the recipient or parental strain should have an established record of safety in the laboratory and/or industry, with no adverse effects on human health and the environment;
(ii) the recipient or parental strain does not meet the conditions of paragraph (i) but it belongs to a species for which there is a

long record of biological work including safety in the laboratory and/or industry, showing no adverse effects on human health and the environment;
(iii) if the recipient or parental organism is a strain which does not satisfy the conditions of paragraph (i) and belongs to a species for which there is no record of biological work including safe use in the laboratory and/or industry, appropriate testing (including, if necessary, animals) must be carried out, in order to establish non-pathogenicity and safety in the environment;
(iv) if a non-virulent strain of an acknowledged pathogenic species is used, the strain should be as deficient as possible in genetic material that determines virulence so as to ensure no reversion to pathogenicity. In the case of bacteria, special attention should be given to plasmid or phage-borne virulence determinants.
2. No adventitious agents
The recipient or parental strain/cell line should be free of known biological contaminating agents (symbionts, mycoplasma, viruses, viroids, etc.), which are potentially harmful.
3. The recipient or parental strain/cell line should have proven and extended history of safe use or built-in biological barriers, which, without interfering with optimal growth in the reactor or fermenter, confer limited survivability and replaceability, without adverse consequences in the environment (applicable only for type B operations).
B. 1: Characteristics of the vector
1.1 The vector should be well characterised
For this purpose the following characteristics should be taken into account.
1.1.1 Information on composition and construction.
(a) The type of vector should be defined (virus, plasmid, cosmid, phasmid, transposable element, minichromosome, etc.);
(b) The following information on the constituent fragments of the vector should be available:
(i) the origin of each fragment (progenitor genetic element, strain of organism in which the progenitor genetic element naturally occurred);
(ii) if some fragments are synthetic, their function should be known.
(c) the methods used for construction should be known.
1.1.2 Information on Vector structure
(a) The size of the vector should be known and expressed in basepairs or D.
(b) The function and relative position of the following should be known:
(i) structural genes;
(ii) marker genes for selection (antibiotic resistance, heavy metal resistance, phage immunity, genes coding for degradation of xenobiotics, etc.);
(iii) regulatory elements;
(iv) target sites (nic-sites, restriction endonuclease sites, linkers, etc.);
(v) transposable elements (including provirus sequences);
(vi) genes related to transfer and mobilisation function (e.g., with respect to conjugation, transduction or chromosomal integration);
(vii) replicon(s).

1.2 The vector should be free from harmful sequences
The vector should not contain genes coding for potentially harmful or pathogenic traits (e.g., virulence determinants, toxins, etc.), (unless, for type A operations, such genes constitute an essential feature of the vector without, under any conditions or circumstances, resulting in a harmful or pathogenic phenotype of the genetically modified micro-organism).
1.3 The vector should be limited in size as much as possible to the genetic sequences required to perform the intended function.
1.4 The vector should not increase the stability of the genetically modified micro-organism in the environment (unless that is a requirement of the intended function).
1.5 The vector should be poorly mobilisable
1.5.1 If the vector is a plasmid:
(i) it should have a restricted host-range;
(ii) it should be defective in transfer-mobilisation factors e.g. Tra -, Mob+, for type A operations or Tra -, Mob -, for type B operations.
1.5.2 If the vector is a virus, cosmid, or phasmid:
(i) it should have a restricted host-range;
(ii) it should be rendered non-lysogenic when used as a cloning vector (e.g., defective in the CL-lamda repressor).
1.6 It should not transfer any resistance markers to micro-organisms not known to acquire them naturally (if such acquisition could compromise use or drug to control disease agents).
B.2: Required characteristics of the insert
2.1 The insert should be well characterised
For this purpose, the following characteristics should be taken into account:
2.1.1 The origin of the insert should be known (genus, species, strain).
2.1.2 The following information on the library from which the insert originated, should be known:
(i) The source and method for obtaining the nucleic acid of interest (cDNA, chromosomal mitochondrial, etc.);
(ii) the vector in which the library was constructed (e.g. lamda GT II, pBR 322, etc.) and the site in which the DNA was inserted;
(iii) the method used for identification (colony, hybridisation, immuno-blot, etc.);
(iv) the strain used for library construction.
2.1.3 If the insert is synthetic, its intended function should be identified.
2.1.4 The following information on the structure of the insert is required:
(i) information on structural genes, regulatory elements;
(ii) size of the insert;
(iii) restriction endonuclease sites flanking the insert;
(iv) information on transposable elements and provirus sequences.
2.2 The insert should be free from harmful sequences
(i) The function of each genetic unit in the insert should be defined (not applicable for type A operations);
(ii) the insert should not contain genes coding for potential pathogenic traits (e.g., virulence determinants, toxins, etc.), (unless for type A operations, such genes constitute an essential part of the insert without, under any circumstances resulting in a harmful

or pathogenic phenotype of the genetically modified micro-organism).
2.3 The insert should be limited in size as much as possible to the genetic sequences required to perform the intended function.
2.4 The insert should not increase the stability of the construct in the environment (unless that is a requirement of intended function).
2.5 The insert should be poorly mobilisable
For instance, it should not contain transposing or transferable provirus sequences and other functional transposing sequences.
C: Required characteristics of the genetically modified micro-organism
1. The genetically modified micro-organism should be non-pathogenic. This requirement is reasonably assured by compliance with all the requirements above.
2. (a) The genetically modified micro-organism should be as safe (to humans and the environment) as the recipient or parental strains (applicable only for type A operations).
(b) The genetically modified micro-organisms should be as safe in the reactor or fermenter as the recipient or parental strains, but with limited survivability and/or replaceability outside the reactor or fermenter without adverse consequences in the environment (applicable only for type B operations).
D: Other genetically modified micro-organisms that could be included in Group I if they meet the conditions in C above:
1. Those constructed entirely from a single prokaryotic recipient (including its indigenous plasmids and viruses) or from a single eukaryotic recipient (including its chloroplasts, mitochondria, plasmids, but excluding viruses).
2. Those that consist entirely of genetic sequences from different species that exchange these sequences by known physiological processes.

THIRD SCHEDULE

Article 13
SAFETY ASSESSMENT PARAMETERS TO BE TAKEN INTO ACCOUNT AS FAR AS THEY ARE RELEVANT
A. Characteristics of the donor, recipient or (where appropriate) parental organism(s)
B. Characteristics of the modified micro-organism or other organism
C. Health considerations
D. Environmental considerations

A. Characteristics of the donor, recipient or (where appropriate) parental organism(s)
— names and designation;
— degree of relatedness;
— source of the organism(s);
— information on reproductive cycles (sexual/asexual) of the parental organism(s) or, where applicable, of the recipient micro-organism or other organism;
— history of prior genetic manipulations;
— stability of parental or of recipient organism in terms of relevant genetic traits;
— nature of pathogenicity and virulence, infectivity, toxicity and vectors of disease transmission;

— nature of indigenous vectors; sequence,
frequency of mobilisation, specificity, presence of genes which confer resistance,
— host range;
— other potentially significant physiological traits; —stability of these traits;
— natural habitat and geographic distribution. Climatic characteristics of original habitats;
— significant involvement in environmental processes (such as nitrogen fixation or pH regulation);
— interaction with, and effects on, other organisms in the environment (including likely competitive or symbiotic properties):
— ability to form survival structures (such as spores or sclerotia).
B. Characteristics of the modified micro-organism or other organism
— the description of the modification including the method for introducing the vector-insert into the recipient organism or the method used for achieving the genetic modification involved;
— the function of the genetic manipulation and/or of the new nucleic acid;
— nature and source of the vector;
— structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified micro-organism or other organism;
— stability of the micro-organism or other organism in terms of genetic traits;
— frequency of mobilisation of inserted vector and/or genetic transfer capability;
— rate and level of expression of the new genetic material. Method and sensitivity of measurement;
— activity of the expressed protein.
C. Health considerations
— toxic or allergenic effects of non-viable organisms and/or their metabolic products;
— product hazards;
— comparison of the modified micro-organism or other organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
— capacity for colonisation;
— if the micro-organism or other organism is pathogenic to humans who are immunocompetent:
(a) diseases caused and mechanism of pathogenicity including invasiveness and virulence;
(b) communicability;
(c) infective dose;
(d) host-range, possibility of alteration;
(e) possibility of survival outside of human host;
(f) presence of vectors or means of dissemination;
(g) biological stability;
(h) antibiotic-resistance patterns;
(i) allergenicity;
(j) availability of appropriate therapies.
D. Environmental Considerations
— factors affecting survival, multiplication and dissemination of the modified micro-organism or other organism in the environment;
— available techniques for detection, identification and monitoring of

the modified micro-organism or other organism;
— available techniques for detecting transfer of the new genetic material to other organisms;
— known and predicted habitats of the modified micro-organism or other organism;
— description of ecosystem to which the micro-organism or other organism could be accidentally disseminated;
— anticipated mechanism and result of interaction between the modified micro-organism or other organism and the organisms or micro-organisms which might be exposed in case of release into the environment;
— known or predicted effects on plants and animals such as pathogenicity, infectivity, toxicity, virulence, vector of pathogen, allergenicity, colonisation;
— known or predicted involvement in biogeochemical processes;
— availability of methods for decontamination of the area in case of release to the environment.

FOURTH SCHEDULE

Article 15
CONTAINMENT MEASURES FOR MICRO-ORGANISMS IN GROUP II
1. The containment measures for micro-organisms from Group II shall be chosen by the user from the categories below as appropriate to the micro-organism and the operation in question in order to ensure the protection of the public health of the general population and the environment.
2. Type B operations shall be considered in terms of their unit operations. The characteristics of each operation will dictate the physical containment to be used at that stage. This will allow selection and design of process, plant and operating procedures best fitted to assure adequate and safe containment. Two important factors to be considered when selecting the equipment needed to implement the containment are the risk of, and the effects consequent on, equipment failure. Engineering practice may require increasingly stringent standards to reduce the risk of failure as the consequence of that failure becomes less tolerable.
3. Specific containment measures for Type A operations shall be established taking into account the containment categories below and bearing in mind the specific circumstances of such operations.

SpecificationsContainment Categories1231. Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system)YesYesYes2. Exhaust gases from the closed system should be treated so as to:Minimise releasePrevent releasePrevent release3. Sample collection, addition of materials to a closed system and transfer of viable micro-organisms to another closed system, should be performed so as to:Minimise releasePrevent releasePrevent release4. Bulk culture fluids should not be removed from the closed system unless the viable micro-organisms have been:Inactivated by validated meansInactivated by validated chemical or physical meansInactivated by validated chemical or physical means5. Seals should be designed so as to:Minimise releasePrevent releasePrevent release6. Closed systems should be located within a controlled areaOptionalOptionalYes, and purpose-built (a) Biohazard

signs should be postedOptionalYesYes (b) Access should be restricted to nominated personnel onlyOptionalYesYes, via airlock (c) Personnel should wear protective clothingYes, work clothingYesA complete change (d) Decontamination and washing facilities should be provided for personnelYesYesYes (e) Personnel should shower before leaving the controlled areaNoOptionalYes (f) Effluent from sinks and showers should be collected and inactivated before releaseNoOptionalYes (g) The controlled area should be adequately ventilated to minimise air contaminationOptionalOptionalYes (h) The controlled area should be maintained at an air pressure negative to atmosphereNoOptionalYes (i) Input air and extract air to the controlled area should be HEPA filteredNoOptionalYes (j) The controlled area should be designed to contain spillage of the entire contents of the closed systemOptionalYesYes (k) The controlled area should be sealable to permit fumigationNoOptionalYes7. Effluent treatment before final dischargeInactivated by validated by means Inactivated by validated chemical or physical meansInactivated by validated chemical means

FIFTH SCHEDULE

Articles 16, 17 and 18
INFORMATION REQUIRED IN THE NOTIFICATION OF A FIRST TIME USE OF AN INSTALLATION, AND/OR A CONTAINED USE
PART I
Information required for the notification referred to in article 16:
— name of person(s) responsible for carrying out the contained use including those responsible for supervision, monitoring and safety and information on their training and qualifications;
— address of installation and grid reference; description of the sections of the installations;
— a description of the nature of the work which will be undertaken and in particular details of the organism or the classification of the micro-organism(s) to be used (Group I or Group II) and the likely scale of the operation;
— a summary of the risk assessment referred to in article 13.
PART II
Information required for the notification referred to in article 17 (2):
— the date of submission of the notification referred to in article 16;
— the parental micro-organism(s) used or, where applicable the host-vector system(s) used;
— the source(s) and the intended function(s) of the genetic material(s) involved in the manipulation(s);
— identity and characteristics of the genetically modified micro-organism;
— the purpose of the contained use including the expected results;
— the culture volumes to be used;
— a summary of the risk assessment referred to in article 13.
PART III
Information required for the notification referred to in article 18 (1):
— the information required in Part II;
— description of the sections of the installation and the methods for handling the micro-organisms;

— description of the predominant meterological conditions and of the potential sources of danger arising from the location of the installation;
— description of the protective and supervisory measures to be applied throughout the duration of the contained use;
— the containment category allocated specifying waste treatment provisions and the safety precautions to be adopted.

PART IV

Information required for the notification referred to in article 18 (2):

— If it is not technically possible, or if it does not appear necessary to give the information specified below, the reasons shall be stated. The level of detail required in response to each subset of considerations is likely to vary according to the nature and the scale of the proposed contained use. In the case of information already submitted to the Agency under the requirements of these Regulations, reference can be made to this information by the user:

(a) the date of submission of the notification referred to in article 16 and the name of the responsible person(s);

(b) information about the genetically modified micro-organism(s):

— the identity and characteristics of the genetically modified micro-organism(s),
— the purpose of the contained use or the nature of the product,
— the host-vector system to be used (where applicable),
— the culture volumes to be used,
— behaviour and characteristics of the micro-organism(s) in the case of changes in the conditions of containment or of release to the environment,
— overview of the potential hazards associated with the release of the micro-organism(s) to the environment,
— substances which are or may be produced in the course of the use of the micro-organism(s) other than the intended product;

(c) information about personnel:

— the maximum number of persons working in the installation and the number of persons who work directly with the micro-organism(s);

(d) information about the installation:

— the activity in which the micro-organism(s) is to be used,
— the technological processes used,
— a description of the sections of the installation,
— the predominant meteorological conditions, and specific hazards arising from the location of the installation;

(e) information about waste management:

— types, quantities, and potential hazards of wastes arising from the use of the micro-organism(s),
— waste management techniques used, including recovery of liquid or solid wastes and inactivation methods,
— ultimate form and destination of inactivated wastes;

(f) information about accident prevention and emergency response plans:

— the sources of hazards and conditions under which accidents might occur,
— the preventive measures applied such as safety equipment, alarm systems, containment methods and procedures and available resources,
— a description of information provided to workers,
— the information necessary for the Agency to enable them to draw

up or establish the necessary emergency response plans for use outside the installation in accordance with article 25;
(g) a comprehensive assessment (referred to in article 13) of the risks to human health and the environment which might arise from the proposed contained use;
(h) all other information required under Parts II and III if it is not already specified above.

SIXTH SCHEDULE

Article 27
INFORMATION TO BE SUPPLIED TO THE COMMISSION OF THE EUROPEAN COMMUNITIES BY THE AGENCY WHERE AN ACCIDENT HAS OCCURRED.
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/research institution:
Address: Grid reference: Principal Activity of installation
.....
.....
Type of installation:AB
Type of activity:Group IGroup II2. Type of accident
Failure of equipment (breakage/leakage etc.)
FireExplosion
Maloperation of equipment (human/mechanical) Other (specify)
.....
.....3.
Organisms released Identity of genetically modified organisms released:
Quantity of genetically modified organisms released: Form and/or concentration in which organisms released:4. Description of the circumstances of the accident5. Was there any emergency plan drawn up in advance?YesNo If yes, by whom?
.....6.
Emergency measures taken (a) inside the installation
.....
.....
(b) Outside the installation.....
.....7.
Assumed or established cause(s) of accident
Known (to be specified)
.....

Not known:
Information will be supplied as soon as possible8. 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
— the danger is still presentIf yes, specify
.....

.....
.....
— the danger no longer exists (b) Outside the installation/to the
environment:
— persons exposed to the accident
— casualties
— damage to health — types of environments exposed (water, sewage
systems, agricultural land, natural environments)
.....
— material damage
— damage affecting the containment equipment
— damage to the environment
— the danger is still presentIf yes, specify
.....
.....
.....
— the danger no longer exists
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 on the accident
7. Monitoring within and outside installations following the accident
8. Final overall assessment of damage to health and the environment
9. Recommendations for avoiding similar accident in future

SEVENTH SCHEDULE

Article 3, 30 and 41
INFORMATION REQUIRED IN THE NOTIFICATION OF INTENT TO MAKE A
DELIBERATE RELEASE
The notifications for a deliberate release referred to in article 30
and of the placing on the market referred to in article 41 is to
include, as appropriate, the information set out below in Parts A
and B of this Schedule.
Not all points included will apply to every case. It is to be
expected that individual notifications will address only the
particular subset of considerations which is appropriate to individual
situations.
The level of detail required in response to each subset of
considerations is also likely to vary according to the nature and
scale of the proposed release.
Part A applies to releases of all types of genetically modified
organisms other than higher plants. Part B applies to releases of
genetically modified higher plants.
The term "higher plants" means plants which belong to the taxonomic
groups Gymnospermae and Angiospermae.
PART A
INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF
GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

I. GENERAL INFORMATION
A. Name and address of the notifier (company or institute)
B. Name, qualifications and experience of the responsible scientist(s)
C. Title of the project
II. INFORMATION RELATING TO THE GENETICALLY MODIFIED ORGANISM
A. Characteristics of (a) the donor, (b) the recipient of (c)
(where appropriate) parental organism(s):
1. scientific name;
2. taxonomy;
3. other names (usual name, strain name, etc.);
4. phenotypic and genetic markers;
5. degree of relatedness between donor and recipient or between
parental organisms;
6. description of identification and detection techniques;
7. sensitivity, reliability (in quantitative terms) and specificity of
detection and identification techniques;
8. description of the geographic distribution and of the natural
habitat of the organism including information on natural predators,
preys, parasites and competitors, symbionts and hosts;
9. potential for genetic transfer and exchange with other organisms;
10. verification of the genetic stability of the organisms and
factors affecting it;
11. pathological, ecological and physiological traits:
(a) classification of hazard according to existing rules of the
European Communities concerning the protection of human health and/or
the environment;
(b) generation time in natural ecosystems, sexual and asexual
reproductive cycle;
(c) information on survival, including seasonability and the
ability to form survival structures e.g.: seeds, spores or sclerotia;
(d) pathogenicity: infectivity, toxigenicity, virulence,
allergenicity, carrier (vector) of pathogen, possible vectors,
host-range including non-target organism. Possible activation of latent
viruses (proviruses). Ability to colonise other organisms;
(e) antibiotic resistance, and potential use of these antibiotics
in humans and domestic organisms for prophylaxis and therapy;
(f) involvement in environmental processes: primary production,
nutrient turnover, decomposition of organic matter, respiration, etc.
12. Nature of Indigenous Vectors
(a) sequence;
(b) frequency of mobilisation;
(c) specificity;
(d) presence of genes which confer resistance.
13. History of previous genetic modifications.
B. Characteristics of the vector:
1. nature and source of the vector;
2. sequence of transposons, vectors and other non-coding genetic
segments used to construct the genetically modified organism and to
make the introduced vector and insert function in the genetically
modified organism;
3. frequency of mobilisation of inserted vector and/or genetic
transfer capabilities and methods of determination;
4. information on the degree to which the vector is limited to the
DNA required to perform the intended function.
C. Characteristics of the modified organism:

1. Information relating to the genetic modification:
(a) methods used for the modification:
(b) methods used to construct and introduce the inserts(s) into the recipient or to delete a sequence;
(c) description of the insert and/or vector construction;
(d) purity of the insert from any unknown sequence and information the degree to which the inserted sequence is limited to the DNA required to perform the intended function;
(e) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.
2. Information on the final genetically modified organism:
(a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer be expressed.
(b) structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;
(c) stability of the organism in terms of genetic traits;
(d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;
(e) activity of the expressed protein(s);
(f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;
(g) sensitivity, reliability (in quantative terms) and specificity of detection and identification techniques;
(h) history of previous releases of uses of the genetically modified organism;
(i) health considerations:
(i) toxic or allergenic effects of the non-viable genetically modified organisms and/or their metabolic products;
(ii) product hazards;
(iii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
(iv) capacity for colonisation;
(v) if the organism is pathogenic to humans who are immu-nocompetent:
— diseases caused and mechanism of pathogenicity including invasiveness and virulence,
— communicability,
— infective dose,
— host-range, possibility of alteration,
— possibility of survival outside of human host,
— presence of vectors or means of dissemination,
— biological stability,
— antibiotic-resistance patterns,
— allergenicity,
— availability of appropriate therapies.
III INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT
A. Information of the release:
1. description of the proposed deliberate release, including the purpose(s) and foreseen products;
2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases;

3. preparation of the site previous to the release;
4. size of the site;
5. method(s) to be used for the release;
6. quantities of genetically modified organisms to be released;
7. disturbance on the site (type and method of cultivation, mining, irrigation or other activities);
8. worker protection measures taken during the release;
9. post-release treatment of the site;
10. techniques foreseen for elimination or inactivation of the genetically modified organisms at the end of the experiment;
11. information on, and results of, previous releases of the genetically modified organisms, especially at different scales and in different ecosystems.

B. Information on the environment (both on the site and in the wider environment):

1. geographical location and grid reference of the site(s) (in case of notifications under Part IV of these Regulations, the site(s) of release will be the foreseen areas of use of the product);
2. physical or biological proximity to humans and other significant biota;
3. proximity to significant biotopes or protected areas;
4. size of local population;
5. economic activities of local populations which are based on the natural resources of the area;
6. distance to closest areas protected for drinking water and/or environmental purpose;
7. climatic characteristics of the region(s) likely to be affected;
8. geographical, geological and pedological characteristics;
9. flora and fauna, including crops, livestock and migratory species;
10. description of target and non-target ecosystems likely to be affected;
11. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release;
12. any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

IV INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GENETICALLY MODIFIED ORGANISMS AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination:

1. biological features which affect survival, multiplication and dispersal;
2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.);
3. sensitivity to specific agents.

B. Interactions with the environment:

1. predicted habitat of the genetically modified organisms;
2. studies of the behaviour and characteristics of the genetically modified organisms and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses;
3. genetic transfer capability:

(a) post-release transfer of genetic material from genetically modified organisms into organisms in affected ecosystems;
(b) post-release transfer of genetic material from indigenous organisms to the genetically modified organisms;

4. likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the modified organism;
5. measures employed to ensure and to verify genetic stability, Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify stability;
6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing etc.;
7. description of ecosystems to which the genetically modified organisms could be disseminated.

C. Potential environmental impact:

1. potential for excessive population increase in the environment;
2. competitive advantage of the genetically modified organisms in relation to the unmodified recipient or parental organism(s);
3. identification and description of the target organisms;
4. anticipated mechanism and result of interaction between the released genetically modified organisms and the target organism;
5. identification and description of non-target organisms which may be affected unwittingly;
6. likelihood of post-release shifts in biological interactions or in host-range;
7. known or predicted effects on non-target organisms in the environment, impact on population levels of competitors: preys, hosts, symbionts, predators, parasites and pathogens;
8. known or predicted involvements in biogeochemical processes;
9. other potentially significant interactions with the environment.

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring techniques

1. methods for tracing the genetically modified organisms, and for monitoring their effects;
2. specificity (to identify the genetically modified organisms, and to distinguish them from the donor, recipient or, where appropriate, the parental organism(s)), sensitivity and reliability of the monitoring techniques;
3. techniques for detecting transfer of the donated genetic material to other organisms;
4. duration and frequency of the monitoring.

B. Control of the release:

1. methods and procedures to avoid and/or minimise the spread of the genetically modified organisms beyond the site of release or the designated area for use;
2. methods and procedures to protect the site from intrusion by unauthorised individuals;
3. methods and procedures to prevent other organisms from entering the site.

C. Waste treatment:

1. type of waste generated;
2. expected amount of waste;
3. possible risks;
4. description of treatment envisaged.

D. Emergency response plans:

1. methods and procedures for controlling the genetically modified organisms in case of unexpected spread;
2. methods for decontamination of the areas affected, e.g.

eradication of the genetically modified organisms;
3. methods for disposal or sanitation of plants, animals, etc., that were exposed during or after the spread;
4. methods for the isolation of the area affected by the spread;
5. plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

SEVENTH SCHEDULE

PART B
INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GYMNOSPERMAE AND ANGIOSPERMAE)
A. General Information
1. Name and address of the notifier (company or institute)
2. Name, qualifications and experience of the responsible scientist(s)
3. Title of the project.
B. Information Relating to (A) the Recipient or (B) (where appropriate) Parental Plants
1. Complete name:
(a) family name;
(b) genus;
(c) species;
(d) subspecies,
(e) cultivar/breeding line;
(f) common name.
2. (a) Information concerning reproduction:
(i) mode(s) of reproduction;
(ii) specific factors affecting reproduction, if any;
(iii) generation time.
(b) Sexual compatibility with other cultivated or wild plant species.
3. Survivability:
(a) ability to form structures for survival or dormancy;
(b) specific factors affecting survivability, if any.
4. Dissemination:
(a) ways and extent of dissemination;
(b) specific factors affecting dissemination, if any.
5. Geographical distribution of the plant.
6. In the case of plant species not normally grown in the Member State(s) of the European Communities, description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.
7. Potentially significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.
C. Information Relating to the Genetic Modification
1. Description of the methods used for the genetic modification.
2. Nature and source of the vector used.
3. Size, source (name of donor organism(s)) and intended function of each constituent fragment of the region intended for insertion.
D. Information Relating to the Genetically Modified Plant
1. Description of the trait(s) and characteristics which have been introduced or modified.
2. Information on the sequences actually inserted/deleted:

(a) size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the Genetically Modified Higher Plant or any carrier or foreign DNA remaining in the Genetically Modified Higher Plant;
(b) in case of deletion, size and function of the deleted region(s);
(c) location of the insert in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination;
(d) copy number of the insert.
3. Information on the expression of the insert:
(a) information on the expression of the insert and methods used for its characterisation;
(b) parts of the plant where the insert is expressed (e.g. roots, stem, pollen, etc.).
4. Information on how the genetically modified plant differs from the recipient plant in:
(a) mode(s) and/or rate of reproduction;
(b) dissemination;
(c) survivability.
5. Genetic stability of the insert.
6. Potential for transfer of genetic material from the genetically modified plants to other organisms.
7. Information on any toxic or harmful effects on human health and the environment, arising from the genetic modification.
8. Mechanisms of interaction between the genetically modified plant and target organisms (if applicable).
9. Potentially significant interactions with non-target organisms.
10. Description of detection and identification techniques for the genetically modified plant.
11. Information about previous releases of the genetically modified plant, if applicable.
E. Information Relating to the Site or Release (only for notification submitted pursuant to Article 30)
1. Location and size of the release site(s).
2. Description of the release site ecosystem, including climate, flora and fauna.
3. Presence of sexually compatible wild relatives or cultivated plant species.
4. Proximity to officially recognised biotopes or protected areas which may be affected.
F. Information Relating to the Release (only for notifications submitted pursuant to Article 30)
1. Purpose of the release.
2. Foreseen date(s) and duration of the release.
3. Method by which the genetically modified plants will be released.
4. Method for preparing and managing the release site, prior to, during and post-release, including cultivation practices and harvesting methods.
5. Approximate number of plants (or plants per m^2).
G. Information on Control, Monitoring, Post-Release and Waste Treatment Plans (only for notifications submitted pursuant to Article 30)
1. Any precautions taken:
(a) distance(s) from sexually compatible plant species;

(b) any measures to minimize/prevent pollen or seed dispersal.
2. Description of methods for post-release treatment of the site.
3. Description of post-release treatment methods for the genetically modified plant material including wastes.
4. Description of monitoring plans and techniques.
5. Description of any emergency plans.
H. Information on the Potential Environmental Impact from the Release of the Genetically Modified Plants
1. Likelihood of the Genetically Modified Higher Plant becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.
2. Any selective advantage or disadvantage conferred to other sexually compatible plants species, which may result from genetic transfer from the genetically modified plant.
3. Potential environmental impact of the interaction between the genetically modified plant and target organisms (if applicable).
4. Possible environmental impact resulting from potential interactions with non-target organisms.

EIGHTH SCHEDULE

Article 41
ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING ON THE MARKET
PART I
The following information shall be provided in the notification for placing on the market of products, in addition to the information contained in the Seventh Schedule.
1. name of the product and names of genetically modified organisms contained therein;
2. name of the manufacturer or distributor and address in the European Community;
3. specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the European community for which the product is suited;
4. type of expected use: industry, agriculture and skilled trades, consumer use by public at large.
PART II
The following information shall be provided, when relevant, in addition to that in Part I of this Schedule, in accordance with article 41:
1. measures to take in case of unintended release or misuse;
2. specific instructions or recommendations for storage and handling;
3. estimated production in and/or imports to the European Community;
4. proposed packaging. This must be appropriate so as to avoid unintended release of the genetically modified organisms during storage, or at a later stage;
5. proposed labelling. This must include, at least in summarised form, the information referred to in points 1, 2, and 3 of Part I of this Schedule and 1 and 2 of Part II of this Schedule.

NINTH SCHEDULE

Article 33
SUMMARY NOTIFICATION INFORMATION FORMAT FOR RELEASES OF GENETICALLY MODIFIED ORGANISMS
PART I
SUMMARY NOTIFICATION INFORMATION FORMAT FOR RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (ANGIOSPERMAE AND GYMNOSPERMAE)
Introduction
The Summary Notification Information Format for genetically modified higher plant releases, has been established for the purposes and according to the procedures envisaged by Article 9 of Council Directive 90/220/EEC.
It is recognised that the Summary Notification Information Format for genetically modified higher plant releases is not designed to contain all the information required for carrying out an environmental risk assessment. The space provided after each question is not indicative of the depth of the information required for the purposes of the Summary Notification Information Format.

A. GENERAL INFORMATION 1. Details of notification Notification number:
.....
Date of acknowledgement of notification:
.....
Title of the project:
.....
.....
....
Proposed period of release:
.....2.
Notifier Name of institute or company:
.....
.....
.....3.
Is the same Genetically Modified Plant release planned elsewhere in the European Community?
Yes
No
Not Known If yes, insert the country code(s)
.....4. Has the same Genetically Modified Plant been notified for release elsewhere in the European Community by the same notifier?
Yes
No If yes, notification number:
.....B. INFORMATION ON THE GENETICALLY MODIFIED PLANT
1. Complete name of the recipient or parental plant
(a) family name
(b) genus
(c) species
(d) subspecies
(e) cultivar/breeding line
(f) common name2. Description of the traits and characteristics

which have been introduced or modified, including marker genes and previous modifications

.....
....
.....
....
.....
....
.....
...3.

Type of the genetic modification:

(a) Insertion of genetic material

(b) Deletion of genetic material

(c) Base substitution

(d) Cell fusion

(e) Other, please specify4. In the case of insertion of genetic material, give the source and intended function of each constituent fragment of the region to be inserted

.....
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.....
.....5.

In the case of deletion of genetic material, give information on the function of the deleted sequences

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.....6.

Brief description of the method used for the genetic modification

.....
.....
.....
.....
.....
.....
.....C.

INFORMATION RELATING TO THE EXPERIMENTAL RELEASE

1. Purpose of the release

.....
.....
.....
.....
.....
.....
.....2.

Geographical location of the release site
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.....
.....
.....
.....
.....
.....
.....3.
Size of the site (m^2)
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.....
.....
.....D.
SUMMARY OF THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GENETICALLY MODIFIED PLANTS
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.....E.
BRIEF DESCRIPTION OF ANY MEASURES TAKEN FOR THE MANAGEMENT OF RISKS
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Article 33
PART II
SUMMARY NOTIFICATION INFORMATION FORMAT FOR RELEASES OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS
Introduction
The Summary Notification Information Format has been established for the purposes and according to the procedures envisaged by Article 9 of Council directive 90/220/EEC.
It is recognised that the Summary Notification Information Format is not designed to contain all the information required for carrying out an environmental risk assessment in the detail necessary for such an assessment. The information entered should, however, adequately reflect (in a condensed form) the information submitted to the Agency in accordance with the provisions of article 30 of these Regulations under the conditions specified in the preface to the Seventh Schedule. The space provided after each question is not indicative of the depth of the information required for the purposes

of the Summary Notification Information Format.
GENERAL INFORMATION

1. Details of Notification. Member State of notification:
.....
Notification number:
.....
Date of acknowledgement of notification:
.....
Title of the project:
.....
.....
Proposed period of release:
.....2.
Notifier Name of institution or company:
.....
.....
.....3.
Genetically Modified Organism Characterisation (a) Indicate whether
the Genetically Modified Organism is a: viroid RNA virus DNA virus
bacterium fungus animal other, please
specify.....
.....
.....
.....
Identity of the Genetically Modified Organism:
.....
.....
.....
.....4.
Is the same Genetically Modified Organism release planned elsewhere
in the European Community?
Yes
No
Not Known If yes, insert the country code(s)
.....5. Has the same Genetically
Modified Organism been notified for release elsewhere in the European
Community by the same notifier?
Yes
No —Member State of notification:
.....
— Notification number:
.....
SUMMARY INFORMATION FROM THE NOTIFICATION (SEVENTH SCHEDULE)
A. INFORMATION RELATING TO THE RECIPIENT OR PARENTAL ORGANISMS FROM WHICH THE GENETICALLY MODIFIED ORGANISM IS DERIVED

1. Indicate whether the recipient or parental organism is a:viroid
RNA virus DNA virus bacterium fungus animal other, please
specify.....
.....2.
Complete name
(i) order and/or higher taxon (for animals)
(ii) genus
(iii) species

(iv) subspecies
(v) strain
(vi) pathovar (biotype, ecotype, race, etc.)
(vii) common name3. Geographical distribution of the organism (a)
Indigenous to the country where the notification is made:
Yes
No
Not Known (b) indigenous to other European Community countries: (i)
Yes
If yes, indicate the type of ecosystem in which it is found:
AtlanticMediterraneanContinental
Arctic
(ii) NoNot Known
(c) Is it regularly used in the country where the notification is
made? YesNo
(d) Is it regularly kept in the country where the notification is
made?
Yes
No4. Natural habitat of the organism:
M (a) If the organism is a micro-organism: water soil, free-living
soil in association with plant-root systems in association with plant
leaf/stem systems in association with animals other (specify) A (b)
If the organism is an animal:
natural habitat or usual agroecosystem:
.....
.....
.....5.
(a) Detection techniques:
.....
.....
.....
(b) Identification techniques:
.....
.....
.....
.....
.....
.....6.
Is the recipient organism classified under existing European Community
rules relating to the protection of human health and/or the
environment? YesNo
If yes, specify:
.....
.....
.....7.
Is the recipient organism pathogenic or harmful in any other way
(including its extra-cellular products) either living or dead? YesNo
If yes:
(a) to which of the following organisms? Humans Animals Plants (b)
give the relevant information specified in the Seventh Schedule, Part
A, Section IIA, paragraph 11(d):
.....
.....
.....
.....8.
Information concerning reproduction (a) Generation time in natural

ecosystems:
.....
.....
.....
(b) Generation time in the ecosystem where the release will take
place:.....
.....
.....(c)
Way of reproduction: SexualAsexual
(d) Factors affecting reproduction:
.....
.....
.....
.....
.....9.
Survivability:
(a) Ability to form structures enhancing survival or dormancy: (i)
endospores (ii) cysts (iii) sclerotia (iv) asexual spores (fungi) (v)
sexual spores (fungi) (vi) eggs (vii) pupae (viii) larvae (ix)
other, please specify
.....
.....
(b) Relevant factors affecting survivability:
.....
.....
.....10.
(a) Ways of dissemination:
.....
.....
.....
(b) Factors affecting dissemination:
.....
.....
.....11.
Previous genetic modifications of the recipient or parental organism
already notified for release in the country where the notification
is made (give notification numbers): .....
.....
.....B.
INFORMATION RELATING TO THE GENETIC MODIFICATION
1. Type of the genetic modification (i) Insertion of genetic
material (ii) Deletion of genetic material (iii) Base substitution
(iv) Cell fusion (v) Other, please specify
.....
.....2.
Intended result of the genetic modification:
.....
.....
.....3.
(a) Has a vector been used in the process of modification?
Yes
No If No, go straight to question 5. (b) If Yes, is the vector
wholly or partially present in the modified organism?
Yes
No If No, go straight to question 5.4. If the answer to 3 (b) is

Yes, supply the following information:
(a) type of vector: plasmid bacteriophage virus cosmid phasmid
transposable element other, please specify
.....
.....
(b) identity of the vector:
.....
.....
.....
(c) host-range of the vector:
.....
.....
.....
(d) presence in the vector of sequences giving a selectable or
identifiable phenotype: Yes NoYesNo
antibiotic resistance
heavy metal resistance
other, please specify
.....
(e) constituent fragments of the vector:
.....
.....
.....
.....
(f) method for introducing the vector into the recipient organism:
(i) transformation (ii) electroporation (iii) macroinjection (iv)
microinjection (v) infection (vi) other, please
specify.....
.....5.
If the answer to question B.3 (a) and (b) is No, what was the
method used to introduce the insert into the recipient/parental cell?
(i) transformation (ii) microinjection (iii) microencapsulation (iv)
macroinjection (v) other, please
specify.....
.....6.
Information of the insert (a) Composition of the insert:
.....
.....
.....
(b) Source of each constituent part of the insert:
.....
.....
.....
(c) Intended function of each constituent part of the insert in the
Genetically Modified Organism:
.....
.....
(d) Location of the insert in the host organism:
— on a free plasmid
— integrated in the chromosome
— other, please
specify.....
.....
(e) Does the insert contain parts whose product or function are not
known?

Yes
No If Yes, please specify:
.....
.....
.....C
.
INFORMATION ON THE ORGANISM(S) FROM WHICH THE INSERT IS DERIVED (DONOR)1. Indicate whether it is a: viroid RNA virus DNA virus bacterium fungus plant animal other, please specify
.....
.....2. Complete name
(i) order and/or higher taxon (for animals)
(ii) family name (for plants)
(iii) genus
(iv) species
(v) subspecies
(vi) strain
(vii) cultivar/breeding line
(viii) pathovar
(ix) common name3. Is the organism pathogenic or harmful in any other way (including its extracellular products), either living or dead?
Yes
No
Not Known If yes, specify the following: (a) to which of the following organisms: humans animals plants (b) are the donated sequences involved in any way to the pathogenic or harmful properties of the organism?
Yes
No
Not Known If yes, give the relevant information in the Seventh Schedule, Part A, section II.A, paragraph 11 (d):
.....
.....4. Is the donor organism classified under existing European Community rules relating to the protection of human health and the environment?
Yes
No If yes, please specify:
.....
.....
.....
.....5
.
Do the donor and recipient organism exchange genetic material naturally?
Yes
No
Not KnownD. INFORMATION RELATING TO THE GENETICALLY MODIFIED ORGANISM1. Genetic traits and phenotypic characteristics of the recipient or parental organism which have been changed as a result of the genetic modification: (a) is the Genetically Modified Organism different from the recipient as far as survivability is concerned?
Yes

No
Not Known If yes, please specify:
.....
.....
.....
(b) is the Genetically Modified Organism in any way different from the recipient as far as mode and/or rate of reproduction is concerned?
Yes
No
Not Known If yes, please specify:
.....
.....
.....
(c) is the Genetically Modified Organism in any way different from the recipient as tar as dissemination is concerned?
Yes
No
Not Known If yes, please specify:
.....
.....
.....2.
Genetic stability of the genetically modified organism:
.....
.....
.....3.
Is the Genetically Modified Organism pathogenic or harmful in any other way (including its extracellular products), either living of dead?
Yes
No
Not Known If yes, (a) to which of the following organisms? humans animals plants (b) Give the relevant ionformation specified in the Seventh Schedule, Part A, section IIA, paragraph 11 (d), and section 11.C, paragraph 2 (i):
.....
.....
.....
.....4.
Description of identification and detection methods. (a) Techniques used to detect the genetically modified organism in the environment
.....
.....
(b) Techniques used to identify the genetically modified organism
.....
.....
.....E.
INFORMATION RELATING TO THE RELEASE1. Purpose of the release
.....
.....
.....2.
Is the site of the release different from the natural habitat or from the ecosystem in which the recipient organism is regularly used, kept or found?
Yes

No If yes, please specify:
.....3.
Information concerning the release and the surrounding area (a)
Geographical location (administrative region and where appropriate grid
reference):
.....
(b) Size of the site (m²): (i) actual release site (m²):
.....
.....
(ii) wider release area (m²):
.....
.....
(c) Proximity to internationally recognised biotopes or protected
areas (including drinking water reservoirs), which could be affected:
.....
.....
(d) Flora and fauna including crops, livestock and migratory species
which may potentially interact with the genetically modified organism:
.....
.....4.
Method and amount of release (a) quantities of Genetically Modified
Organisms to be released:
.....
.....
(b) duration of the operation:
.....
.....
.....
(c) methods and procedures to avoid and/or minimise the spread of
the Genetically Modified Organisms beyond the site of the release:
.....
.....F.
INTERACTIONS OF THE GENETICALLY MODIFIED ORGANISM WITH THE
ENVIRONMENT
AND POTENTIAL IMPACT ON THE ENVIRONMENT1. Complete name of target
organisms. (i) order and/or higher taxon (for animals)
(ii) family name (for plants)
(iii) genus
(iv) species
(v) subspecies
(vi) strain
(vii) cultivar
(viii) pathovar
(ix) common name2. Anticipated mechanism and result of interaction
between released Genetically Modified Organisms and the target
organism:
.....
.....
.....
.....3
.
Other potentially significant interactions with other organisms in the
environment:.....
.....
.....

.....4.
Is post-release selection for the Genetically Modified Organism likely
to occur?
Yes
No
Not Known If yes, give details:
.....
.....5
.
Types of ecosystems to which the Genetically Modified Organism could
be disseminated from the site of release and in which it could
become established:
.....
.....
.....6
.
Complete name of non-target organisms which may be affected
unwittingly (i) order and/or higher taxon (for animals)
(ii) family name (for plants)
(iii) genus
(iv) species
(v) subspecies
(vi) strain
(vii) cultivar
(viii) pathovar
(ix) common name7. Likelihood of genetic exchange in vivo
(a) from the Genetically Modified Organism to other organisms in the
release ecosystem:
.....
.....
(b) from other organisms to the genetically modified organism:
.....
.....8.
Give references to relevant results from studies of the behaviour
and characteristics of the Genetically Modified Organism and its
ecological impact carried out in simulated natural environments (e.g.,
microcosms, etc.):
.....
.....
.....
.....G.
INFORMATION RELATING TO MONITORING
1. Methods for monitoring the Genetically Modified Organisms:
.....
.....
.....
.....2.
Methods for monitoring ecosystem effects:
.....
.....
.....
.....3.
Methods for detecting transfer of the donated genetic material from
the Genetically Modified Organism to other organisms:
.....

.....
.....4.
Spatial extent of the monitoring area (m²):
.....
.....5.
Duration of the monitoring:
.....
.....6.
Frequency of the monitoring:
.....
.....H.
INFORMATION ON POST-RELEASE AND WASTE TREATMENT
1. Post-release treatment of the site:
.....
.....
.....
.....2.
Post-release treatment of the Genetically Modified Organisms:
.....
.....
.....3.
(a) Type and amount of waste generated:
.....
.....
.....
(b) Treatment of waste:
.....
.....
.....
.....I.
INFORMATION ON EMERGENCY RESPONSE PLANS
1. Methods and procedures for controlling Genetically Modified
Organisms in case of unexpected spread:
.....
.....
.....2.
Methods for decontamination of the areas affected:
.....
.....
.....
.....3.
Methods for disposal or sanitation of plants, animals, soils, etc.,
that were exposed during or after the spread:
.....
.....
.....
.....4.
Plans for protecting human health and the environment in case of
the occurrence of an undesirable effect:
.....
.....
.....
.....

TENTH SCHEDULE

Article 42
SUMMARY NOTIFICATION INFORMATION FORMAT FOR PRODUCTS CONTAINING GENETICALLY MODIFIED ORGANISMS

Introduction
This Schedule is designed to serve as the format of the summary of the dossier submitted to the Commission of the European Communities for the placing on the market of a product containing Genetically Modified Organisms under article 42 (2) of these Regulations and does not prejudice the provisions of these Regulations.
The summary notification information format for products containing Genetically Modified Organisms when completed will contain a summary of the information entered under the corresponding points of the full dossier. It is, therefore, recognised that the risk assessment stipulated in article 42 of these Regulations cannot be carried out on the basis of the summary.
A. GENERAL INFORMATION
1. Details of notification
(a) Member State of notification
.....
(b) Notification number
.....
(c) Name of the product (commercial and other names)
.....
.....
(d) Date of acknowledgement of notification
.....
.....2.
Notifier/manufacturer/importer
(a) Name of
notifier.....
(b) Address of notifier
.....
(c) The notifier is:
domestic manufacturer
importer (d) In case of import (i) Name of manufacturer
.....
(ii) Address of manufacturer
.....3.
Characterisation of the Genetically Modified Organisms contained in the product
Indicate the name and nature of each type of Genetically Modified Organism contained in the product
.....
.....
.....
.....
....4.
General description of the product
(a) Type of product
.....
.....
.....
(b) Composition of the product
.....

.....
.....
(c) Specificity of the product
.....
.....
.....
(d) Types of users
.....
.....
.....
(e) Exact conditions of use and handling
.....
.....
.....
(f) Geographical areas for which the product is intended
.....
.....
.....
(g) Type of environment for which the product is suited
.....
.....
.....
(h) Annual estimated production in and/or imports into the European Community
.....
.....
.....5.
Has the combination of Genetically Modified Organisms contained in the product been notified under Part III of these Regulations?
Yes
No (i) If yes, give country and notification number:
.....
.....
.....
(ii) If no, refer to risk analysis data on the basis of the elements of Part III of these Regulations.
.....
.....
.....6.
Is the product being simultaneously notified to another Member State of the European Communities?
Yes
No If Yes, please specify
.....
.....
.....7.
Has another product with the same combination of Genetically Modified Organisms been placed on the European Community market by another notifier?
Yes
No
Not Known If Yes, please specify
.....
.....
.....8.

Information on releases of the same Genetically Modified Organisms or of the same combination of Genetically Modified Organisms previously or currently notified and/or carried out by the notifier either inside or outside the European Community

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.....

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.....9.

Specify instructions and/or recommendations for storage and handling

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.....10.

Proposed packaging

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.....11.

Proposed labelling

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.....12.

Measures to take in case of unintended release or misuse

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.....13.

Measures for waste disposal and treatment

.....

.....

.....B.

NATURE OF THE GENETICALLY MODIFIED ORGANISMS CONTAINED IN THE PRODUCT INFORMATION RELATING TO THE RECIPIENT OR PARENTAL ORGANISM(S) FROM WHICH THE GENETICALLY MODIFIED ORGANISM IS DERIVED14. Scientific name and othernames

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.....1

5.

Phenotypic and genetic traits

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.....

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.....1

6.

Geographical distribution and natural habitats of the organisms

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.....17
.
Genetic stability of the organism and factors affecting it
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.....
.....1
8.
Potential for genetic transfer and exchange with other organisms
.....
.....
.....
.....19.
Information concerning reproduction and factors affecting it
.....
.....
.....
.....20.
Information on survival and factors affecting it
.....
.....
.....
.....21.
Ways of dissemination and factors affecting it
.....
.....
.....
.....22.
Interactions with the environment
.....
.....
.....
.....23
(a) Detection techniques
.....
.....
.....
.....
23 (b) Identification techniques
.....
.....
.....
.....24.
Classification under existing European Community rules concerning the
protection of human health and/or the environment
.....
.....
.....
.....25
(a) Pathogenic characteristics
.....
.....
25 (b) Other harmful characteristics of the organism living or dead,
including its extracellular products
.....

.....
.....26.
Nature and description of known extrachromosomal genetic elements
.....
.....
.....
.....27
.
History of previous genetic modifications
.....
.....
.....
.....IN
FORMATION
RELATING TO THE GENETIC MODIFICATION
28. Methods used for the genetic modification
.....
.....
.....
.....29
.
Characteristics of the vector
(a) Nature and source of the vector
.....
.....
.....
(b) Description of the vector construction
.....
.....
.....
(c) Genetic map and/or restriction map of the vector
.....
.....
.....
(d) Sequence data
.....
.....
.....
(e) Information on the degree to which the vector contains sequences
whose product or function area is not known
.....
.....
.....
(f) Genetic transfer capabilities of the vector
.....
.....
.....
(g) Frequency of mobilisation of the vector
.....
.....
.....
(h) Part of the vector which remains in the Genetically Modified
Organism
.....
.....

.....3
0.
Information on the insert
(a) Methods used to construct the insert
.....
.....
.....
(b) Restriction sites
.....
.....
.....
(c) Sequence of the insert
.....
.....
.....
(d) Origin and function of each constituent part of the insert in
the Genetically Modified Organism
.....
.....
.....
(e) Information on the degree to which the insert is limited to
the required function
.....
.....
.....
(f) Location of the insert in the Genetically Modified Organism
.....
.....
.....IN
FORMATION
ON THE ORGANISM(S) FROM WHICH THE INSERT IS DERIVED (DONOR)
31. Scientific and other names
.....
.....
.....
.....
.....32
(a) Pathogenic characteristics of the donor organism
.....
.....
.....32
(b) Other harmful characteristics of the organism living or dead,
including its extracellular products
.....
.....
.....33.
If the donor organism has any pathogenic or harmful characteristics,
indicate whether the donated sequences are in any way involved in
them
.....
.....
.....
.....34
.
Classification under existing European Community rules relating to the

protection of human health and the environment
.....
.....
.....
.....35
.
Potential for natural exchange of genetic material between the
donor(s) and recipient organism
.....
.....
.....
.....IN
FORMATION
RELATING TO THE GENETICALLY MODIFIED ORGANISM(S) CONTAINED IN THE
PRODUCT
36. Description of genetic traits or phenotypic characteristics and
in particular any new traits and characteristics which may be
expressed or no longer expressed.
.....
.....
.....
.....37.
Genetic stability of the Genetically Modified Organism
.....
.....
.....
.....38.
Rate and level of expression of the new genetic material
.....
.....
.....
.....39
.
Activity of the expressed proteins
.....
.....
.....
.....40
(a) Description of detection techniques for the Genetically Modified
Organism in the environment
.....
.....
.....
.....
40 (b) Description of identification techniques
.....
.....
.....41.
Health considerations
(a) toxic or allergenic effects of the non-viable Genetically
Modified Organisms and/or their metabolic products
.....
.....
.....
(b) product hazards

.....
.....
.....
(c) comparison of the Genetically Modified Organism with the donor, recipient or parental organism regarding pathogenicity
.....
.....
.....
(d) capacity for colonisation
.....
.....
.....
(e) If the organism is pathogenic to humans who are immono-competent, supply the information specified in the Seventh Schedule, Part A, section II.C, paragraph 2 (i) (V)
.....
.....
.....IN TERACTIONS
OF THE GENETICALLY MODIFIED ORGANISM WITH THE ENVIRONMENT42. Survival, multiplication and dissemination of the Genetically Modified Organism(s) in the environment
.....
.....
.....
.....43. Interactions of the Genetically Modified Organisms with the environment
.....
.....
.....
.....44. Environmental impacts of the Genetically Modified Organism(s)
.....
.....
.....
.....C. PREDICTED BEHAVIOUR OF THE PRODUCT
1. ENVIRONMENTAL IMPACT OF THE PRODUCT
2. HUMAN HEALTH EFFECTS OF THE PRODUCTD. INFORMATION RELATING TO PREVIOUS RELEASES
I. HISTORY OF PREVIOUS RELEASES NOTIFIED UNDER PART III OF THESE REGULATIONS
1.Notification number:.....2.Release site:.....3.Aim of the release:
.....4.Duration of the release:.....5.Duration of post-release monitoring:.....6.Aim of post-release monitoring:
.....

.....7.Conclusions
of post-release monitoring:
.....
.....8.Result of the release in respect to any risk to human health and the environment (submitted to the Agency according to article 36 of these Regulations):
.....
.....
.....
.....

II. HISTORY OF PREVIOUS RELEASES CARRIED OUT INSIDE OR OUTSIDE THE COMMUNITY

1.Release country:.....2.Authority overseeing the release:
.....3.Release site:
.....4.Aim of the release:
.....5.Duration of post-release monitoring:
.....6.Aim of post-release monitoring:
.....
.....7.Conclusions of post-release monitoring:
.....
.....8.Results of the release in respect to any risk to human health and the environment:
.....
.....
.....
.....

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III. HISTORY OF PREVIOUS WORK RELEVANT TO RISK ASSESSMENT PRIOR TO COMMERCIALISATION

_____

ELEVENTH SCHEDULE

FEES

PART I
Fees payable to the Agency in respect of notifications or amended notifications

Notification or amended notificationAmount of FeeGroup IGroup IIType AType BType AType B(1)(2)(3)(4)(5)Notification of a first time use of an installation for the contained use of a Group I or Group II genetically modified micro-organism under article

162001,0002,00010,000Notification of a contained use of a Group I genetically modified micro-organism under article 17Not applicable500Not applicableNot applicableNotification of a contained use of a Group II genetically modified micro-organism under article 18Not applicableNot applicable1,0005,000Amended notification of a contained use of a Group I or Group II genetically modified micro-organism under article 23Not applicable3757503,750
PART II(1)(2)Notification of a first time use of an installation for the contained use of a genetically modified organism, other than a Group I or Group II genetically modified micro-organism, under article 16200
PART IIIDeliberate ReleaseAmount of Free(1)(2)Notification of a deliberate release under article 302,000
PART IVPlacing on the MarketAmount of Fee(1)(2)Notification of the placing of a product on the market under article 4120,000
".
Dated this 16th day of November, 1994.

JOHN BROWNE,
Minister of State at the Department
of the Environment.

EXPLANATORY NOTE.

These Regulations give effect to Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms, and Council Directive 90/220/EEC on the deliberate release of genetically modified organisms into the environment.
The Regulations provide for various procedural matters in relation to the contained use, deliberate release and placing on the market of genetically modified organisms. They provide for notifications for consent, application of principles of good microbiological practive, risk assessment, reviews of consents, accident procedures, and the contents of a register of notifications. Users of genetically modified organisms are required under the Regulations to ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment. A consent to place a product, containing or consisting of a genetically modified organism, on the market must include conditions relating to the labelling and packaging of the product.