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GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) REGULATIONS 2003

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GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) REGULATIONS 2003

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GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) REGULATIONS 2003

The Minister for the Environment, Heritage and Local Government, in exercise of the powers conferred on him by sections 6 and 111 (as amended by section 17 of the Protection of the Environment Act 2003 (No. 27 of 2003)) of the Environmental Protection Agency Act 1992 (No. 7 of 1992), and for the purpose of giving effect to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001[1] on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[2], hereby makes the following Regulations.

PART I

PRELIMINARY AND GENERAL

Citation

1. These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) Regulations 2003.

Commencement

2. These Regulations shall come into operation on 1 November 2003.

Interpretation

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

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

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

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

"deliberate release" means any intentional introduction into the environment of a genetically modified organism or a combination of genetically modified organisms for which no specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment, and cognate words and expressions shall be construed accordingly;

[1] OJ No. L106, 17.04.2001, p.1.
[2] OJ No. L117, 08.05.1990, p.15, as last amended by Commission Directive 97/35/EC, OJ No. L169, 27.06.1997, p.72.

"the Directive" means Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC;

"environmental risk assessment" means an evaluation, carried out in accordance with the Second Schedule, of risks to human health or the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of a genetically modified organism may pose;

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

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

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

"notifier" means any legal or natural person submitting a notification or, where the context so requires, any legal or natural person responsible for a deliberate release or for a placing on the market, or for meeting any other requirement of these Regulations in relation to a deliberate release or a placing on the market;

"organism" has the meaning given 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 any transaction in which a genetically modified organism is supplied or made available to a third party, whether in return for payment or otherwise, but does not include—

(a) supplying or making a genetically modified organism available for use in an activity to which the Genetically Modified Organisms (Contained Use) Regulations 2001 apply,

(b) supplying or making a genetically modified organism, other than a genetically modified organism to which the Genetically Modified Organisms (Contained Use) Regulations 2001 apply, available for use exclusively in an activity in respect of which appropriate stringent containment measures, based on the principles of containment established in the said Regulations, are used for the purposes of limiting contact with, and to provide a high level of safety for, the general population and the environment,

(c) supplying or making a genetically modified organism available for use exclusively in a deliberate release to be carried out in compliance with Part II,

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.

(2) In these Regulations, a reference to a genetically modified organism shall, where it arises, be construed as including a reference to a combination of genetically modified organisms.

(3) (a) Within the terms of the definition of a "genetically modified organism" as set out in sub-article (1), for the purposes of these Regulations genetic modification occurs at least through the use of the techniques listed in Part I of the First Schedule.

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

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

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

Competent authority

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

Obligations

5. (1) A person who carries out a deliberate release or placing on the market shall ensure that all appropriate measures are taken to avoid adverse effects on human health or the environment arising from the deliberate release or placing on the market.

(2) (a) Without prejudice to any other provision of these Regulations, a person who proposes to submit a notification for consent in accordance with Part II to deliberately release a genetically modified organism or in accordance with Part III to place a genetically modified organism on the market shall, prior to submitting the said notification, carry out an environmental risk assessment in accordance with the Second Schedule.

(b) In making an assessment pursuant to paragraph (a), the person proposing to carry out the deliberate release or placing on the market shall give particular attention to the risks to human health or the environment posed by the deliberate release or the placing on the market of a genetically modified organism which contains 1 or more genes expressing resistance to antibiotics used in human or veterinary medicine.

Savings

6. A person shall not be entitled solely by reason of compliance with these Regulations to—

(a) deliberately release, or

(b) place on the market,

a genetically modified organism.

Exclusions

7. These Regulations shall not apply to—

(a) organisms obtained through the techniques or methods of—

(i) mutagenesis,

(ii) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods,

provided that the said techniques or methods do not involve the use of recombinant nucleic acid molecules or a genetically modified organism, other than recombinant nucleic acid molecules or a genetically modified organism produced by 1 or more of the said techniques or methods; or

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

Calculation of time and payment of fees

8. (1) For the purposes of calculating periods within which the Agency may make a decision under these Regulations, a period of time during which the Agency is awaiting any further information on a

notification or an amended notification which it may have requested from the notifier shall not be taken into account.

(2) Where a provision of these Regulations requires that a notification or an amended notification being given to the Agency shall be accompanied by a fee specified in these Regulations, the said notification or amended notification shall not be considered by the Agency until such time as the said fee is paid to the Agency.

Register and public information

9. (1) Subject to article 10, the Agency shall maintain a register, in these Regulations referred to as the "register", which shall contain at least the following entries, as appropriate, for each notification or record—

(a) the name and address of the notifier,

(b) the location (including, where necessary, the name of the townland or townlands) of a deliberate release proposed under, or granted consent in accordance with, Part II, and the location of any genetically modified organisms grown in the State pursuant to a consent granted in accordance with Part C of the Directive insofar as that information is supplied to the Agency on foot of monitoring requirements specified in the consent,

(c) the date or dates of a deliberate release,

(d) the date or dates of a placing on the market,

(e) the description and intended uses of each genetically modified organism involved,

(f) the purpose of the deliberate release or placing on the market,

(g) the date of receipt of a notification or amended notification,

(h) the date of publication of a notice under article 15(1) or 29(3),

(i) the number of representations, if any, received under article 16(1),

(j) the date of any request by the Agency for further information,

(k) the date of receipt by the Agency of any further information,

(l) the date of receipt, or the date on which the Agency otherwise became aware, of any information or other matter referred to in article 22(1), 28(1) or 28(2),

(m) the date of any exercise by the Agency of its powers under article 22(1), 28(1) or 28(2),

(n) the date and nature of any comment or reasoned objection of the Commission of the European Communities or a competent authority of another Member State of the European Communities under article 32(5), 38(3) or 44(2),

(o) the date and nature of any decision by the Commission of the European Communities under Article 18(1) or 23(2) of the Directive,

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

(q) the date and nature of the decision by the Agency on a notification or an amended notification, or under article 45.

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

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

(a) in the case of a notification, an amended notification, a record or any other information given to the Agency by a notifier or any other person, within 7 days of its receipt by the Agency,

(b) in the case of a request by the Agency referred to in sub-article (1)(j), within 7 days of the making of the request,

(c) in the case of an exercise by the Agency of a power referred to in sub-article (1)(m), within 7 days of such exercise, or

(d) in the case of a decision by the Agency or the Commission of the European Communities referred to in sub-article (1)(o) or (q), within 7 days of the issuing by the Agency or receipt from the Commission, as the case may be, of the decision.

(4) Subject to article 10 and without prejudice to sub-article (1), the Agency shall make publicly available, in such form it considers appropriate, information in relation to the matters the subject of these Regulations.

(5) The information made publicly available by the Agency pursuant to sub-article (4) shall, subject to article 10, include -

(a) the summary of the notifications under articles 14 and 29 in the format established in accordance with the procedure laid down in Article 30(2) of the Directive and for the time being extant,

(b) the environmental risk assessment pursuant to article 5(2),

(c) the conclusions of the Agency on the evaluation of risks in accordance with articles 18(1)(g) and (h), subject to the proviso that the said conclusions shall only be made publicly available following the issuing of the Agency's response to the notifier under article 18(5),

(d) any information or other matter referred to in, and details of any requirements placed on a notifier in accordance with, article 22(1), 28(1) or 28(2),

(e) the assessment report prepared in accordance article 32(2), 38(2) or 44(1),

(f) methods and plans for monitoring the genetically modified organism and for emergency response submitted to the Agency in accordance with the Third Schedule or the Sixth Schedule,

(g) the decision of the Agency pursuant to article 18, 33, 39 or 45,

(h) the decision taken under Article 23(2) of the Directive and conveyed by the Agency to the notifier in accordance with article 28(6),

(i) the results of monitoring carried out pursuant to a consent granted under Part III insofar as that information is supplied to the Agency on foot of monitoring requirements specified in the consent, and

(j) details of the arrangements, for the time being extant, made by the Commission of the European Communities for access to information in relation to notifications pursuant to Part C of the Directive.

Confidential information

10. (1) Where a notifier gives a notification or otherwise provides, in pursuance of these Regulations, information to which access may be refused under article 7 or 8(1) of the European Communities Act 1972 (Access to Information on the Environment) Regulations 1998, and requests that

specified information should be treated by the Agency as confidential information, verifiable justification for that request shall be given by the notifier.

(2) (a) 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.

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

(3) The Agency shall comply with the provisions of article 9 in respect of a deliberate release or the placing on the market of a genetically modified organism not less than 14 days after informing the notifier of its decision on a request under sub-article (1), unless the notifier decides not to proceed with the deliberate release or placing on the market and informs the Agency accordingly within the said 14 days.

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

(a) the name and address of the notifier and the location of a deliberate release proposed under, or granted consent in accordance with, Part II, and the location of any genetically modified organisms grown in the State pursuant to a consent granted in accordance with Part C of the Directive insofar as that information is supplied to the Agency on foot of monitoring requirements specified in the consent,

(b) the purpose of the deliberate release or placing on the market,

(c) the description and intended uses of the genetically modified organism involved,

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

(e) the environmental risk assessment, or

(f) any information or other matter referred to in article 22(1), 28(1) or 28(2).

(5) If, before the Agency has reached a decision as to whether information should be treated as confidential information or within 14 days of such decision, the notifier decides not to proceed with the 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 information.

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

Transitional arrangements

11. Every consent granted by the Agency under Part III of the Genetically Modified Organisms Regulations 1994 (in this article referred to as “the 1994 Regulations”) and in force immediately before the commencement of these Regulations shall, notwithstanding article 69, continue in force and be regarded as having been granted under Part II; for the avoidance of doubt, the provisions of articles 20, 21, 22, 23(2) and 24 of these Regulations, and not any corresponding provisions of the 1994 Regulations, shall apply to such a consent.

PART II

DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS INTO THE ENVIRONMENT FOR PURPOSES OTHER THAN PLACING ON THE MARKET

Exclusions from this Part

12. Without prejudice to article 7, this Part shall not apply to a medicinal substance or a compound for human use which consists of, or contains, a genetically modified organism to which an exemption from the requirements of Articles 6 to 11 of the Directive applies in accordance with Article 5 of the Directive.

Duty to comply with this Part

13. Without prejudice to article 7 and subject to the exclusions in article 12, a person shall not deliberately release a genetically modified organism for purposes other than placing on the market unless consent in writing has been received from the Agency under this Part and any conditions attached to the consent have been complied with.

Notification of intent to make a deliberate release

14. (1) A person proposing to carry out a deliberate release of a genetically modified organism for purposes other than placing on the market shall give a notification to the Agency.

(2) A notification under sub-article (1) shall include-

(a) a technical dossier on the proposed deliberate release containing the information specified in the Third Schedule, insofar as that Schedule is appropriate to the particular deliberate release,

(b) a summary of the notification in the format established in accordance with the procedure laid down in Article 30(2) of the Directive and for the time being extant [1],

(c) an environmental risk assessment pursuant to article 5(2) and in accordance with the Second Schedule, and

(d) the conclusions arrived at by the notifier in accordance with Part D of the Second Schedule, together with any bibliographic references and details of the methods used.

(3) A notification under sub-article (1) shall be accompanied by the fee payable in accordance with article 46.

(4) The notifier may, in making a notification under sub-article (1),—

(a) refer to data or results from a notification previously given by another notifier, provided that the data or results are not confidential information in accordance with article 10 or that the said other notifier has agreed in writing to such reference and a copy of this agreement is included in the notification,

(b) provide relevant information, additional to that required under sub-article (2).

(5) Notwithstanding sub-article (1), the Agency may accept that the deliberate release of—

(a) a combination of genetically modified organisms on the same site, or

[1] OJ No. L280, 18.10.2002, p.62.

(b) a genetically modified organism or a combination of genetically modified organisms on different sites,

may be notified in a single notification under sub-article (1), provided that the proposed deliberate release is for the same purpose and will be carried out within a defined period of time.

Advertisement of notification for consent to a deliberate release

15. (1) Subject to sub-article (2), the notifier of a proposed deliberate release for purposes other than placing on the market shall, not more than 14 days after the date of receipt by the Agency of the notification, cause to be published in a newspaper circulating in the area of the proposed deliberate release a notice with the heading "PROPOSED DELIBERATE RELEASE OF A GENETICALLY MODIFIED ORGANISM" and containing the following information—

(a) the name and address of the notifier,

(b) the description of the genetically modified organism proposed to be released,

(c) the fact that a notification has been submitted to the Agency, and the location and purpose of the proposed deliberate release,

(d) the period of time in which the proposed deliberate release is to be carried out,

(e) the fact that further information on the proposed deliberate release may be obtained from the Agency,

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

(g) the fact that, in accordance with article 16(1), any person or body may, within the period of 28 days beginning on the day of publication of the notice and subject to the payment of the fee specified in article 48, make representations in writing to the Agency regarding the notification,

and shall send a copy of the notice to the Agency within the said 14 days.

(2) The information on the location of the proposed deliberate release published pursuant to sub-article (1) shall be the same as the information on its location which is placed on the register maintained by the Agency in accordance with article 9, and, for that purpose, the notifier shall ascertain from the Agency the information on the location which is to be or has been placed on the said register.

(3) The notifier shall, not more than 14 days after the date of receipt by the Agency of the notification, send a copy of the notice published pursuant to sub-article (1) to—

(a) the owner of the site of the proposed deliberate release, if the said owner is a person other than the notifier, and

(b) the local authority in whose functional area the proposed deliberate release is to be carried out.

Representations in respect of matters comprehended by this Part

16. (1) Any person or body may, within the period of 28 days beginning on the day of publication of a notice pursuant to article 15(1), make representations to the Agency in relation to the notification.

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

(a) made in writing,

(b) addressed to the Agency at its headquarters,

(c) forwarded so as to reach the Agency within the period of 28 days beginning on the day of publication of the notice pursuant to article 15(1), and

(d) accompanied by the fee payable in accordance with article 48.

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

(4) Where the Agency receives representations in accordance with sub-articles (1) and (2), it shall—

(a) acknowledge receipt of the representations, and

(b) consider the representations in determining the notification.

Modification of notification or new information prior to the Agency's decision

17. (1) If, after the receipt by the Agency of a notification under article 14 but before the making of a decision by it on a proposed deliberate release under this Part, —

(a) there is a modification of the proposed deliberate release, or

(b) new information relevant to the proposed deliberate release becomes available,

which could have consequences for the risks to human health or the environment, the notifier shall inform the Agency immediately in writing and submit an amended notification to the Agency, and the first notification under article 14 shall not be further considered by the Agency.

(2) An amended notification under sub-article (1) shall be accompanied by the fee payable in accordance with article 49.

(3) Where the Agency receives an amended notification in accordance with sub-article (1), it shall deal with the amended notification as if it were a new notification under article 14 in relation to the proposed deliberate release.

(4) The provisions of this Part shall apply to an amended notification under sub-article (1) as if it were a new notification under article 14, and the proposed deliberate release shall not be carried out unless and until a consent is granted under this Part.

Duty of the Agency on foot of notification

18. (1) On receipt of a notification under article 14, the Agency shall—

(a) acknowledge to the notifier the date of such receipt in writing,

(b) forward to the Commission of the European Communities, within 30 days of the receipt of the notification, a copy of the summary of the notification received in accordance with article 14(2)(b),

(c) examine it for compliance with these Regulations,

(d) having regard to the Second Schedule, decide whether the environmental risk assessment carried out by the notifier pursuant to article 5(2) is appropriate,

(e) consider any observations received from a competent authority of another Member State of the European Communities for the purposes of the Directive where such observations are received by the Agency within a period of 30 days beginning with the day on which the summary of the notification was forwarded by the Commission of the European Communities

to the competent authorities of the Member States of the European Communities for the purposes of the Directive,

(f) if requested by a competent authority of a Member State of the European Communities for the purposes of the Directive, forward a copy of the notification to the said authority,

(g) evaluate the risks posed by the proposed deliberate release for human health or the environment, and

(h) record its conclusions in writing.

(2) (a) The evaluation in accordance with sub-article (1)(g) shall include an assessment conducted in accordance with the Second Schedule of the potential adverse effects that the proposed deliberate release may pose, whether direct or indirect, for human health or the environment, or both, arising from the transfer of 1 or more genes from a genetically modified organism to another organism.

(b) The evaluation in accordance with sub-article (1)(g) shall take into account the nature of the organism to be released and the receiving environment.

(3) In carrying out the evaluation in accordance with sub-article (1)(g), the Agency shall give particular attention to the risks to human health or the environment posed by the proposed deliberate release of a genetically modified organism which contains 1 or more genes expressing resistance to antibiotics which are used in human or veterinary medicine and shall aim to phase out the use of such genes where such use may have an adverse effect on human health or the environment.

(4) The Agency shall not grant consent under this Part after 31 December 2008 where the genetically modified organism contains 1 or more genes expressing resistance to antibiotics which are used in human or veterinary medicine and the Agency considers that the deliberate release of the said organism may have an adverse effect on human health or the environment.

(5) The Agency shall respond in writing to the notifier within 90 days of receipt of the notification by indicating that consent to the deliberate release is either—

(a) granted, with or without, conditions, or

(b) refused and the reasons for the refusal.

Power of the Agency to request further information.

19. (1) (a) The Agency may, in the case of a notification under article 14, request the notifier to provide further information on the proposed deliberate release.

(b) Where, in accordance with paragraph (a), the Agency requests further information, it shall give its reasons in writing for so doing.

(2) Notwithstanding any other provision of this Part, where the Agency makes a request under sub-article (1)(a), the deliberate release shall not be carried out unless, following a response to the request from the notifier, the Agency has granted consent in accordance with article 18(5)(a) and any conditions attached to the consent have been complied with.

Modification of deliberate release following grant of consent by the Agency

20. (1) A notifier who, after the Agency has granted consent in writing for a deliberate release under this Part, proposes to modify the said deliberate release in a way which could have consequences for the risks to human health or the environment shall amend the notification on foot of which consent was granted and submit the amended notification to the Agency.

(2) An amended notification under sub-article (1) shall be accompanied by the fee payable in accordance with article 49.

(3) Where the Agency receives an amended notification in accordance with sub-article (1), it shall deal with the amended notification as if it were a new notification under article 14 in relation to the proposed modified deliberate release.

(4) The provisions of this Part shall apply to an amended notification under sub-article (1) as if it were a new notification under article 14, and the proposed modified deliberate release shall not be carried out unless and until a consent is granted under this Part.

Duty to inform the Agency of new information, etc.

21. If, after the Agency has granted consent in writing to a deliberate release under this Part,—

(a) there is any unintended change to the deliberate release, or

(b) new information relevant to the deliberate release becomes available,

which could have consequences for the risks to human health or the environment, the notifier shall—

(i) immediately take the measures necessary to protect human health and the environment;

(ii) inform the Agency as soon as the unintended change is known or the new information becomes available; and

(iii) inform the Agency as soon as possible of such further measures he or she has taken or proposes to take in relation to the matters concerned.

Power of the Agency to modify, suspend or terminate consent

22. (1) If, after granting consent in writing to a deliberate release under this Part, the Agency—

(a) becomes aware of information which, in its view, could have significant consequences for the risks to human health or the environment, or

(b) is notified of a proposed modification in accordance with article 20, or

(c) is informed of an unintended change or new information in accordance with article 21,

it may, following an evaluation of the matters concerned, require the notifier, in writing, to modify the conditions of, suspend or terminate the deliberate release.

(2) A deliberate release suspended in accordance with sub-article (1) shall not be resumed unless the written consent of the Agency for the resumption has been received by the notifier and any modifications to the original consent which the Agency may require have been complied with in respect of the deliberate release.

Notification of decisions

23. (1) The Agency shall, within 14 days of indicating its decision to the notifier in accordance with article 18(5), inform in writing—

(a) any person or body to whom a copy of a notice in respect of the notification was sent in accordance with article 15(3),

(b) the Commission of the European Communities, and

(c) any person or body who made representations in respect of the notification to the Agency in accordance with article 16(1),

of its decision in relation to a notification.

(2) The Agency shall, within 14 days of requiring the notifier to modify the conditions of, suspend or terminate the deliberate release in accordance with article 22(1) or of granting consent for the resumption of the deliberate release in accordance with article 22(2), inform in writing—

(a) any person or body to whom a copy of a notice in respect of the notification was sent in accordance with article 15(3),

(b) the Commission of the European Communities, and

(c) any person or body who made representations in respect of the notification to the Agency in accordance with article 16(1).

Post-release procedures

24. (1) Without prejudice to the generality of article 18(5)(a), the notifier shall—

(a) on completion of the deliberate release, and

(b) at any subsequent intervals specified in the consent,

submit a report to the Agency on the results of the deliberate release.

(2) The report referred to in sub-article (1) shall be provided in such format or formats as may be determined in accordance with the procedure laid down in Article 30(2) of the Directive and for the time being extant[1], or, in the absence of such a determination appropriate to the relevant consent, in such format as may be specified in the consent, and shall include—

(a) a post-release evaluation of the risks to human health or the environment, and

(b) where appropriate, a statement on the results of the deliberate release in relation to any product, or type of product, in respect of which consent to placing on the market may be sought.

(3) A copy of any report received by the Agency pursuant to sub-article (1) shall, as soon as may be after its receipt, be sent by the Agency to the Commission of the European Communities.

[1] OJ No. L 254, 08.10.2003, p. 21

PART III

PLACING ON THE MARKET OF PRODUCTS CONTAINING OR CONSISTING OF GENETICALLY MODIFIED ORGANISMS

CHAPTER 1
GENERAL PROVISIONS RELATING TO THIS PART

Exclusions from this Part

25. This Part shall not apply to any genetically modified organism to which Article 12(1) or 12(2) of the Directive applies.

Duty to comply with this Part

26. Without prejudice to article 7 and subject to the exclusions in article 25, a person shall not place on the market any product containing or consisting of a genetically modified organism unless-

(a) consent in writing has been received from the Agency 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 the Directive,

and the conditions attached to the consent have been complied with.

Mandatory requirements in consents under this Part

27. (1) Notwithstanding any other provision of this Part, a consent or renewed consent granted by the Agency under this Part shall specify at least-

(a) the scope of the consent, including the identity of any genetically modified organism to which the consent refers and the unique identifier of the genetically modified organism concerned,

(b) the period of validity of the consent,

(c) conditions under which the product may be placed on the market, including any specific condition of use, handling and packaging and conditions for the protection of ecosystems, environments or geographical areas,

(d) a requirement, without prejudice to article 10, on the notifier to make control samples available to the Agency on request,

(e) labelling requirements, in accordance with the Fourth Schedule, clearly stating the presence of a genetically modified organism and including, either on a label or in a document accompanying the product, the words, "This product contains genetically modified organisms" and the name and address of the person established in the European Community who is responsible for the placing on the market,

(f) monitoring requirements in accordance with the Sixth Schedule, including the time period of the monitoring plan, an obligation to report on the monitoring to the Commission of the European Communities and to the competent authorities of the Member States of the European Communities for the purposes of the Directive and, where appropriate, obligations on a person selling the product or any user of it, which may include an obligation to provide information at an appropriate level on the location at which the genetically modified organism concerned is grown.

(2) The Agency shall not grant consent under this Part after 31 December 2004 where the genetically modified organism contains 1 or more genes expressing resistance to antibiotics which are used in human or veterinary medicine and the Agency considers that the placing on the market of the said organism may have an adverse effect on human health or the environment.

Power of the Agency to restrict or prohibit use or placing on market

28. (1) Where, as a result of either-

(a) new or additional information made available since the date of a consent granted under this Part or under Part C of the Directive and affecting the environmental risk assessment in respect of the product concerned, or

(b) a reassessment of existing information in respect of that product on the basis of new or additional scientific information,

the Agency has detailed grounds for considering that the product constitutes a risk to human health or the environment, it may, notwithstanding article 26, 33 or 39, by notice in writing to the notifier or other person concerned provisionally restrict or prohibit the use, or placing on the market, in the State of the product.

(2) Where, in the circumstances described in sub-article (1), the Agency considers that a product constitutes a severe risk to human health or the environment, it shall, notwithstanding article 26, 33 or 39, by notice in writing to the notifier or other person concerned require such measures to be taken as it considers appropriate (including suspension or termination of the placing on the market).

(3) Where the Agency avails of the provisions of sub-article (1) or (2), it shall immediately inform-

(a) the Commission of the European Communities,

(b) the competent authorities of the other Member States of the European Communities for the purposes of the Directive, and

(c) the public, by means of, at least, publication of a notice in a newspaper circulating in the State,

of its decision and the reasons therefor.

(4) In informing the Commission of the European Communities and the competent authorities of the other Member States of the European Communities in accordance with sub-article (3), the Agency shall provide-

(a) a review of the environmental risk assessment,

(b) information as to whether or not it considers that the conditions of the consent should be amended and, if so, how, or whether the consent should be revoked, and

(c) any additional information on which it has based its action under sub-article (1) or (2).

(5) The notifier shall comply with any notice in writing given by the Agency under sub-article (1) or (2), within any period specified in the notice.

(6) A decision taken under Article 23(2) of the Directive shall be accepted by the Agency in respect of any notice in writing given by it under sub-article (1) or (2) and the Agency shall send a copy of the said decision to the person who had been granted consent under article 33 or 39.

CHAPTER 2
PLACING ON THE MARKET FOR THE FIRST TIME

Duty to give notification and to advertise

29. (1) A person proposing to place a product containing or consisting of a genetically modified organism on the market for the first time shall, in the absence of an appropriate consent granted by the competent authority of another Member State of the European Communities under Part C of the Directive, give a notification to the Agency.

(2) A notification under this article shall be accompanied by the fee specified in article 47.

(3) The notifier shall, not more than 14 days after the date of receipt by the Agency of the notification, cause to be published in a newspaper circulating in the State a notice of its proposal to place on the market a product containing or consisting of a genetically modified organism and shall send a copy of the notice to the Agency within the said 14 days.

(4) A notice under sub-article (3) shall have the heading, "PROPOSED PLACING ON THE MARKET OF A PRODUCT CONTAINING/CONSISTING OF A GENETICALLY MODIFIED ORGANISM" and shall contain the following information—

(h) the name and address of the notifier,

(i) the description of the genetically modified organism concerned,

(j) the fact that a notification has been submitted to the Agency,

(k) the fact that further information on the proposed placing on the market may be obtained from the Agency,

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

(m) the full postal address of the Commission of the European Communities and said title in respect of the Commission,

(n) the fact that any person or body may make representations in writing to the said Commission regarding the notification within the period of 30 days beginning on the day that the Commission makes the summary of the notification received by it in accordance with article 32(1)(b) available to the public,

(5) In this article, an "appropriate consent" means a consent granted by the competent authority of another Member State of the European Communities under Part C of the Directive and the conditions specified in that consent relating to use, handling and packaging, and ecosystems, environments or geographical areas, enable it to be placed on the market in accordance with Article 19 of the Directive.

Information to be contained in a notification

30. (1) A notification under article 29 shall include either the following—

(a) the information specified in the Third Schedule, insofar as that Schedule is appropriate to the particular placing on the market,

(b) subject to sub-article (3), the information specified in the Fourth Schedule,

(c) information on data and results obtained from any previous release of the organism or of organisms of the same description, which has been carried out by the notifier, whether inside or outside the European Community, and such information from any previous notification in connection with a release of the organism 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 for the purposes of the Directive, which satisfies the provisions of Part C of the Directive,

(d) an environmental risk assessment pursuant to article 5(2) and in accordance with the Second Schedule,

(e) the conclusions arrived at by the notifier in accordance with Part D of the Second Schedule, together with any bibliographic references and details of the methods used,

(f) conditions for the placing on the market of the product, including specific conditions of use and handling,

(g) a proposed period of validity of the consent not exceeding 10 years,

(h) a plan for monitoring in accordance with the Sixth Schedule, including a proposal for a time-period for the monitoring plan (which may vary from the proposed period of validity of the consent),

(i) a proposal for labelling in accordance article 27(1)(e),

(j) a proposal for packaging in accordance with the Fourth Schedule, and

(k) a summary of the notification in the format established in accordance with the procedure laid down in Article 30(2) of the Directive and for the time being extant[1],

or, in a case to which Article 16 of the Directive applies, information specified for the purposes of that Article in accordance with the procedures set out in Article 30(2) of the Directive.

(2) The notifier shall give the Agency a separate notification under article 29 in respect of a genetically modified organism for which a consent has been sought or granted under this Part or under Part C of the Directive, where the product concerned is intended for a use that is different to the use for which consent has been sought or granted.

(3) Where the notifier considers, on the basis of the results of any release on foot of a consent granted under Part II, or a consent granted by the competent authority of another Member State of the European Communities on foot of Part B of the Directive, or on substantive, reasoned scientific grounds, that the placing on the market and use of the product would not pose a risk to human health or the environment, the notifier may propose to the Agency not to supply part or all of the information specified in Part II of the Fourth Schedule.

(4) The notifier may, in making a notification under sub-article (1), -

(a) refer to data or results from a notification previously given by another notifier, provided that the data or results are not confidential information in accordance with article 10 or that the said other notifier has agreed in writing to such reference and a copy of this agreement is included in the notification,

(b) provide relevant information, additional to that required under sub-article (1).

(5) The information provided by the notifier pursuant to sub-articles (1)(a) and (b) shall take into account the diversity of sites of use of the genetically modified organism concerned and shall include information obtained from research and development releases concerning the impact of the release on human health and the environment.

Modification of notification prior to the Agency's decision

31. (1) If, after the receipt by the Agency of a notification under article 29 but before the making of a decision by it on a proposed placing on the market, -

(a) there is a modification of the proposed placing on the market, or

[1] OJ No. L280, 18.10.2002, p.37.

(b) new information relevant to the proposed placing on the market becomes available,

which could have consequences for the risks to human health or the environment, the notifier shall inform the Agency immediately in writing and submit an amended notification to the Agency, and the first notification under article 29 shall not be further considered by the Agency.

(2) An amended notification under sub-article (1) shall be accompanied by the fee payable in accordance with article 50.

(3) Where the Agency receives an amended notification in accordance with sub-article (1), it shall deal with the amended notification as if it were a new notification under article 29 in relation to the proposed placing on the market.

(4) The provisions of this Part shall apply to an amended notification under sub-article (1) as if it were a new notification under article 29, and the proposed placing on the market shall not be carried out unless and until a consent is granted under this Part.

Duty of the Agency on foot of notification

32. (1) On receipt of a notification under article 29, the Agency shall—

(a) acknowledge to the notifier the date of such receipt in writing,

(b) immediately forward a copy of the summary of the notification received in accordance with article 30(1)(k) to the competent authorities of the other Member States of the European Communities for the purposes of the Directive and to the Commission of the European Communities,

(c) without delay examine it for compliance with articles 30(1), (2) and (5) and the other relevant provisions of these Regulations,

(d) having regard to the Second Schedule, decide whether the environmental risk assessment carried out by the notifier pursuant to article 5(2) is appropriate,

(e) ask the notifier in writing for any further information which the Agency considers necessary, stating its reasons for so doing, and

(f) once it is satisfied that the requirements of articles 30(1), (2) and (5) have been complied with, and, in any event, no later than the time at which it sends to the Commission of the European Communities a copy of the assessment report in accordance with sub-article (3) or (4), send a copy of the notification to the said Commission.

(2) Within 90 days of the receipt of a notification under article 29, the Agency shall—

(a) prepare, in accordance with the Fifth Schedule, an assessment report which shall indicate whether:

(i) the genetically modified organism concerned should be placed on the market and under which conditions (in this Chapter referred to as a “favourable assessment”); or

(ii) the genetically modified organism concerned should not be placed on the market (in this Chapter referred to as an “unfavourable assessment”), and

(b) send a copy of the assessment report to the notifier.

(3) In the case of a favourable assessment, the Agency shall, at the same time as it sends a copy of the assessment report to the notifier, send to the Commission of the European Communities a copy of the said report, any further information obtained from the notifier in accordance with sub-article (1)(e), and any other information on which the Agency has based its report.

(4) In the case of an unfavourable assessment, the Agency shall, no sooner than 15 days after it sends a copy of the assessment report to the notifier and no later than 105 days after it received the notification, send to the Commission of the European Communities a copy of the said report, any further information obtained from the notifier in accordance with sub-article (1)(e), and any other information on which the Agency has based its report.

(5) In the case of a favourable assessment, the Agency shall—

(a) provide any further information to the Commission of the European Communities, where such information is requested by the said Commission or by a competent authority of a Member State of the European Communities for the purposes of the Directive,

(b) consider any comments concerning, or reasoned objections to, the placing of the product on the market made by the Commission of the European Communities or by a competent authority of another Member State of the European Communities for the purposes of the Directive where such comments or objections are made within a period of 60 days beginning on the day on which the documents referred to in sub-article (3) were forwarded to each such competent authority by the Commission, and

(c) participate in any discussions in relation to the assessment report initiated by the Commission of the European Communities on foot of reasoned objections made in accordance with paragraph (b) with a view to reaching an agreement within a period of 105 days, beginning on the day on which the documents referred to in sub-article (3) were forwarded to each such competent authority by the Commission.

Decision on the notification

(a) 33. (1) The Agency shall grant consent to the notifier to place the product on the market where it has concluded a favourable assessment of the proposal, and

(i) no reasoned objection to the favourable assessment has been made by the Commission of the European Communities or by a competent authority of a Member State of the European Communities in accordance with article 32(5)(b), or

(ii) a reasoned objection to the favourable assessment has been made by the Commission of the European Communities or by a competent authority of a Member State of the European Communities in accordance with article 32(5)(b) but the matters concerned have been resolved in accordance with the provisions of Article 15(1) of the Directive, or

(iii) a reasoned objection to the favourable assessment has been made by the Commission of the European Communities or by a competent authority of a Member State of the European Communities in accordance with article 32(5)(b) and the said Commission has adopted a favourable decision in accordance with the provisions of Article 18(1) of the Directive.

(2) The Agency shall, within a period of 30 days beginning on the day that a consent is granted, inform the competent authority of each Member State of the European Communities and the Commission of the European Communities that it has done so.

(3) The Agency shall, where it has concluded an unfavourable assessment, or where the Commission of the European Communities has adopted an unfavourable decision in accordance with the provisions of Article 18(1) of the Directive, inform the notifier that consent is refused and stating the reasons for the refusal.

(4) A grant or a refusal of consent under this article shall be conveyed by the Agency to the notifier in writing.

Limitation on consent

34. (1) Subject to the provisions of sub-article (2), the Agency shall not grant a consent under this Chapter for a period which exceeds 10 years beginning on the date on which the consent is issued.

(2) In cases relating to a genetically modified organism or a progeny of that organism intended only for the marketing of its seeds under legislation of the European Communities for the time being in force, or to genetically modified forest reproductive material, the period of first consent shall be limited in accordance with the provisions of Article 15(4) of the Directive.

CHAPTER 3
RENEWAL OF CONSENT

Duty to comply with renewal requirements

35. A person seeking to maintain on the market a product containing or consisting of a genetically modified organism beyond the date of the expiry of a consent granted under article 33, or of a consent previously renewed under article 39, shall comply with the requirements of this Chapter.

Submission of renewal notification

36. (1) A person seeking to renew a consent granted by the Agency under article 33 or a consent previously renewed under article 39 shall submit a notification to the Agency no later than 9 months before the expiry of the consent that it is proposed to have renewed.

(2) A notification under this article shall be accompanied by the fee specified in article 47.

(3) A person who has submitted a notification under this article may continue to market the product concerned in accordance with the terms and conditions of the relevant consent until a final decision has been made on the notification.

Information to be contained in a renewal notification

37. A notification under article 36 shall include—

(a) a copy of the consent granted by the Agency to the product being placed on the market and of any renewed consent,

(b) a report on the monitoring carried out on foot of the consent or renewed consent in accordance with article 27(1)(f),

(c) any new information that has become available with regard to the risks of the product to human health or to the environment, and

(d) any proposals the notifier considers appropriate for the amendment of, or measures additional to, the conditions contained in the consent granted by the Agency, including conditions relating to future monitoring and time limitation of the consent.

Duty of the Agency on foot of renewal notification

38. (1) On receipt of a notification under article 36, the Agency shall—

(a) acknowledge to the notifier the date of such receipt in writing,

(b) examine it for compliance with article 37, and

(c) ask the notifier in writing for any further information which the Agency considers necessary, stating its reasons for so doing.

(2) As soon as may be after the Agency is satisfied that the notification is in compliance with article 37, the Agency shall—

(a) prepare, in accordance with the Fifth Schedule, an assessment report which shall indicate whether:

(i) the genetically modified organism concerned should remain on the market and under which conditions (in this Chapter referred to as a “favourable assessment”); or

(ii) the genetically modified organism concerned should not remain on the market (in this Chapter referred to as an "unfavourable assessment"),

(b) send a copy of the notification and of the assessment report to the Commission of the European Communities, and

(c) send a copy of the assessment report to the notifier.

(3) In the case of a favourable assessment, the Agency shall—

(a) provide any further information to the Commission of the European Communities, where such information is requested by the said Commission or by a competent authority of a Member State of the European Communities for the purposes of the Directive,

(b) consider any comments concerning, or reasoned objections to, the product remaining on the market made by the Commission of the European Communities or by a competent authority of another Member State of the European Communities for the purposes of the Directive where such comments or objections are made within a period of 60 days beginning on the day on which the documents referred to in sub-article (2)(b) were forwarded to each such competent authority by the Commission, and

(c) participate in any discussions in relation to the assessment report initiated by the Commission of the European Communities on foot of reasoned objections made in accordance with paragraph (b) with a view to reaching an agreement within a period of 75 days, beginning on the day on which the documents referred to in sub-article (2)(b) were forwarded to each such competent authority by the Commission.

Decision on the renewal notification

(a) 39. (1) The Agency shall renew consent to market a product where it has concluded a favourable assessment of the proposal, and

(i) no reasoned objection to the favourable assessment has been made by the Commission of the European Communities or by a competent authority of a Member State of the European Communities in accordance with article 38(3)(b), or

(ii) a reasoned objection to the favourable assessment has been made by the Commission of the European Communities or by a competent authority of a Member State of the European Communities in accordance with article 38 (3)(b) but the matters concerned have been resolved in accordance with the provisions of Article 17(7) and (8) of the Directive, or

(iii) a reasoned objection to the favourable assessment has been made raised by the Commission of the European Communities or by a competent authority of a Member State of the European Communities in accordance with article 38(3)(b) and the said Commission has adopted a favourable decision in accordance with the provisions of Article 18(1) of the Directive.

(2) The Agency shall, within a period of 30 days beginning on the day that consent is renewed, inform the competent authority of each Member State of the European Communities and the Commission of the European Communities that it has done so.

(3) The Agency shall, where it has concluded an unfavourable assessment, or where the Commission of the European Communities has adopted an unfavourable decision in accordance with the provisions of Article 18(1) of the Directive, inform the notifier that renewal of the consent is refused and stating the reasons for the refusal.

(4) A renewal or a refusal of consent under this article shall be conveyed by the Agency to the notifier in writing.

Limitation on renewal of consent

40. (1) Subject to the provisions of sub-article (2), the Agency shall not renew a consent under this Chapter for a period which exceeds 10 years beginning on the date on which the renewal of the consent is issued.

(2) Where the Agency has specific grounds for considering that it would not be appropriate to renew a consent for a period of 10 years, it may, subject to compliance with article 39 and the other provisions of this Chapter, renew the consent for such longer or shorter period as it considers justified, in which case it shall give its reasons in writing.

CHAPTER 4
POST APPROVAL

General

41. (1) The notifier shall comply with all conditions attached to a grant of consent under article 33 or a renewal of consent under article 39.

(2) The notifier shall submit reports as specified in the monitoring plan under the consent, as soon as may be after they are completed, to the Agency, the Commission of the European Communities and the competent authorities of the Member States of the European Communities for the purposes of the Directive.

Power of the Agency to adapt monitoring plan

42. The Agency may adapt a monitoring plan under any consent it has granted or renewed on foot of consideration of the first or a subsequent report submitted by the notifier in accordance with the monitoring plan.

Duty to inform the Agency of new information

43. If, after the Agency has granted consent under article 33 or a renewal of consent under article 39, new information relevant to the placing on the market becomes available which could have consequences for the risks to human health or the environment, the notifier shall—

(a) immediately take the measures necessary to protect human health and the environment;

(b) inform the Agency as soon as the new information becomes available; and

(c) inform the Agency as soon as possible of such further measures he or she has taken or proposes to take in relation to the matters concerned.

Duty of the Agency on receipt of new information

44. (1) If, after granting consent under article 33 or renewing a consent under article 39, the Agency is informed under article 43, or otherwise becomes aware, of information which, in its view, could have consequences for the risks to human health or the environment, it shall-

(a) immediately forward the information to the Commission of the European Communities and to the competent authorities of the Member States of the European Communities for the purposes of the Directive,

(b) prepare, in accordance with the Fifth Schedule, an assessment report which shall indicate whether:

(i) the genetically modified organism concerned should remain on the market and under which conditions (in this Chapter referred to as a "favourable assessment"); or

(ii) the genetically modified organism concerned should not remain on the market (in this Chapter referred to as an "unfavourable assessment"),

(c) within 60 days of the receipt of the information, forward a copy of the assessment report to the Commission of the European Communities, and

(d) send a copy of the assessment report to the notifier.

(2) In the case of a favourable assessment, the Agency shall-

(a) provide any further information to the Commission of the European Communities, where such information is requested by the said Commission or by a competent authority of a Member State of the European Communities for the purposes of the Directive,

(b) consider any comments concerning, or reasoned objections to, the assessment report referred to in sub-article (1)(b)(i) made by the Commission of the European Communities or by a competent authority of another Member State of the European Communities for the purposes of the Directive where such comments or objections are made within a period of 60 days beginning on the day on which a copy of the said assessment report was forwarded to each such competent authority by the Commission, and

(c) participate in any discussions in relation to the assessment report initiated by the Commission of the European Communities on foot of reasoned objections made in accordance with paragraph (b) with a view to reaching an agreement within a period of 75 days, beginning on the day on which a copy of the assessment report referred to in sub-article (1)(b)(i) was forwarded to each such competent authority by the Commission.

Decision on foot of new information

45. (1) The Agency shall consent to the continued marketing of the product where it has concluded a favourable assessment of the information and

(i) no reasoned objection to the favourable assessment has been made by the Commission of the European Communities or by a competent authority of a Member State of the European Communities in accordance with article 44(2)(b), or

(ii) a reasoned objection to the favourable assessment has been made by the Commission of the European Communities or by a competent authority of a Member State of the European Communities in accordance with article 44(2)(b) but the matters concerned have been resolved in accordance with the provisions of Article 20(3) of the Directive, or

(iii) a reasoned objection to the favourable assessment has been made by the Commission of the European Communities or by a competent authority of a Member State of the European Communities in accordance with article 44(2)(b) and the said Commission has

adopted a favourable decision in accordance with the provisions of Article 18(1) of the Directive.

(2) The Agency shall, within a period of 30 days beginning on the day that consent to the continued marketing is granted, inform the competent authority of each Member State of the European Communities and the Commission of the European Communities that it has done so.

(3) The Agency shall, where it has concluded an unfavourable assessment, or where the Commission of the European Communities has adopted an unfavourable decision in accordance with the provisions of Article 18(1) of the Directive, direct the notifier to cease marketing the product and stating the reasons for the direction.

(4) The notifier shall comply with any direction given by the Agency under sub-article (3).

(5) A consent to continue, or a direction to cease, marketing under this article shall be conveyed by the Agency to the notifier in writing.

PART IV

FEES AND CHARGES

Fee for notification of a proposed deliberate release

46. (1) A fee shall be paid to the Agency in respect of a notification under article 14 of a proposed deliberate release for purposes other than placing on the market.

(2) The fee payable under sub-article (1) shall be €3,000.

Fee for notification of a proposed placing of a product on the market and renewal of consent

47. (1) A fee shall be paid to the Agency in respect of a notification under article 29 of a proposed placing on the market of a product and a notification under article 36 of a proposal for renewal of a consent.

(2) The fee payable under sub-article (1) shall in each case be €30,000**.**

Fee for representations

48. (1) A fee shall be paid to the Agency in respect of representations made to it under article 16.

(2) The fee payable under sub-article (1) shall be €10.

Fee for amended notification in relation to a deliberate release

49. (1) A fee shall be paid to the Agency in respect of an amended notification under articles 17 and 20 in relation to a deliberate release for purposes other than placing on the market.

(2) The fee payable under sub-article (1) shall in each case be €1,125.

Fee for amended notification of a proposed placing of a product on the market

50. (1) A fee shall be paid to the Agency in respect of an amended notification under article 31 in connection with the proposed placing of a product on the market.

(2) The fee payable under sub-article (1) shall be €11,250.

Refund of fee in case of certain repeat notifications

51. (1) Where a notification under article 14, 29 or 36 is withdrawn before a decision is made by the Agency and a subsequent such notification is made by or on behalf of the same notifier, the Agency shall, subject to article 52, refund three quarters of the fee paid to it in respect of the subsequent notification if each of the conditions mentioned in sub-article (2) is complied with.

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

(a) the Agency is satisfied that the subsequent notification relates to a deliberate release or placing on the market, as the case may be, of the same nature and scale as the earlier notification related,

(b) a fee has been paid in respect 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 12 months,

(d) no previous refund under sub-article (1) has at any time been made to the same notifier in respect of a notification which related substantially to the same deliberate release or placing on the market, as the case may be, 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 53.

Claim for refund to be in writing

52. A refund under article 51 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 2 months beginning on the day of the giving of the decision by the Agency on the subsequent notification.

Discretionary power to refund or waive fee in certain limited circumstances

53. (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 the limited scale of the proposal.

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

Periodic charges for monitoring

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

Agency investigations

55. The Agency may carry out, or arrange to have carried out, such investigations as it considers necessary, as part of its examination of a notification, amended notification or other matter related to these Regulations, to enable it properly to assess the notification, amended notification or other matter concerned, and may require the notifier to defray or contribute towards the cost of any such investigations.

Recovery of costs or charges

56. The Agency may recover the amount of any payment due to it arising from a requirement under article 54 or 55 as a simple contract debt in any court of competent jurisdiction.

PART V

ENFORCEMENT AND REGULATION

Authorised persons

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

Prosecution of offences

58. An offence under these Regulations, or an offence arising from the exercise of powers under the Act by authorised persons appointed pursuant to article 57, may be prosecuted by the Agency.

High Court injunction

59. The High Court may, on the application of the Agency, by order, prohibit or restrict any activity involving a deliberate release or placing on the market where the Court is satisfied that the commencement or continuation of the activity would-

    (a) constitute a contravention of these Regulations, or

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

Notice to take measures

60. (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 notifier.

    (2) A notice pursuant to this article shall-

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

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

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

PART VI

GENETICALLY MODIFIED ORGANISMS ADVISORY COMMITTEE

Genetically Modified Organisms Advisory Committee

61. The Agency shall appoint a committee to be known as the "Genetically Modified Organisms Advisory Committee" for the purposes of consultation on any aspect of its functions in relation to genetically modified organisms which the Agency considers appropriate.

Membership of Advisory Committee

62. (1) Subject to sub-article (3), the membership of the Genetically Modified Organisms Advisory Committee shall include persons nominated by the following:

(a) the Agency,

(b) the Minister,

(c) the Minister for Agriculture and Food,

(d) the Minister for Health and Children,

(e) the Minister for Enterprise, Trade and Employment,

(f) the National Authority for Occupational Safety and Health,

(g) the Director of Consumer Affairs,

(h) organisations which in the opinion of the Agency are representative of persons whose professions or occupations relate to biotechnology research or the biotechnology industry,

(i) organisations which in the opinion of the Agency are concerned with environmental protection,

(j) organisations, other than the Office of the Director of Consumer Affairs, which in the opinion of the Agency are concerned with consumer affairs.

(2) The number of members of the Genetically Modified Organisms Advisory Committee, including the person appointed under article 64 to chair the meetings, shall not exceed 14.

(3) Pending the expiry, following the coming into operation of these Regulations, of the term of office of the Advisory Committee on Genetically Modified Organisms established under Part VI of the Genetically Modified Organisms Regulations 1994, the membership of the said Committee on the day immediately before the said coming into operation shall serve as the membership of the Genetically Modified Organisms Advisory Committee.

Term of appointment of members of Advisory Committee

63. Subject to article 62(3), a member shall be appointed to the Genetically Modified Organisms Advisory Committee for such term (not exceeding 3 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.

Appointment of person to chair meetings

64. The Agency shall appoint a person to chair the meetings of the Genetically Modified Organisms Advisory Committee and a person to act in the absence of the person appointed.

Regulation of procedure or business

65. The Genetically Modified Organisms Advisory Committee may regulate, by standing orders or otherwise, its procedure or business.

PART VII

MISCELLANEOUS

Testing, monitoring etc.

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

Reporting on functions under these Regulations

67. The Agency shall provide to the Minister such information in relation to the performance of its functions under these Regulations as the Minister may specify from time to time.

Amendment of Genetically Modified Organisms (Contained Use) Regulations 2001

68. (1) Article 26(1) of the Genetically Modified Organisms (Contained Use) Regulations 2001 is amended by-

(a) the insertion of the word "or" after "article 10," in paragraph (ii) and

(b) the insertion, after paragraph (ii) of the following:

"(iii) a notification has been given to the Agency in relation to a class two contained use in accordance with article 18(3) and the Agency has required the user to give notice of the notification in a newspaper under article 20 (1),".

(2) Articles 59 and 60 of the Genetically Modified Organisms (Contained Use) Regulations 2001 are revoked.

Revocation and application of Genetically Modified Organisms Regulations 1994

69. The Genetically Modified Organisms Regulations 1994 are revoked and, subject to articles 10 and 41 of the Genetically Modified Organisms (Contained Use) Regulations 2001 and article 11 of these Regulations, shall cease to apply.

Article 3

FIRST SCHEDULE

TECHNIQUES OF GENETIC MODIFICATION

PART I

Techniques of genetic modification are inter alia:

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

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

(3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of 2 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 nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by article 7(a):

(1) in vitro fertilisation,

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

(3) polyploidy induction.

Articles 3,5,14,18, 30 and 32

SECOND SCHEDULE

PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

This schedule describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform an environmental risk assessment required by these Regulations. It is supplemented by guidance notes developed in accordance with the procedure laid down in Article 30(2) of the Directive and for the time being extant[3].

With a view to contributing to a common understanding of the terms "direct, indirect, immediate and delayed" when implementing this schedule, without prejudice to further guidance in this respect and in particular as regards the extent to which indirect effects can and should be taken into account, these terms are described as follows:

- 'direct effects' refers to primary effects on human health or the environment which are a result of the genetically modified organism (hereinafter referred to as "GMO") itself and which do not occur through a causal chain of events;

- 'indirect effects' refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management. Observations of indirect effects are likely to be delayed;

- 'immediate effects' refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;

- 'delayed effects' refers to effects on human health or the environment which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

A general principle for environmental risk assessment is also that an analysis of the 'cumulative long-term effects' relevant to the release and the placing on the market is to be carried out. 'Cumulative long-term effects' refers to the accumulated effects of consents on human health and the environment, including *inter alia*, flora and fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

A. Objective

The objective of an environmental risk assessment is, on a case by case basis, to identify and evaluate potential adverse effects of the genetically modified organisms, either direct and indirect, immediate or delayed, on human health or the environment which the deliberate release or the placing on the market of genetically modified organisms may have. The environmental risk assessment should be conducted with a view to identifying if there is a need for risk management and, if so, the most appropriate methods to be used.

B. General Principles

In accordance with the precautionary principle, the following general principles should be followed when performing the environmental risk assessment:

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[3] OJ No. L200, 30.07. 2002, p.22.

- identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;

- the environmental risk assessment should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;

- the environmental risk assessment should be carried out on a case by case basis, meaning that the required information may vary depending on the type of the genetically modified organisms concerned, their intended use and the potential receiving environment, taking into account *inter alia*, genetically modified organisms already in the environment;

- if new information on the genetically modified organism and its effects on human health or the environment becomes available, the environmental risk assessment may need to be re-addressed in order to:

  determine whether the risk has changed;

  determine whether there is a need for amending the risk management accordingly.

C. **Methodology**

C.1. Characteristics of genetically modified organisms and releases

Depending on the case, the environmental risk assessment has to take into account the relevant technical and scientific details regarding characteristics of:

- the recipient or parental organism(s);

- the genetic modification(s), be it inclusion or deletion of genetic material, and relevant information on the vector and the donor;

- the GMO;

- the intended release or use including its scale;

- the potential receiving environment; and

- the interaction between these.

Information from releases of similar organisms with similar traits and their interaction with similar environments can assist the environmental risk assessment.

C.2. Steps in the environmental risk assessment

In drawing conclusions for the environmental risk assessment, the following points should be addressed:

1. *Identification of characteristics which may cause adverse effects:*

   Any characteristics of the genetically modified organisms linked to the genetic modification that may result in adverse effects on human health or the environment shall be identified. A comparison of the characteristics of the GMO(s) with those of the non-modified organism under corresponding conditions of the release or use will assist in identifying the particular potential adverse effects arising from the genetic modification.

   It is important not to discount any potential adverse effect on the basis that is unlikely to occur.

Potential adverse effects of genetically modified organisms will vary from case to case, and may include:

- disease to humans including allergenic or toxic effects (see for example items II.A.11. and II.C.2(i) in Part I of the Third Schedule, and B.7. in Part II of that Schedule);

- disease to animals and plants including toxic, and where appropriate, allergenic effects (see for example items II.A.11. and II.C.2.(i) in Part I of the Third Schedule, and B.7. and D.8. in Part II of that Schedule);

- effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see for example items IV.B.8, 9 and 12 in Part I of the Third Schedule);

- altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;

- compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see for example items II.A.11.(e) and II.C.2.(i)(IV) in Part I of the Third Schedule);

- effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11.(f) and IV.B.15 in Part I of the Third Schedule, and D.11 in Part II of that Schedule).

Adverse effects may occur directly or indirectly through mechanisms which may include:

- the spread of the genetically modified organism(s) in the environment;

- the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not;

- phenotypic and genetic instability;

- interactions with other organisms;

- changes in management, including, where applicable, in agricultural practices.

2. Evaluation of the potential consequences of each adverse effect, if it occurs:

The magnitude of the consequences of each potential adverse effect should be evaluated.

This evaluation should assume that such an adverse effect will occur. The magnitude of the consequences is likely to be influenced by the environment into which the genetically modified organism(s) is (are) intended to be released and the manner of the release.

3. *Evaluation of the likelihood of the occurrence of each identified potential adverse effect:*

A major factor in evaluating the likelihood or probability of adverse effects occurring is the characteristics of the environment into which the genetically modified organism(s) is (are) intended to be released, and the manner of the release.

4. *Estimation of the risk posed by each identified characteristic of the genetically modified organism(s):*

An estimation of the risk to human health or the environment posed by each identified characteristic of the genetically modified organism which has the potential to cause adverse effects should be made as

far as possible, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs.

5. *Application of management strategies for risks from the deliberate release or marketing of genetically modified organism(s):*

The risk assessment may identify risks that require management and how best to manage them, and a risk management strategy should be defined.

6. Determination of the overall risk of the genetically modified organism(s):

An evaluation of the overall risk of the GMO(s) should be made taking into account any risk management strategies which are proposed.

D. **Conclusions on the potential environmental impact from the release or the placing on the market of genetically modified organisms**

On the basis of an environmental risk assessment carried out in accordance with the principles and methodology outlined in parts B and C of this schedule, information on the points listed in parts D1 or D2 of this schedule should be included, as appropriate, in notifications with a view to assisting in drawing conclusions on the potential environmental impact from the release or the placing on the market of genetically modified organisms.

D.1. In the case of genetically modified organisms other than higher plants:

1. Likelihood of the genetically modified organism to become persistent and invasive in natural habitats under the conditions of the proposed release(s).

2. Any selective advantage or disadvantage conferred to the genetically modified organism and the likelihood of this becoming realised under the conditions of the proposed release(s).

3. Potential for gene transfer to other species under conditions of the proposed release of the genetically modified organism and any selective advantage or disadvantage conferred to those species.

4. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the genetically modified organism and target organisms (if applicable).

5. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the genetically modified organism with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the genetically modified organism and persons working with, coming into contact with or in the vicinity of the genetically modified organism release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the genetically modified organism and any product derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the genetically modified organism and target and non-target organisms in the vicinity of the genetically modified organism release(s).

9. Possible immediate and/or delayed, direct, and indirect environmental impacts of the specified techniques used for the management of the genetically modified organism where these are different from those used for non-genetically modified organisms.

D.2. In the case of genetically modified higher plants (hereinafter referred to as "GMHP"):

1. Likelihood of the GMHP 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 the GMHP.

3. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species.

4. Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids and pathogens (if applicable).

5. Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

Articles 14 and 30

THIRD SCHEDULE

INFORMATION REQUIRED IN NOTIFICATIONS

The notifications referred to in article 14 or 30 shall include, as appropriate, the information set out in Parts I and II of this Schedule.

Not all the 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 the scale of the proposed release.

The description of the methods used or the reference to standardised or internationally recognised methods shall also be mentioned in the dossier, together with the name of the body or bodies responsible for carrying out the studies.

Part I applies to releases of all types of genetically modified organisms other than higher plants. Part II applies to releases of genetically modified higher plants.

The term 'higher plants' means plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

PART I

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 or (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. organisms with which transfer of genetic material is known to occur under natural conditions,
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 Community rules 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;
    (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 insert(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 on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;
(e) methods and criteria used for selection;
(f) 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 characteristic(s) and in particular any new traits and characteristics which may be expressed or no longer 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 quantitative terms) and specificity of detection and identification techniques;
(h) history of previous releases or uses of the genetically modified organism;
(i) considerations for human health and animal health, as well as plant health:

(I) toxic or allergenic effects of the genetically modified organisms and/or their metabolic products;
(II)comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
(III)capacity for colonisation;
(IV)if the organism is pathogenic to humans who are immunocompetent:

- 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.

(V)other product hazards

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

A. **Information on 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 to be taken during 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 the case of a notification referred to in article 30, 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, protected areas or drinking water supplies,
4. climatic characteristics of the region(s) likely to be affected,
5. geographical, geological and pedological characteristics,
6. flora and fauna, including crops, livestock and migratory species,
7. description of target and non-target ecosystems likely to be affected,
8. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release,
9. 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. Descriptions of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify genetic 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,
8. potential for excessive population increase in the environment,
9. competitive advantage of the genetically modified organisms in relation to the unmodified recipient or parental organism(s),
10. identification and description of the target organisms if applicable,
11. anticipated mechanism and result of interaction between the released genetically modified organisms and the target organism(s) if applicable,
12. identification and description of non-target organisms which may be adversely affected by the release of the genetically modified organism, and the anticipated mechanisms of any identified adverse interaction,
13. likelihood of post-release shifts in biological interactions or in host range,
14. known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens,
15. known or predicted involvement in biogeochemical processes,
16. other potential 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 organisms), 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. 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, for example eradication of the genetically modified organisms,
3. methods for disposal or sanitation of plants, animals, soils, 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.

PART II

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GMHPs) (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:

      (ii) mode(s) of reproduction;
      (iii) specific factors affecting reproduction, if any;
      (iv) generation time.

   (b) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible 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 (for example, an estimation of how viable pollen and/or seeds declines with distance) 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. Other potential interactions, relevant to the genetically modified organism, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, 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) copy number of the insert;
   (d) location(s) of the insert(s) in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination;
3. Information on the expression of the insert:
   (a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation;
   (b) parts of the plant where the insert is expressed (for example, roots, stems, 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 and phenotypic stability of the genetically modified higher plant;
6. Any change to the ability of the GMHP to transfer genetic material to other organisms;
7. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification;
8. Information on the safety of the genetically modified higher plant to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the genetically modified higher plant is intended to be used in animal feedstuffs.
9. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).
10. Potential changes in the interactions of the genetically modified higher plant with non-target organisms resulting from the genetic modification.
11. Potential interactions with the abiotic environment.
12. Descriptions of detection and identification techniques for the genetically modified plant.
13. Information about previous releases of the genetically modified plant, if applicable.

E. INFORMATION RELATING TO THE SITE OF RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED IN ACCORDANCE WITH ARTICLE 14)

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 IN ACCORDANCE WITH ARTICLE 14)

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 IN ACCORDANCE WITH ARTICLE 14)

1. Any precautions taken:
   (a) distance(s) from sexually compatible plant species, both wild relatives and crops;
   (b) any measures to minimise/prevent dispersal of any reproductive organ of the genetically modified higher plant (for example, pollen, seeds, tuber).
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.
6. Methods and procedures to protect the site.

FOURTH SCHEDULE

ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING ON THE MARKET OF PRODUCTS CONTAINING OR CONSISTING OF GENETICALLY MODIFIED ORGANISMS

PART I

The following information shall be provided in the notification for placing on the market of a product containing or consisting of a genetically modified organism, in addition to that required pursuant to the Third Schedule:

1. proposed commercial name(s) of the product and name(s) of genetically modified organisms contained therein, and any specific identification, name or code used by the notifier to identify the genetically modified organism. After any consent, any new commercial name(s) should be provided to the Agency by the notifier,
2. name and full address of the person established in the European Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor,
3. name and full address of the supplier(s) of control samples,
4. description of how the product and the genetically modified organism as or in product are intended to be used. Differences in use or management of the genetically modified organism compared to similar non-genetically modified products should be highlighted,
5. description of the geographical area(s) and types of environment where the product is intended to be used within the European Community, including, where possible, estimated scale of use in each area,
6. intended categories of users of the product (e.g. industry, agriculture and skilled trades, consumer use by public at large),
7. information on the genetic modification for the purpose of placing on one or several registers, established by the Commission of the European Communities pursuant to Article 31(2) of the Directive, modifications in organisms which can be used for the detection and identification of particular GMO products to facilitate post-marketing control and inspection. This information should include, where appropriate, the lodging of samples of the GMO or its genetic material, with the Agency and details of nucleotide sequences or other type of information which is necessary to identify the GMO product and its progeny, for example, the methodology for detecting and identifying the GMO product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the said register or registers should be identified.
8. proposed labelling on a label or in an accompanying document. This shall include, at least in summarised form, a commercial name of the product, a statement that "This product contains genetically modified organisms", the name of the genetically modified organism and the information referred to at 2 above. The labelling should indicate how to access the information in the publicly accessible part of the register or registers referred to at 7 above.

PART II

The following information shall be provided in the notification, in accordance with article 30, when relevant, in addition to that required by Part I of this schedule:

1. measures to take in case of unintended release or misuse;
2. specific instructions or recommendations for storage and handling;
3. specific instructions for carrying out monitoring and reporting to the notifier and, if required, the Agency, so that the Agency and the competent authorities of other Member States of the European Communities for the purposes of the Directive can be effectively informed of any adverse effect. These instructions shall be consistent with Part C of the Sixth Schedule;
4. proposed restrictions on the approved use of the genetically modified organism, for example, where the product may be used and for what purposes;
5. proposed packaging;
6. estimated production in and/or imports to the European Community;
7. proposed additional labelling to include, at least in summarised form, the information referred to in points 4 and 5 of Part I of this schedule and points 1, 2, 3 and 4 of this Part.

FIFTH SCHEDULE

GUIDELINES FOR THE ASSESSMENT REPORTS

An assessment report prepared in accordance with articles 32, 38 and 44 should include, in particular, the following:

1. identification of the characteristics of the recipient organism which are relevant to the assessment of the genetically modified organism(s) in question. Identification of any known risks to human health and the environment resulting from the release into the environment of the recipient non-modified organism;

2. description of the result of the genetic modification in the modified organism;

3. assessment of whether the genetic modification has been characterised sufficiently for the purpose of evaluating any risks to human health and the environment;

4. identification to any new risks to human health and the environment that may arise from the release of the genetically modified organism(s) in question as compared to the release of the corresponding non-modified organism(s) based on the environmental risk assessment carried out in accordance with the Second Schedule;

5. a conclusion on whether the genetically modified organism (s) in question should be placed on the market or as (a) product(s) and under which conditions, whether the genetically modified organism(s) in question shall not be placed on the market, or whether the views of other competent authorities for the purposes of the Directive and the Commission of the European Communities are being sought on specific issues of the environmental risk assessment. These aspects should be specified. The conclusion should clearly address the use proposed, risk management and the monitoring plan proposed. In the case that it has been concluded that the genetically modified organism(s) should not be placed on the market, the Agency shall give reasons for its conclusion.

SIXTH SCHEDULE

MONITORING PLAN

This schedule describes in general terms the objective to be achieved and the general principles to be followed to design the monitoring plan referred to in articles 27, 30, 41 and 42. It is supplemented by guidance notes developed in accordance with the procedure laid down in Article 30(2) of the Directive and for the time being extant[1].

A. **Objective**

The objective of a monitoring plan is to:

- confirm that any assumption regarding the occurrence and impact of potential adverse effects of the genetically modified organism or its use in the environmental risk assessment are correct, and
- identify the occurrence of adverse effects of the genetically modified organism or its use on human health or the environment which were not anticipated in the environmental risk assessment.

B. **General principles**

Monitoring, as referred to in articles 27, 30, 41 and 42, takes place after the consent to the placing of a genetically modified organism on the market.

The interpretation of the data collected by monitoring should be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment should be considered to establish whether they are a consequence of the genetically modified organism or its use, as such changes may be the result of environmental factors other than the placing of the genetically modified organism on the market.

Experience and data gained through the monitoring of experimental releases of genetically modified organisms may assist in designing the post marketing monitoring regime required for the placing on the market of products containing or consisting of genetically modified organisms.

C. **Design of the monitoring plan**

The design of the monitoring plan should:

1. be detailed on a case by case basis taking into account the environmental risk assessment,
2. take into account the characteristics of the genetically modified organism, the characteristics and scale of its intended use and the range of relevant environmental conditions where the genetically modified organism is expected to be released,
3. incorporate general surveillance for unanticipated adverse effects and, if necessary, (case-) specific monitoring focusing on adverse effects identified in the environmental risk assessment:
   - 3.1 whereas case-specific monitoring should be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the environmental risk assessment,
   - 3.2 whereas surveillance could, if appropriate, make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. An explanation should be provided as to how relevant information collected through established routine surveillance practices will be made available to the notifier.

[1] OJ No. L280 18.10.2002, p.27.

4. facilitate the observation, in a systematic manner, of the release of a genetically modified organism in the receiving environment and the interpretation of these observations with respect to safety to human health or in the environment,
5. identify who (notifier, users) will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the notifier and the Agency will be informed on any observed adverse effects on human health and the environment. (Time points and intervals for reports on the results of the monitoring shall be indicated),
6. give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and the environment and enable the notifier or the Agency, where appropriate, to take the measures necessary to protect human health and the environment.

GIVEN under the Official Seal of the Minister for the Environment, Heritage and Local Government this 22nd day of October 2003.

L.S. Martin Cullen
Minister for the Environment, Heritage and Local Government.

EXPLANATORY NOTE

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

These Regulations give effect to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. They replace the Genetically Modified Organisms Regulations 1994 (other than Part II, and certain other provisions, of those Regulations in relation to the contained use of genetically modified organisms which were already replaced by the Genetically Modified Organisms (Contained Use) Regulations 2001).

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

The fundamental objective of the Regulations is to protect people and the environment from any adverse effects arising from the deliberate release into the environment or marketing of genetically modified organisms (GMOs). In this regard, they provide for the application of various safety, public notice and procedural matters to deliberate releases and marketing.

Subject to limited exclusions, all deliberate releases of GMOs to the environment (whether for marketing or not) must comply with the Regulations. Proposed releases must be subjected to an environmental risk assessment (e.r.a.) which must be submitted to the EPA. Information on all proposals submitted to the EPA must be included in a publicly available register maintained by the Agency and information on all proposals made to the Agency, including the Agency's assessment of the proposal, must be circulated to the competent authorities of the other Member States of the European Communities to enable such bodies to comment on, or object to, the Agency's analysis of the proposal. Public comment on proposals is also provided for by the Regulations.

Part II regulates the deliberate release of GMOs to the environment for purposes other than marketing (for example, field trials). Among the requirements of the Regulations are- notification (accompanied by a comprehensive e.r.a) to the EPA of proposals; public advertisement by the notifier; consideration of comments by the public and from other Member States in relation to the proposal by the EPA; and entry in a public register of proposals and decisions thereon.

Part III regulates the first time placing on the market of products containing or consisting of GMOs. The Regulations include requirements in relation to - notification; the carrying out of an e.r.a. by the notifier; public advertisement of the proposal including information on how to make objections known to the European Commission; inclusion of the other Member States of the European Communities in the decision-making process; a limitation on any period of consent; monitoring procedures; and labelling of approved products to facilitate consumer choice. Procedures for the renewal of consent are also provided as is power for the EPA, where it is concerned as to possible risks to human health or the environment, to restrict or prohibit use or placing on the market.

Part IV enables the EPA to impose fees and charges in respect of its duties under the Regulations, including in respect of applications and monitoring. Part V provides for enforcement by the EPA, including powers to prosecute offences, to obtain a High Court order to prohibit or restrict any activity involving a GMO, or to serve notice on a notifier to take specific measures for the protection of people or the environment.

The Regulations come into effect on 1November 2003.