

Subsidiary Legislation made under s.180X.

**Public Health (Genetically Modified Organisms)
(Deliberate Release) Regulations 1995**

LN.1995/156

		<i>Commencement</i>	8.1.1995
Amending enactments	Relevant current provisions	Commencement date	
LN. 1997/124	rr. 2, 6(1)(a)(ii), 10(1)(a), (2)-(4)	30.10.1997	
1998/004	Sch. 3	15.1.1998	

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SCHEDULE 3

Information to be contained in an application for consent to market genetically modified organisms

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Title and commencement.

1. (1) These Regulations may be cited as the Public Health (Genetically Modified Organisms) (Deliberate Release) Regulations 1995 and, subject to sub-regulation (2) and regulations 5(3) and 11, shall come into effect on 8th day of January 1996.

(2) Where a person is carrying out an activity to which these Regulations apply at the coming into effect of these Regulations the provisions of these Regulations shall not apply to such person for a period of 90 days commencing on the day on which these Regulations shall have come into effect.

**PART I
GENERAL**

Interpretation.

2. In these Regulations, unless the context shall otherwise require—

“application for a consent to release” includes any notification made under the First Simplified Procedure (crop plants) Decision and cognate expressions shall be construed accordingly;

“competent authority” means the person or body designated as the competent authority by the Government from time to time by notice in the Gazette under section 180A;

“a competent authority of a member State” means a competent authority of the United Kingdom or of another member State appointed by the United Kingdom or that State, as the case may be, for the purposes of the Deliberate Release Directive;

“the Deliberate Release Directive” means Council Directive 90/220/EEC, as amended by Council Directive 94/15/EEC, on the deliberate release into the environment of genetically modified organisms and includes any changes made to that Directive to reflect technical or scientific change and any further Directives made for that purpose;

“the First Simplified Procedure (crop plants) Decision” means Commission Decision 94/730/EC;

“higher plant” means a plant belonging to the taxonomic group Gymnospermae or Angiospermae;

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“genetically modified organisms” means genetically modified organisms or a combination of genetically modified organisms;

“heritable genetic material” means genes or other genetic material, in any form whether in cellular or sub-cellular entities, which are, capable of being replicated or transferred by any means;

“member State” means a member State of the European Union and shall include states that are members of the European Economic Area;

“product” means a product consisting of or including genetically modified organisms, and “approved product” means a product marketed in pursuance of and in accordance with a consent granted by the competent authority under section 180F(1) of the Act or a written consent given by a competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive.

Artificial techniques of genetic modification.

3. The following techniques are prescribed as artificial techniques for the purposes of section 180A(4), that is to say—

- (a) the insertion by any method into a virus, bacterial plasmid or other vector system of a nucleic acid molecule which has been produced by any method outside that virus, bacterial plasmid or other vector system so as to produce a new combination of genetic material which is capable of being inserted into an organism in which that combination does not occur naturally and within which it will be heritable genetic material;
- (b) the insertion into an organism, by micro-injection, macro-injection, micro-encapsulation or other direct means, of heritable genetic material prepared outside that organism;
- (c) the fusion (including protoplast fusion) or hybridisation, by any method that does not occur naturally, of two or more cells to form cells which have new combinations of heritable genetic material and which (if derived solely from plant cells) cannot be produced by traditional breeding methods;
- (d) where they involve the use of recombinant DNA molecules—
 - (i) in vitro fertilisation,

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- (ii) conjugation, transduction, transformation or any other natural process,
- (iii) polyploidy induction.

Capacity of organisms for causing harm.

4. (1) For the purposes of sections 180E(1), 180G(5) and (7)(a) and 180M(1) there shall be disregarded—

- (a) the capacity of genetically modified organisms of the description specified in sub-regulation (2) for causing harm of the description specified in sub-regulation (3), and
- (b) harm, caused by genetically modified organisms of the description specified in sub-regulation (2), which is of the description specified in sub-regulation (3).

(2) The genetically modified organisms specified in this sub-regulation are genetically modified organisms which control—

- (a) the number or activity (or both) of any organisms, or
- (b) toxic wastes.

(3) The harm specified in this sub-regulation is harm caused to any organisms by genetically modified organisms which have been released or marketed in pursuance of and in accordance with—

- (a) a consent granted by the competent authority under section 180F(1) of the Act, or
- (b) a written consent given by a competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive.

**PART II
RELEASING ORGANISMS**

Consent to release organisms.

5. (1) Subject to sub-regulations (3) and (4), the cases and circumstances prescribed under section 180F(1) in relation to the release of any genetically modified organisms are any cases and circumstances other than the release of an approved product in accordance with the conditions and limitations to which the use of the product is subject.

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(2) An application for a consent to release genetically modified organisms shall be made in writing to the competent authority, unless made under and in accordance with the provisions set out in the First Simplified Procedure (crop plants) Decision and shall be made either—

- (a) for one or more releases of one or more descriptions of genetically modified organisms on the same site for the same purpose within a limited period, or
- (b) for one or more releases of one description of genetically modified organisms on one or more sites for the same purpose within a limited period.

(3) Sub-regulation (1) shall not apply to a person who releases a product which was marketed in the Gibraltar before the 8th day of January 1996 and is not an approved product.

Information to be contained in application for consent to release.

6. (1) Subject to regulation 7, an application for a consent to release genetically modified organisms shall contain—

- (a) the information prescribed in—
 - (i) Schedule 1 where the application is for the consent to release any genetically modified higher plants; or
 - (ii) Schedule 2, in any other case,to the extent that such information is appropriate to the proposed release.
- (b) information on data or results from any previous release of the organisms, or of organisms of the same description, which has been carried out by the applicant, and information from any previous application for the release of the organisms, or of organisms of the same description, which the applicant has made to the competent authority in accordance with the Act and these Regulations or to a competent authority of a member State in accordance with Article 5 of the Deliberate Release Directive;
- (c) a statement evaluating the impacts and risks posed to human health and the environment by the release of the organisms;

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- (d) a statement of whether or not the detailed description of the organisms and the details of the purpose for which the organisms will be released have been published, and the bibliographic reference for any information so published;
 - (e) a summary, in the format established by the Commission under Article 9(1) of the Deliberate Release Directive, of the information contained in the application.
- (2) The information prescribed in Schedule 1 and Schedule 2 shall be included in the application at the level of detail which is appropriate to the nature and scale of the proposed release.
- (3) The application may, in addition to the information required by sub-regulation (1), contain data or results from an application for consent to release genetically modified organisms previously made by some other person, provided that a copy of that person's agreement in writing is contained in the application.

Exemptions from regulation 6.

7. An application for a consent to release genetically modified organisms need not contain the information prescribed in regulation 6(1)(a) and (b) if—

- (a) the information was contained either—
 - (i) in an application which was made by the same person in relation to a previous release of those organisms or of the same description of organisms; or
 - (ii) in an application which was made by some other person in relation to a previous release of those organisms or of the same description of organisms;
- (b) the application refers to the previous application in which the information was contained; and
- (c) where sub-paragraph (a)(ii) applies, the application contains the agreement in writing of the person who made the previous application to a reference to that application being made.

Advertisement of application for consent to release.

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8. (1) Subject to sub-regulations (2) and (3), a person who makes an application for a consent to release genetically modified organisms shall, not less than fourteen days and not more than twenty-eight days after acknowledgment of receipt of that application is sent to him by the competent authority, cause to be published in a newspaper or newspapers circulating in the areas likely to be affected by the proposed release a notice containing the—

- (a) the name and address of the applicant;
- (b) the general description of the organisms to be released;
- (c) the location and general purpose of the release; and
- (d) the foreseen dates of the release.

(2) A notice under sub-regulation (1) need not contain the information referred to in paragraphs (c) and (d) of that sub-regulation insofar as the First Simplified Procedure (crop plants) Decision does not require that information to be submitted with the application and that information is not submitted with the application.

(2) A person who makes an application for a consent to release genetically modified organisms shall, not less than fourteen days and not more than twenty-eight days after acknowledgment of receipt of that application is sent to him by the competent authority, give notice that he has made the application and the information prescribed in paragraphs (a) to (d) of sub-regulation (1) to—

- (a) the owner or owners of the site of the proposed release, if a person other than the applicant;
- (b) the person responsible by virtue of Part III of the Act for the provision of the water supply in Gibraltar.

PART III MARKETING ORGANISMS

Consent to market products.

9.(1) The cases and circumstances prescribed under section 180F in relation to the marketing of any genetically modified organisms are any cases and circumstances other than —

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- (a) the marketing of a product in accordance with a written consent given by a competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive;
 - (b) the marketing of a product containing genetically modified micro-organisms within the meaning of Article 2 of Council Directive 90/219/EEC on the use of genetically modified micro-organisms, the conditions of sale for which specify that it is to be used only in conditions of contained use in accordance with that Directive;
 - (c) the marketing of a medical product for human or veterinary use within the meaning of Council Regulation (EEC) No 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.
- (2) An application for a consent to market genetically modified organisms shall be made in writing to the competent authority, and shall be made either—
- (a) where the product has not previously been marketed in pursuance of and in accordance with a consent granted by the competent authority under section 180F(1) or a written consent given by a competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive; or
 - (b) where the product is intended for a use for which it has not previously been marketed in pursuance of and in accordance with a consent granted by the competent authority under section 180F(1) of the Act or a written consent given by a competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive;

Information to be contained in application for consent to market.

10. (1) An application for a consent to market genetically modified organisms shall contain—
- (a) the information prescribed in—
 - (i) Schedule 1, where the application is for consent to market any genetically modified higher plant, or
 - (ii) Schedule 2, in any other case,

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to the extent that such information is appropriate to the nature of and scale of the release which may result from the marketing;

- (b) information on data or results from any previous release of the organisms, or of organisms of the same description, which have been carried out by the applicant, and information from any previous application for consent to release the organisms, or organisms of the same description, which the applicant has made to the competent authority in accordance with the Act and these Regulations or to a competent authority of a member State in accordance with Article 5 of the Deliberate Release Directive;
- (c) subject to sub-regulation (5), the information prescribed in Schedule 3;
- (d) a summary, in the format established by the Commission under Article 12(3) of the Deliberate Release Directive, of the information contained in the application.

(2) The information prescribed in Schedule 1 and Schedule 2 shall be included in the application at the level of detail which is appropriate to the nature and scale of the release which may result from the marketing, and shall take into account the diversity of sites of use of the product, including—

- (a) information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product; and
- (b) an assessment of any risks for human health or the environment related to the genetically modified organisms contained in the product, including information obtained from the research and development stage on the impact of the release on the environment.

(3) *Deleted*

(4) *Deleted*

(5) Where the applicant considers, on the basis of the results of any release in pursuance of and in accordance with a consent granted by the competent authority under section 180F(1) of the Act or a written consent given by a competent authority of a member State in accordance with Article 13(4) of the Deliberate Release Directive, or on substantive, reasoned scientific grounds, that the placing on the market and use of the product do not pose a risk to human health or the Environment, he may propose not to supply the information prescribed in Part II of Schedule 3.

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(6) The application may in addition contain data or results from an application for consent to market genetically modified organisms previously made by some other person, provided that a copy of that person's agreement in writing is contained in the application.

Transitional provision for marketing.

11. Regulation 10(1) shall not apply to a person who markets a product which—

- (a) was marketed by him in the Gibraltar before the 8th day of January 1996; and
- (b) is not an approved product, until 8th day of January 1999.

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

Duties of the competent authority on receiving applications for consent to release.

12. (1) The competent authority shall within 30 days of receiving an application for a consent to release genetically modified organisms forward to the Commission a summary of that application in the format established by the Commission under Article 9(1) of the Deliberate Release Directive.

(2) The competent authority shall—

- (a) examine an application for a consent to release genetically modified organisms for its conformity with the requirements of the Act and of these Regulations;
- (b) evaluate the risks posed by the proposed release;
- (c) if necessary, carry out such tests or inspections as may be necessary for control purposes;
- (d) where appropriate, take into account any comments made by the competent authority or authorities of member states following the circulation to them by the Commission of the summary referred to in sub-regulation (1); and
- (e) record its conclusions in writing.

Decisions by the competent authority on applications for consent to release.

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13. (1) Upon a decision by the competent authority to grant a consent to release genetically modified organisms the competent authority shall communicate its decision on an application for a consent to release genetically modified organisms to the applicant before the end of a period of 90 days beginning with the day on which the application was received.

(2) The period prescribed in sub-regulation (1) shall not include any period beginning with the day on which the competent authority gives notice in writing under section 180F(6) that further information in respect of the application is required and ending with the day on which that information is received by the competent authority.

(3) The competent authority shall inform the competent authority or authorities of each member State and the Commission of its decision on each application for consent to release genetically modified organisms.

(4) The competent authority may revoke or vary a consent to release genetically modified organisms as it relates to the protection of human health.

Duties of the competent authority in relation to applications for consent to market.

14. (1) The competent authority shall examine an application for consent to market genetically modified organisms for its conformity with the requirements of the Act and of these Regulations, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.

(2) Before the end of a period of 90 days beginning with the day on which it receives an application for consent to market genetically modified organisms the competent authority shall either—

- (a) forward to the Commission—
 - (i) the application;
 - (ii) a summary of the application in the format established by the Commission under Article 12(3) of the Deliberate Release Directive;
 - (iii) a statement of the conditions under which it proposes to consent to the marketing of the product;
 - (iv) where acceded to by the competent authority, details of any proposal by the applicant under regulation 10(5) not to comply with any of the requirements of regulation 10(1)(c); and

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- (v) its favourable opinion on the application; or
 - (b) inform the applicant that the proposal does not fulfil the requirements of the Act and of these Regulations and is rejected.
- (3) The period prescribed in sub-regulation (2) shall not include any period beginning with the day on which the competent authority gave notice in writing under section 180F(6) that further information in respect of the application is required and ending with the day on which that information is received by the competent authority.
- (4) The competent authority shall immediately inform the competent authority or authorities of each member State and the Commission of any other information it receives from the applicant before or after the granting of the consent.
- (5) Where no objection has been raised by a competent authority of a member State the competent authority shall, within a period of 60 days beginning with the day on which the documents referred to in sub-regulation (2)(a) were forwarded to the competent authority or authorities of the member States by the Commission, grant consent to market the genetically modified organisms and inform the competent authority or authorities of each member States and the Commission that it has done so.
- (6) Where an objection has been raised by a competent authority of a member state and the Commission has taken a favourable decision under Article 13(3) of the Deliberate Release Directive, the competent authority shall grant consent to market the genetically modified organisms and inform the competent authority or authorities of the member States and the Commission that it has done so.
- (7) The competent authority may revoke or vary a consent to market genetically modified organisms as it relates to the protection of human health and shall immediately inform the competent authority or authorities of each member State and the Commission of any decision to revoke or vary a consent.

SCHEDULE 1

Regulations 6 and 10

**APPLICATIONS FOR CONSENT TO RELEASE OR MARKET GENETICALLY
MODIFIED HIGHER PLANTS**

**PART I
GENERAL INFORMATION**

1. The name and address of the applicant and the name, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the release of the organisms and for the supervision, monitoring and safety of the release
2. The title of the project.

**PART II
INFORMATION RELATING TO THE PARENTAL OR
RECIPIENT PLANT**

3. The full name of the plant —
 - (a) family name,
 - (b) genus,
 - (c) species,
 - (d) subspecies,
 - (e) cultivar/breeding line,
 - (f) common name.
4. Information concerning—
 - (a) the reproduction of the plant —
 - (i) the mode or modes of reproduction;
 - (ii) any specific factors affecting reproduction;

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- (iii) generation time; and
 - (b) the sexual compatibility of the plant with other cultivated or wild plant species.
5. Information concerning the survivability of the plant —
- (a) its ability to form structures for survival or dormancy,
 - (b) any specific factors affecting survivability
6. Information concerning the dissemination of the plant:
- (a) the means and extent of dissemination; and
 - (b) any specific factors affecting dissemination.
7. The geographical distribution of the plant.
8. Where the application relates to a plant species which is not normally grown in the member State or States, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.
9. The potentially significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

PART III

INFORMATION RELATING TO THE GENETIC MODIFICATION

10. A description of the methods used for the genetic modification.
11. The nature and source of the vector used.
12. The size, intended function and name of the donor organism or organisms of each constituent fragment of the region intended for insertion.

PART IV

INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

13. A description of the trait or traits and characteristics of the genetically modified plant which have been introduced or modified.

14. The following information on the sequences actually inserted or deleted —
- (a) the size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced into the genetically modified plant or an carrier or foreign DNA remaining in the genetically modified plant,
 - (b) the size and function of the deleted regions,
 - (c) the location of the insert in the plant cells (whether it is integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form) and the methods for its determination,
 - (d) the copy number of the insert.
15. The following information on the expression of the insert:
- (a) information on the expression of the insert and methods used for its characterisation,
 - (b) the parts of the plant where the insert is expressed, such as roots, stem or pollen.
16. Information on how the genetically modified plant differs from the parental or recipient plant in the following respects —
- (a) mode or modes and/or the rate of reproduction;
 - (b) dissemination;
 - (c) survivability.
17. The genetic stability of the insert.
18. The potential for a transfer of genetic material from the genetically modified plants to other organisms.
19. Information on any toxic or harmful effects on human health and the environment arising from the genetic modification.

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20. The mechanism of interaction between the genetically modified plants and target organisms.
21. Any potentially significant interactions with non-target organisms.
22. A description of detection and identification techniques for the genetically modified plants.
23. Information about previous releases of the genetically modified plants.

PART V

INFORMATION RELATING TO THE SITE OF RELEASE
(Applications for consent to release only)

24. The location and size of the release site or sites.
25. A description of the release site ecosystem, including climate, flora and fauna.
26. Details of any sexually compatible wild relatives or cultivated plant species present at the release sites,
27. The proximity of the release sites to officially recognised biotopes or protected areas which may be affected.

PART VI

INFORMATION RELATING TO THE RELEASE
(Applications for consent to release only)

28. The purpose of the release.
29. The foreseen dates and duration of the release.
30. The method by which the genetically modified plants will be released.
31. The method for preparing and managing the release site, prior to, during and after the release, including cultivation practices and harvesting methods.
32. The approximate number of genetically modified plants (or plants per m²) to be released.

PART VII

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INFORMATION ON CONTROL, MONITORING, POST-RELEASE PLANS AND
WASTE TREATMENT PLANS
(Applications for consent to release only)

33. A description of any precautions to—
- (a) maintain the genetically modified plant at a distance from sexually compatible plant species;
 - (b) minimise or prevent pollen or seed dispersal.
34. A description of the methods for post-release treatment of the site or sites,
35. A description of post-release treatment methods for the genetically modified plant material including wastes.
36. A description of monitoring plans and techniques.
37. A description of any emergency plans.

PART VIII

INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT OF THE
RELEASE OF THE GENETICALLY MODIFIED PLANTS

38. The likelihood of the genetically modified plant becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.
39. Any selective advantage or disadvantage conferred to other sexually compatible plants species, which may result from genetic transfer from the genetically modified plant.
40. The potential environmental impact of the interaction between the genetically modified plant and target organisms.
41. Any possible environmental impact resulting from potential interactions with non-target organisms.

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SCHEDULE 2

Regulations 6 and 10

**APPLICATIONS FOR CONSENT TO RELEASE OR MARKET ORGANISMS
OTHER THAN GENETICALLY MODIFIED HIGHER PLANTS**

PART I

GENERAL INFORMATION

1. The name and address of the applicant and the name, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the release of the organisms and for the supervision, monitoring and safety of the release.
2. The title of the project.

PART II

INFORMATION RELATING TO THE ORGANISMS

Characteristics of the donor, parental and recipient organisms

3. Scientific name and taxonomy.
4. Usual strain, cultivar or other name.
5. Phenotypic and genetic markers.
6. The degree of relatedness between the donor and recipient or between parental organisms.
7. The description of identification and detection techniques.
8. The sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.
9. The description of the geographical distribution and of the natural habitat of the organisms including information on natural predators, prey, parasites and competitors, symbionts and hosts.
10. The potential of the organisms for genetic transfer and exchange with other organisms.
11. Verification of the genetic stability of the organisms and factors affecting that stability

12. The following pathological, ecological and physiological traits–
- (a) the classification of hazard according to existing Community rules concerning the protection of human health and the environment;
 - (b) the generation time in natural ecosystems, and sexual and asexual reproductive cycle,
 - (c) survivability, including seasonability and the ability to form survival structures, including seeds, spores and sclerotia;
 - (d) pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and 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 including primary production, nutrient turnover, decomposition of organic matter and respiration.

13. The sequence, frequency of mobilisation and specificity of indigenous vectors and the presence in those vectors of genes which confer resistance to environmental stresses.

14. The history of genetic modification.

Characteristics of the vector.

15. The nature and source of the vector.

16. The sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organisms and to make the introduced vector and insert function in those organisms.

17. The frequency of mobilisation, genetic transfer capabilities and/or methods of determination of the inserted vector.

18. The degree to which the vector is limited to the DNA required to perform the intended function.

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Characteristics of the modified organisms.

19. The methods used for the modification.
20. The methods used—
 - (a) to construct inserts and introduce them into the recipient organism;
 - (b) to delete a sequence.
21. The description of any insert and/or vector construction.
22. The 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.
23. The sequence, functional identity and location of the altered, inserted or deleted nucleic acid segments in question and, in particular, any known harmful sequence.

Characteristics of the genetically modified organisms.

24. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.
25. The structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organisms.
26. The stability of the organism in terms of genetic traits.
27. The rate and level of expression of the new genetic material in the organisms and the method and sensitivity of measurement of that rate and level.
28. The activity of the gene product.
29. The description of identification and detection techniques, including techniques for the identification and detection of the inserted sequence and vector.
30. The sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.
31. The history of previous releases or uses of the organisms.

32. In relation to human health—

- (a) the toxic or allergenic effects of the non-viable organisms and/or their metabolic products;
- (b) the product hazards;
- (c) the comparison of the organisms to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
- (d) the capacity of the organisms for colonisation, and
- (e) if the organisms are pathogenic to humans who are immunocompetent—
 - (i) diseases caused and mechanisms of pathogenicity including invasiveness and virulence;
 - (ii) communicability;
 - (iii) infective dose;
 - (iv) host range and possibility of alteration;
 - (v) possibility of survival outside of human host;
 - (vi) presence of vectors or means of dissemination;
 - (vii) biological stability,
 - (viii) antibiotic-resistance patterns,
 - (ix) allergenicity, and
 - (x) availability of appropriate therapies.

PART III
CONDITIONS OF RELEASE

The release.

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33. The description of the proposed deliberate release, including the purpose or purposes and foreseen products of the release.
34. The foreseen dates of the release and time planning of the experiment including frequency and duration of releases.
35. The preparation of the site before the release.
36. The size of the site.
37. The methods to be used for the release.
38. The quantity of organisms to be released.
39. The disturbance of the site, including the type and method of cultivation, mining, irrigation, or other activities.
40. The worker protection measures taken during the release.
41. The post-release treatment of the site.
42. The techniques foreseen for elimination or inactivation of the organisms at the end of the experiment.
43. Information on, and the results of, previous releases of the organisms and in particular, releases on a different scale or into different ecosystems.

The environment (both on the site and in the wider environment).

44. The geographical location and national grid reference of the site onto which the release will be made, or the foreseen areas of use of the product.
45. The physical or biological proximity of the site to humans and other significant biota.
46. The proximity to significant biotopes or protected areas.
47. The size of local human population.
48. The local economic activities which are based on the natural resources of the area.

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49. The distance to the nearest drinking water supply zone areas and/or areas protected for environmental purposes.
50. The climatic characteristics of the region or regions likely to be affected.
51. The geographical, geological and pedological characteristics.
52. The flora and fauna, including crops, livestock and migratory species.
53. The description of target and non-target ecosystems likely to be affected.
54. The comparison of the natural habitat of the recipient organisms with the proposed site or sites of release.
55. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

PART IV
THE ORGANISMS AND THE ENVIRONMENT

Characteristics affecting survival etc.

56. The biological features which affect survival, multiplication and dispersal.
57. The known or predicted environmental conditions which may affect survival, multiplication and dissemination, including wind, water, soil, temperature, pH.
58. The sensitivity to specific agents.

Interactions with the environment.

59. The predicted habitat of the organism.
60. The studies of the behaviour and characteristics of the organisms and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms and greenhouses.
61. The capability of post-release transfer of genetic material—
 - (a) from the genetically modified organisms into organisms in affected ecosystems,

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- (b) from indigenous organisms to the genetically modified organisms.
62. The likelihood of post-release selection leading to the expression of unexpected or undesirable traits in the genetically modified organisms.
63. The measures employed to ensure and to verify genetic stability, the description of genetic traits which may prevent or minimise dispersal of genetic material and methods to verify genetic stability.
64. The routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing.
65. The description of ecosystems to which the organisms could be disseminated.

Potential environmental impact.

66. The potential for excessive population increase of the organisms in the environment.
67. The competitive advantage of the organisms in relation to the unmodified recipient or parental organisms.
68. The identification and description of the target organisms.
69. The anticipated mechanism and result of interaction between the released organisms and the target organisms.
70. The identification and description of non-target organisms which may be affected.
71. The likelihood of post-release shifts in biological interactions or in the host range.
72. The known or predicted effects on non-target organisms in the environment and the impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.
73. The known or predicted involvement in biogeochemical processes.
74. Any other potentially significant interactions with the environment.

PART V
MONITORING, CONTROL WASTE TREATMENT AND EMERGENCY RESPONSE
PLANS

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Monitoring Techniques.

- 75. Methods for tracing the organisms and for monitoring their effects.
- 76. Specificity (to identify the organisms and to distinguish them from the donor, recipient or the parental organisms), sensitivity and reliability of the monitoring techniques.
- 77. Techniques for detecting transfer of the donated genetic material to other organisms.
- 78. Duration and frequency of the monitoring.

Control of the release.

- 79. Methods and procedures to avoid and/or minimise the spread of the organisms beyond the site of release or the designated area for use.
- 80. Methods and procedures to protect the site from intrusion by unauthorised individuals.
- 81. Methods and procedures to prevent other organisms from entering the site.

Waste treatment.

- 82. Type of waste generated.
- 83. Expected amount of waste.
- 84. Possible risks.
- 85. Description of treatment envisaged.

Emergency response plans.

- 86. Methods and procedures for controlling the organisms in case of unexpected spread.
- 87. Methods, such as eradication of the organisms, for decontamination of the areas affected.
- 88. Methods for disposal or sanitation of plants, animals, soils and any other thing exposed during or after the spread.
- 89. Methods for the isolation of the areas affected by the spread.

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90. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

SCHEDULE 3

Regulation 10

**INFORMATION TO BE CONTAINED IN AN APPLICATION FOR CONSENT TO
MARKET GENETICALLY MODIFIED ORGANISMS**

PART I

GENERAL INFORMATION

1. The name of the product and the name of the genetically modified organism in the product.
2. The name and address in the Community of the manufacturer or distributor of the product.
3. The specificity of the product and the exact conditions of use including, where appropriate, the type of environment and/or the geographical areas within the Community for which the product is suited.
4. The type of expected use of the product and the description of the persons who are expected to use the product.
- 4a. Information relating to the introduced genetic modification which could be of relevance to the establishment of a possible register of modifications introduced into organisms (species). This may include nucleotide sequences or any other type of information, which is relevant for inclusion in such a register.
- 4b. Information regarding proposed labeling, which must include, in a label or an accompanying document, an indication that the product contains, or consists of, genetically modified organisms. In the case of products to be placed on the market in mixtures with non-genetically modified organisms, it is sufficient to indicate the possibility that genetically modified organisms may be present.

PART II

ADDITIONAL RELEVANT INFORMATION

5. The measures to be taken in the event of the escape of the organisms in the product or misuse of the product.
6. Specific instructions or recommendations for storage and handling of the product.

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7. The estimated level and amount of product within the Community and the estimated level and amount of imports of the product into the Community.
8. Information regarding the proposed packaging for the product and its appropriateness so as to avoid the escape of genetically modified organisms during the storage or at later stage.
9. Information regarding proposed labelling including the proposals for stating in full or summarised form, the information prescribed in paragraphs 1 to 3, 5 and 6.