S U P P L E M E N T No. 2
TO
THE SOVEREIGN BASE AREAS GAZETTE
No. 1422 of 8th August 2006
L E G I S L A T I O N

ORDINANCE 10 OF 2006

THE GENETICALLY MODIFIED ORGANISMS ORDINANCE 2006

ARRANGEMENT OF SECTIONS

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DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS FOR ANY PURPOSE OTHER THAN FOR PLACING THEM ON THE MARKET

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AN ORDINANCE TO PROVIDE FOR THE PROTECTION OF HUMAN HEALTH AND FOR PREVENTING OR MINIMISING ANY DAMAGE TO THE ENVIRONMENT FROM THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS OR FROM PLACING ON THE MARKET PRODUCTS CONSISTING IN OR CONTAINING GENETICALLY MODIFIED ORGANISMS, AND FOR RELATED MATTERS

R. H. LACEY
ADMINISTRATOR *7th June 2006.*

BE it enacted by the Administrator of the Sovereign Base Areas of Akrotiri and Dhekelia as follows:—

PART I
PRELIMINARY PROVISIONS

1. This Ordinance may be cited as the Genetically Modified Organisms Ordinance 2006. Short title.

2.—(1) In this Ordinance, unless the text otherwise requires— Interpretation.

"contained use" in relation to any organism means any operation in which organisms are genetically modified or in which such genetically modified micro-organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers, or a combination of physical barriers together with chemical or biological barriers, are used to limit their contact with the general population and the environment;

"deliberate release", in relation to a genetically modified organism (a "GMO") means any deliberate introduction of the GMO into the environment without there being in place specific containment measures for limiting the GMO's contact with, or for providing a high level of safety for, the general population and the environment;

"environmental risk assessment" means an evaluation, carried out in accordance with Schedule I, of risks to human health and Schedule I.

the environment (which includes plants, animals and micro-organisms), whether direct or indirect, immediate or delayed, which the deliberate release into the environment of a GMO or the placing on the market of a GMO product may pose;

"GMO" means genetically modified organism (and "GMOs" means genetically modified organisms);

"GMO product" means a product which consists of a GMO or which contains a GMO, and which is placed on the market;

"organism" means any biological entity capable of replication or of transferring genetic material;

"placing on the market", in relation to a GMO product means making the GMO product available to third parties, whether or not for a consideration; and cognate expressions shall be construed accordingly.

(2) The following operations shall not be regarded as placing a GMO product on the market—

(a) making available genetically modified micro-organisms for activities on the contained use of genetically modified micro-organisms including culture collections;

(b) making available GMOs other than micro-organisms referred to in paragraph (a) above, to be used exclusively for activities where appropriate stringent containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment, that is to say measures based on the same principles of containment described in Schedule II;

Schedule II.

(c) making available GMOs to be used exclusively for deliberate releases complying with the requirements of Part II of this Ordinance;

(3) A genetically modified organism (or "GMO") is 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 both). Genetic modification shall be taken to occur through the use of the techniques described in Part 1 of Schedule IIIA but not through the use of the techniques described in Part 2 of that Schedule.

Schedule IIIA.

Purpose and scope of this Ordinance.

3. The purpose of this Ordinance is to protect human health and the environment when genetically modified organisms—

(a) are deliberately released into the environment or are spread through asexual or sexual propagation with cultured or bred or naturally growing plants or indigenous animals, for any purpose other than placing on the market; or

(b) are placed on the market, whether as genetically modified organisms or as GMO products.

Matters outside the scope of this Ordinance.

4. This Ordinance does not apply—

(a) to the carriage of genetically modified organisms by rail, road, inland waterway, sea or air; or

(b) to organisms obtained through the techniques of genetic modification described in Schedule IIIB.

Schedule IIIB.

General obligations.

5.—(1) The Chief Officer shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release of GMOs or the placing on the market of GMO products.

(2) GMOs shall only be deliberately released in accordance with Part II and GMO products shall only be placed on the market in accordance with Part III.

(3) In the event of a release of a GMO into the environment or the placing on the market of a GMO product without a licence under this Ordinance or in contravention of any condition attaching to such a licence, the Chief Officer shall take all measures necessary to end the release or the marketing and shall take such remedial action as may be necessary, and may provide the public with such information as he considers necessary.

(4) It is prohibited to release GMOs into the environment—

(a) within any site prescribed as a special protection zone under section 7 of the Protection and Management of Game and Wild Birds Ordinance 2004; or Ordinance 15/2004 .

(b) of any species which is related to the GMO and which is indigenous to the Areas.

Environmental risk assessment.

6.—(1) Any person who intends to make an application under Part II or Part III shall present an environmental risk assessment carried out by a person who has made similar assessments which have been accepted by appropriate authorities of any member State of the European Union.

(2) The information which is required for the carrying out of an environmental risk assessment is set out in Schedule IV. Schedule IV.

(3) The possible adverse effects on human health and the environment which may be caused directly or indirectly by the transfer of genetic material from GMOs to other organisms shall be accurately assessed for each individual case. Such assessment shall be carried out in accordance with the principles set out in Schedule I, having regard to the potential adverse environmental effects, depending on the nature of the organism concerned. Schedule I.

(4) The Chief Officer shall take all such measures as may be necessary to ensure, in accordance with the requirements of Schedule V, that GMO products whose placing on the market has been permitted under Part III can be traced at all their stages on the market. Schedule V.

Licences.

7.—(1) The deliberate release of a GMO or the possession, importation or placing on the market of any GMO product is prohibited, unless it is carried out pursuant to a licence granted under this Ordinance by the Chief Officer and in accordance with any conditions attaching to such a licence.

(2) The Chief Officer may at any time revoke a licence such as is referred to in subsection (1) above if he has reasonable cause to believe that any condition attaching to the licence has been breached, or that there is a threat to public health or the environment as a result of any act (or failure to act) done under the licence.

Chief Officer's duties in relation to applications.

8. Where an application is made under section 11, 20 or 23 in relation to a GMO or a GMO product, the Chief Officer shall—

(a) examine the application;

(b) evaluate any risk which may be posed to public health or the environment if the application is accepted, taking into consideration the environmental risk assessment prepared pursuant to section 6 relating to the application;

(c) determine whether the application should be accepted or rejected and, if accepted, what conditions (if any) should be imposed on the applicant;

(d) determine into which category of risk the GMO or GMO product in question should be placed;

(e) determine measures concerning the production, movement or use of the GMO or GMO product and the security measures to be taken for the protection of human health and the environment, including measures which ensure that any person engaged to implement such measures has appropriate scientific qualifications;

(f) take into consideration any moral or social issue concerning the release, production, marketing or use of GMOs or GMO products;

(g) have regard to observations from the authorities of member States of the European Union concerning GMOs and GMO products;

(h) any responses from members of the public or from interest groups arising from the publication of information under section 31.

Requests for further information.

9. If the Chief Officer considers that the information submitted with an application is insufficient or incomplete he may request of the applicant such further information as he considers necessary.

PART II
DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS FOR ANY PURPOSE OTHER THAN FOR PLACING THEM ON THE MARKET

GMOs contained in medicinal substances and compounds.

10. This Part does not apply to GMOs consisting of, or contained in medicinal substances or compounds for humans, provided that —

(a) the deliberate release of the GMO for any purpose other than that of placing it on the market is authorised by other legislation which has provisions—

(i) for a specific environmental risk assessment in accordance with Schedule I and on the basis of information such as is described in Schedule IV; without prejudice to further requirements which may be provided for by the other legislation;

Schedule I.

Schedule IV.

(ii) for explicit written consent and licence prior to the release;

(iii) for a monitoring plan in accordance with the relevant parts of Schedule IV, with a view to detecting the effects of the GMO on human health or the environment;

(iv) concerning requirements relating to the use of new information about the GMO, informing the public about it, gathering information on the results of releases, and the exchanging of information, being provisions which are no less stringent than those provided by this Ordinance relating to such matters;

(b) a risk assessment of the GMO is carried out;

(c) there are provisions corresponding to the provisions of this Ordinance which ensure that due regard is given to the risk assessment, and also provisions expressly referring to this Ordinance.

Applications under Part II.

11.—(1) Where a person intends deliberately to release a GMO into the environment he must first apply to the Chief Officer for a licence to do so, submitting with his application the following—

(a) a technical dossier containing the information described in Schedule IV necessary for carrying out the assessment of risks, immediate or prospective, to which people or the environment may be exposed by the release of the GMO, and the methods which will be applied on the release and any bibliographical references which support the use of such methods. The technical dossier must in particular contain — Schedule IV.

(i) general information including information as to the persons who will be engaged in connection with the GMO and their training,

(ii) information relating to the GMO in question,

(iii) information relating to the conditions of release and the environment into which the GMO might be released ,

(iv) information on the interaction between the GMO and the environment,

(v) a plan for monitoring in accordance with the relevant parts of Schedule IV, in order to identify effects of the GMO on human health or the environment,

(vi) information on control, remedial methods, waste treatment and emergency response plans;

(b) the environmental risk assessment and the conclusions required under Part D of Schedule I, together with any bibliographic references and indications of the methods to be used; Schedule I.

(c) any data or results arising from applications previously made by other applicants or by an earlier release of the same GMO by other persons whether in the Areas or elsewhere, provided that such data and results are not confidential or the persons concerned have given their agreement in writing to such disclosure:

Provided that the applicant may submit such additional information as he may consider to be relevant;

(d) a summary of the dossier, in the form described in Schedule VI, which form may be changed by an order of the Administrator. Schedule VI.

(2) Where a person intends to release a GMO for which a licence to release has been given on a previous occasion in respect of the same research programme, he must submit a new application and include in it reference both to the particulars of his previous application and to the results of the releases made under his previous licence.

(3) For releases of the same GMO—

(a) on the same site for the same purpose and within a defined period, a single application may be submitted;

(b) on different sites, an application is required in respect of each site.

(4) The Chief Officer shall certify the date of his receipt of any application made to him under this section.

Consideration of applications under Part II.

12.—(1) When considering an application under this Part the Chief Officer may seek the opinion of such experts in matters relating to GMOs and GMO products as he considers appropriate.

(2) If the Chief Officer approves the application, he shall grant the applicant a licence in writing which shall include such conditions as the Chief Officer may consider necessary for the protection of human health and the environment.

(3) A condition for the grant of any licence under this Part is that the applicant provides such security, whether by way of deposit, guarantee or otherwise, as the Chief Officer may require in respect of the costs which might be incurred by the Administration in dealing with the risks to which the environment or any person may be exposed as a result of a release by the applicant of GMOs.

Modifications and new information.

13.—(1) If any modification or unintended change occurs to the manner authorised by a licence for the deliberate release of a GMO into the environment so that the risks of adverse consequences to human health or the environment are increased, or if new information becomes available concerning such risks, whether at a time while the application is still being examined or after a licence has been granted, the applicant must immediately—

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

(b) inform the Chief Officer in advance of any modification, or as soon as the unintended change is known or the new information is available, and request approval for the conditions attaching to the licence to be appropriately amended.

(2) If the Chief Officer receives information which could have significant adverse consequences with regard to risks to human health or the environment, or in circumstances such as are described in subsection (1) above, he shall evaluate such information and may make it available to the public. The Chief Officer may require the applicant or licensee to comply with modified conditions or to suspend or terminate the deliberate release of GMOs.

(3) Subject to the provisions of section 47, the applicant shall be responsible for the management and destruction of any waste containing GMOs and for the reinstatement of any land or premises and for the payment of compensation for any damage caused by reason of any modifications or changes such as are referred to in subsection (1) above.

Notification of results of the release.

14.—(1) A person carrying out a release of a GMO pursuant to a licence granted to him under this Part shall, at such intervals as may be specified in his licence and on the basis of the risk assessment, send to the Chief Officer the results of the release with respect to the risks to human health or the environment. He shall also send to the Chief Officer any new information which becomes available to him in respect of any matter concerning GMOs which he is releasing, whether or not he considers such information to be significant.

(2) A person sending results to the Chief Officer pursuant to subsection (1) above shall do so in such form and manner as the Chief Officer shall direct.

(3) A contravention of the provisions of subsection (1) or (2) is an offence punishable with imprisonment not exceeding six months or a fine not exceeding five thousand pounds to both such penalties.

Fees under Part II.

15. For an application under this Part to be examined the applicant must pay the following fees—

(a) if the application is made under section 11(1), ten thousand pounds;

(b) if the application is made under section 11(2), five thousand pounds;

(c) if further particulars are submitted after the application has been made, six thousand pounds.

PART III
PLACING GMO PRODUCTS ON THE MARKET

GMO products to which this Part does not apply.

16.—(1) Subject to subsections (3) and (4) below, this Part does not apply to GMO products if their placing on the market is permitted under other legislation which provides for a specific environmental risk assessment carried out in accordance with the principles set out in Schedule I and on the basis of information such as is described in Schedule IV, and without prejudice to such further provisions as may be provided for by such other legislation concerning risk management, labelling, monitoring as appropriate, information to the public and safeguard clauses, being provisions which are no less stringent than those provided by this Ordinance relating to such matters.

Schedule I.
Schedule IV.

(2) Subject to subsections (3) and (4) below, in respect of the approval and monitoring of medicinal products for humans and for veterinary use, this Part does not apply to any GMO product so far as it is authorised under other legislation which expressly provides for the carrying out of a specific environmental risk assessment in accordance with the principles set out in Schedule I and on the basis of information such as is described in Schedule IV, and without prejudice to other provisions concerning risk assessment, risk management, labelling, monitoring as appropriate, information to the public and safeguard clauses provided by specific legislation concerning medicinal products for humans and for veterinary use.

Schedule I.
Schedule IV.

(3) Subsections (1) and (2) above apply only if procedures which ensure that the risk assessment, requirements regarding risk management, labelling, monitoring as appropriate, information to the public and safeguard clauses are no less stringent than those provided under this Ordinance and the specific legislation providing for them expressly refers to this Ordinance.

(4) In the absence of specific legislation such as is referred to in subsection (3) above, a GMO product which is authorised under any other legislation may only be placed on the market if it placing there is also authorised under this Ordinance.

Placing GMO products on the market .

17. It is prohibited to place on the market any GMO product derived from a GMO which was deliberately released into the environment in accordance with Part II otherwise than in accordance with this Part.

Licence to market GMO products.

18. Subject to any other enactment, a person may only place a GMO product on the market in the Areas pursuant to, and subject to any conditions attaching to, a licence granted under this Part by the Chief Officer.

Free circulation.

19. Subject to section 28, the Chief Officer may not prohibit, restrict or otherwise obstruct the placing on the market of a GMO product in respect of which the requirements of this Ordinance are satisfied.

Applications under Part III.

20.—(1) Before a person may place a GMO product on the market for the first time he must apply to the Chief Officer for a licence under this Part and include with his application the following—

Schedules IV and V.

(a) the information described in Schedules IV and V. This information must take into account the variety of places where the GMO product will be used and must include information and results obtained from research and developmental releases concerning the impact of the release on human health and the environment;

(b) the proposed conditions for placing the product on the market, including specific conditions of its use and handling and the proposed duration of the licence which may not exceed five years;

Schedule I.

(c) the environmental risk assessment and the conclusions required in accordance with Part D of Schedule I;

Schedule VII.

(d) a monitoring plan in accordance with Schedule VII, including a proposal for the duration of such plan;

Schedule V.

(e) a proposal for labelling which must at the minimum meet the requirements laid down in Schedule V. The labelling must clearly state that a GMO is present in the product. The words "this product contains genetically modified organisms" must appear either on a label or where that is not possible, in a document which accompanies the GMO product;

Schedule V.

(f) a proposal for packaging which must fulfil the requirements laid down in Schedule V;

(g) any information, particulars or knowledge acquired as a result of any previous release of the GMO whether in the Areas or elsewhere;

(h) any particulars, information and results concerning or contained in applications previously made by others or which have arisen from such applications, provided that such particulars, information and results are not confidential or the applicants concerned have given their consent in writing to such disclosures;

(i) a summary of the dossier in the form and manner described in Schedule VIII or such other form and manner as the Chief Officer may direct. Schedule VIII.

(2) The Chief Officer shall certify the date of his receipt of any application made to him under this section.

Consideration of applications under Part III.

21.—(1) In considering an application under this Part the Chief Officer may seek the opinion of such experts in matters relating to GMOs and GMO products as he considers appropriate.

(2) If the Chief Officer approves the application, he shall grant the applicant a licence in writing which shall include such conditions as the Chief Officer may impose for the protection of human health and the environment.

(3) A condition for the grant of any licence under this Part is that the applicant provides such security, whether by way of deposit, guarantee or otherwise, as the Chief Officer may require in respect of the costs which might be incurred by the Administration in dealing with the risks to which the environment or any person may be exposed as a result of a contravention of any condition imposed under this section or under section 22.

(4) If the Chief Officer rejects an application for a licence under this Part he must give his reasons for doing so.

Conditions of licence under Part III.

22.—(1) A licence granted under section 21 shall include the following particulars or conditions—

(a) the field of application of the licence, including a description of the GMO product to which it relates;

(b) the period of validity of the licence;

(c) the conditions for the placing of the GMO product on the market, including special conditions of use, handling or packaging of the GMO product, as well as conditions for the protection of particular eco-systems or types of environment or geographical areas;

(d) the obligation of the applicant, subject to section 45, to provide the Chief Officer, if he so requests, with samples for checks;

(e) the requirements for labelling in accordance with the provisions of Schedule V, which shall clearly state that a GMO is present with the words "this product contains genetically modified organisms" or, where that is not possible, in a document accompanying the product ; Schedule V.

(f) the monitoring requirements, in accordance with Schedule VII, and in particular the obligations to submit reports to the Chief Officer, the timetable of the monitoring plan, and, in the case of cultured GMOs, any obligation placed on the seller or user of the product, or on any other person to provide adequate information concerning their location. Schedule VII.

(2) A licence granted under this Part may not be for a period exceeding five years.

(3) For the purpose of approval of a GMO product or a derivative of a GMO product intended only for the marketing of its seeds under legislation relating to plant varieties, the period of validity of the first licence shall

end at the latest five years after the date of the first registration of the first plant variety containing the GMO in any catalogue of plant varieties recognised for the purposes of this section by the Chief Officer.

(4) In the case of forest reproductive material, the last day of the period of validity of the first licence shall be no later than two years after the day that the basic material containing the GMO is first registered in any register of basic material that the Chief Officer may approve for the purposes of this section.

Renewal of licence.

23.—(1) The procedure described in subsections (2) to (6) below shall apply in relation to the renewal of a licence which has been granted under this Part.

(2) No later than nine months before the licence expires the holder of the licence must make a new application to the Chief Officer together with—

(a) a copy of the current licence;

(b) a report on the results of monitoring carried out in accordance with section 31;

(c) any other new information which has become available regarding risks posed to human health or the environment by the product; and

(d) if appropriate, any proposals for amending or complementing the conditions of the current licence, including conditions concerning future monitoring and the period for which the new licence is to be valid.

(3) The Chief Officer shall certify the date of his receipt of the application.

(4) When considering an application under this section the Chief Officer may seek the opinion of such experts in matters relating to GMOs and GMO products as he considers appropriate.

(5) If a licence is renewed it shall be for a period of no longer than five years unless the Chief Officer is satisfied that the circumstances of a particular case are such as to justify the renewing of the licence for a longer period.

(6) Until such time as the Chief Officer gives his decision in relation to an application under this section, the applicant may continue to place the GMO product concerned on the market under the conditions attaching to the latest licence granted to him.

New licence required if GMO product is applied to a different use.

24.—(1) Any licence granted under this Part shall be effective only so as to allow GMO product of the description to which the licence relates to be used as it was intended to be used, as described in the licence or, in the absence of any description there, in the application for the licence.

(2) Accordingly, where it is intended to use a GMO product in relation to which there is a licence under this Part in a different way to the way allowed by or under the licence, a separate licence under this Part is required for that different way of use.

New information becoming known to licence holder or applicant.

25.—(1) If new information comes to the knowledge of the holder of a licence under this Part concerning the risks posed to human health or the environment by the GMO product in question, the licence holder must immediately apprise the Chief Officer of that

information, and request that the conditions attaching to the licence be revised in such way as may be necessary to protect human health and the environment, and must take such further measures as may be necessary for those purposes.

(2) If new information such as is described in subsection (1) above comes to the knowledge of an applicant for a licence under this Part before a licence is granted to him, the applicant must immediately apprise the Chief Officer of that information and must make such modifications to his application as may be appropriate.

Monitoring and reporting effects.

26.—(1) When a GMO product has been placed on the market, the licence holder must ensure that he arranges for the effects of the GMO product on human health and the environment to be monitored, and he must submit reports on such monitoring, in accordance with the conditions attaching to his licence.

(2) The Chief Officer may, having regard to anything contained in any report such as is described in subsection (1) above, require the monitoring plan to be modified.

Labelling and packaging of GMO product.

27.—(1) The Chief Officer shall take all necessary measures to ensure that at all stages of the placing on the market of a GMO product, the labelling and packaging conditions of the licence granted under this Part in respect of the product are observed.

(2) Where there are adventitious traces of an authorised GMO in a GMO product or traces of such a GMO whose presence in the product is technically unavoidable, the Chief Officer may by order establish a minimum threshold below which the GMO product need not be labelled in accordance with subsection (1) above.

(3) A GMO product such as is described in section 2(2) shall be labelled in accordance with Schedule V and there must be a label attached to the product, or a document accompanying the product, bearing the words "This product contains GMOs". Schedule V.

(4) The Chief Officer may by order published in the Gazette provide for conditions subject to which subsection (3) shall apply, having regard to any other legislation concerning the labelling of goods.

Safeguards.

28.—(1) Where the Chief Officer receives further information relating to a GMO product for which a licence under this Part has been granted and he concludes from that information that the GMO product poses a risk to human health or the environment, he may by order provisionally restrict or prohibit the use or sale of that GMO.

(2) If a GMO product which has been placed on the market appears to the Chief Officer to pose a grave risk to human health or the environment, he shall immediately introduce all such emergency measures as may be necessary to eliminate or reduce the risk, including the suspension or termination of the licence for placing the GMO product on the market and the dissemination of information and advice to the public.

Fees under Part III.

29.—(1) For an application under this Part to be examined the applicant must pay the following fees—

(a) if the application is made under section 20(1), twenty thousand pounds;

(b) if the application is made under section 23(2), fifteen thousand pounds;

(c) if the application is made under section 24(2), ten thousand pounds;

(d) if further particulars are submitted under section 25 after the application has been made, ten thousand pounds.

(2) If during the examination of an application the Administration incurs any additional costs because of its need to require the services of any specialist advisers or laboratories or because of the need to have carried any experiments or investigations, such costs shall be a liability of the applicant who shall be liable to pay them on demand and in any event before the grant to him of the licence for which he has applied.

PART IV
MAINTENANCE OF A REGISTER AND PROVISION OF INFORMATION TO THE PUBLIC

Register.

30. The Chief Officer shall maintain a register to which the public shall have access and in which the following shall be recorded—

(a) any application received by him under Part II or Part III;

(b) any licence granted by him under this Ordinance;

(c) any further information which is supplied to him and which is relevant to any application made, or to any licence granted, under this Ordinance;

(d) any opinion given to him in connection with the matters for which this Ordinance provides;

(e) the places where GMOs are allowed to be released under Part II and where GMO products are allowed to be placed on the market under Part III;

(f) any conviction for an offence under this Ordinance; and

(g) such other details or particulars as may be prescribed by regulations made under section 50.

Information to the public.

31.—(1) Before making a decision on any application for a licence made under this Ordinance the Chief Officer shall ensure that the public is informed about the application.

(2) The applicant shall arrange for the publication, in at least two newspapers with a daily circulation in the Island of Cyprus, of a brief summary of the particulars of the application and an invitation for any person to submit his observations on the application within a period of 30 days starting from the day of publication of the second newspaper in which the particulars are published.

PART V
APPLICATION OF THE RELEVANT LEGISLATION OF THE EUROPEAN UNION

Placing certain GMO products on the market if their marketing in a member State is allowed

32. The Chief Officer may grant a licence for the placing on the market of a GMO product if he is satisfied that—

(a) consent has been given for the placing on the market of GMO products of that description by at least one member State of the European Union, in accordance with any European Union Directive relating to the deliberate release into the environment of genetically modified organisms; and

(b) the GMO product does not pose any risks to human health or the environment.

PART VI
MISCELLANEOUS PROVISIONS

Authorisation of inspectors.

33. The Chief Officer may authorise any person to act as an inspector for the purposes of this Ordinance in order to ensure that its provisions are observed, and to perform such other duties and to exercise such other powers as the Chief Officer may specify for the purpose of the more effective application of this Ordinance.

Powers of inspectors.

34. An inspector may—

(a) enter any place or premises, other than a dwelling, if he has reasonable cause to suspect that there is to be found there—

(i) a GMO or GMO product or evidence of damage to the environment arising from such organisms; or

(ii) a person who has in his possession any GMO or GMO product which has been produced otherwise than under or in accordance with a licence granted under this Ordinance; or

(iii) evidence that a GMO has been released or escaped into the environment;

(b) take samples from the water, air, soil, plants, animals, GMOs or other substances that is present at any place or premises that he has lawfully entered;

(c) direct that any place or premises that he has lawfully entered or any equipment or substance that he finds there be left undisturbed for such reasonable period as may be necessary to enable the carrying out of any necessary test, measurement, examination or other control;

(d) carry out any such test, measurement, examination or other control;

(e) make harmless (including by destroying it if necessary) any GMO or GMO product that he finds at any place or premises that he has lawfully entered which has caused or which may cause damage to the environment;

(f) take into his possession any GMO or GMO product which may be evidence of an offence under this Ordinance;

(g) require any person to produce for inspection any document relating to a GMO or GMO product with which that person has been concerned (in whatever capacity).

Providing facilities and information.

35. Any person concerned in the deliberate release of a GMO into the environment shall provide an inspector with such facilities and information as the inspector may reasonably require for the purpose of his carrying out his duties under this Ordinance.

Confidentiality.

36. Any information given to the Chief Officer or to an inspector by any person for the purposes of this Ordinance shall be treated as given in confidence and may be only be disclosed by the Chief Officer or, as the case may be, the inspector to any other person, so far as is strictly necessary to enable him to perform his duties under this Ordinance.

Trade or industrial secrets.

37.—(1) An applicant for a licence under this Ordinance may indicate which of the particulars that he gives in support of his application he considers to be trade or industrial secrets and which he requests be kept in absolute confidence so that his competitive position is not adversely affected. The applicant must justify his request so that it may be verified:

Provided that the confidentiality of a trade or industrial secret may only be disregarded where it is considered by the Chief Officer absolutely essential in order to deal with any risk to public health or the environment.

(2) The following particulars shall not be considered to be confidential—

(a) the description of the GMO in respect of which an application is submitted;

(b) the name and the address of the applicant;

(c) the purpose for which the release of a GMO is, or is to be, carried out;

(d) the place at which the release of a GMO is to be carried out;

(e) the intended uses of a GMO;

(f) the methods, programmes and plans for the continuing monitoring of a GMO and for dealing with any risks or emergency situation which may arise as a result of any release of the GMO;

(g) any assessment on the risks to public health and to the environment.

Offences and penalties.

38.—(1) Any person who without a licence granted to him under this Ordinance—

(a) releases any GMO into the environment;

(b) places any GMO product on the market;

(c) imports or possesses any GMO or any GMO product,

or who causes any other person to do any of those acts is guilty of an offence and is liable to imprisonment of up to five years or to a fine not exceeding £200,000 or to both such penalties.

(2) Any person who knowingly, negligently or in breach of the conditions of any licence granted to him under this Ordinance releases a GMO in consequence of which public health is harmed, or damage is done to the environment or to the property of any other person, is guilty of an offence and is liable to imprisonment of up to 5 years or to a fine of £200,000 or to both such penalties. In addition the court may—

(a) order the offender to pay the whole or a proportion of the costs in restoring the environment or repairing the damaged property;

(b) order the confiscation and the safe destruction of the GMO concerned;

(c) order the revocation of any licence granted to the offender under this Ordinance or the cessation of any activity which the offender could only lawful carry on under the provisions of this Ordinance.

(3) Any person who intentionally or negligently fails to do any thing which he is required to do under this Ordinance is guilty of an offence, and if no other penalty is provided for that offence, he is liable to imprisonment not exceeding 3 months or to a fine not exceeding £3,000 or to both such penalties.

Defences.

39.—(1) In any proceedings for an offence under this Ordinance it is a defence for the accused to prove that—

(a) he did not know and he could not reasonably have been expected to know that the offence was being or would be committed;

(b) he took all measures that he could reasonably have been expected to take and his behaviour was reasonable in all the circumstances of the case; or

(c) his act of commission or omission which the prosecutor alleges constitutes the offence arose because of some factor beyond his control including natural destruction, technical damage or the fraudulent act of a third person, and that the consequences of his act could not be reasonably foreseen or it was not possible to take any measures to prevent those consequences.

(2) For the avoidance of doubt it is hereby declared that the burden placed on an accused under subsection (1) above is an evidential burden and not a legal burden.

(3) Where a body corporate commits an offence under this Ordinance, any director or similar officer of the body corporate is also guilty of a like if—

(a) he authorised, allowed, encouraged or his permitted the commission of the offence; or

(b) he knew or he ought reasonably to have known that the offence was being or would be committed yet took no, or insufficient, steps to prevent the commission of the offence or to terminate its commission.

Court order where there is risk of serious harm.

40.—(1) Where as a direct or indirect result of any act of any person or of any failure to act by any person or as a result of an accident, a risk is created or may be created of serious and irreversible or long-term damage to the environment, or where an offence under this Ordinance appears to have been committed, or is about to be committed by any person, an application may be made to the Court for an order against the person concerned requiring him to prevent, eliminate or minimise that risk or to terminate or prevent the commission of the offence, and if the Court is satisfied that the circumstances are as alleged in the application, it shall make such an order.

(2) If the damage to the environment is imminent or the commission of an offence is imminent or manifest, the court may allow an application for an order under this section to be made ex parte.

(3) An order made under this section may require that any procedure, action or operation or the performance of any particular activity be immediately terminated or not be carried out or not be repeated and may order the taking of such other measures as appear to the Court to be necessary for the prevention, elimination or minimisation of the risk.

(4) An order under this section may in addition specify the period within which it has to be complied with and the course of action which the Chief Officer or such other person as may be specified in the order is authorised to take if the person to whom the order is directed fails to, or is incapable of complying with the order or if it is not possible to serve the order on the person to whom the order is directed within such period as may be specified in the order.

(5) An order under this section may also require the suspension of a particular activity if the person engaged in that activity fails to comply with the order, and may impose a penalty of not more than £500 for each day that the person to whom the order is directed fails to comply with the order.

Regulations.

41. The Administrator may make regulations for the more effective application of this Ordinance and more generally for the regulation of any matter concerning the release of GMOs, or the placing on the market, possession or use of GMO products.

Amending Schedule I or VII.

42. The Administrator may by order published in the Gazette amend Schedule I or VII.

Commencement .

43. This Ordinance comes into force on the day of its publication in the Gazette.

SCHEDULE I

(Sections 2(1), 6(3), 10(a)(i), 11(1)(d), 16(1), 16(2), 20(1)(c) and 42)

PRINCIPLES APPLICABLE IN CARRYING OUT AN 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 in carrying out any environmental risk assessment for the purposes of this Ordinance.

For the purposes of this Schedule the following terms are to be understood as described below but without prejudice to guidance given elsewhere, in particular as regards the extent to which indirect effects can and should be taken into account—

(a) "direct effects" refers to the primary effects on human health or the environment which are a direct result of the GMO itself and which do not occur through a causal chain of events;

(b) "indirect effects" refers to the 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;

(c) "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;

(d) "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 which become apparent as a direct or indirect effect either at a later stage or after the releasing of the GMO has ceased.

A general principle for environmental risk assessment is that an analysis of the "cumulative long-term effects" must be carried out of

the release into the environment of the GMO or the placing on the market of the GMO product. "Cumulative long-term effects" refers to the accumulated effects on human health and the environment, including flora and fauna, soil fertility, soil degradation of organic material, the food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

Part 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 GMO or the GMO product, whether direct, indirect, immediate or delayed, on human health and the environment which the deliberate release of the GMO into the environment or the placing on the market of the GMO product 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.

Part B
General Principles

In accordance with the precautionary principle, the following general principles are to be applied when carrying out an environmental risk assessment—

(a) 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;

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

(c) 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 GMOs concerned, their intended use and the potential receiving environment, taking into account, amongst other things, GMOs already in the environment;

(d) if new information on the GMO and its effects on human health or the environment becomes available, the environmental risk assessment must be reconsidered in order to determine whether—

(i) the risk has changed;

(ii) there is a need for amending the risk management accordingly;

(e) the place where the GMO is to be released into the environment must be at a sufficient distance from any place where organic farming is taking place or where bees for the production of honey are hived.

Part C
Methodology

C.1. Characteristics of GMOs and releases

Depending on the case, an environmental risk assessment must take account of the relevant technical and scientific details regarding the characteristics of—

(a) the recipient or parental organism;

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

(c) the GMO;

(d) the intended release or use including its scale;

(e) the potential receiving environment; and

(f) the interaction between any of the characteristics described in paragraphs (a) to (e) above.

Regard may be had to information acquired from releases of similar organisms and organisms with similar traits and their interaction with similar environments.

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 GMO 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 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 it is unlikely to occur.

Potential adverse effects of GMOs will vary from case to case, and may include—

(a) disease to humans including allergenic or toxic effects (see for example paragraphs II.A.11. and II.C.2(i) in Part A of Schedule IV and paragraph B.7. in Part B of that Schedule);

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

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

(d) altered susceptibility to pathogens facilitating the dissemination of infectious diseases or creating new reservoirs or vectors;

(e) 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 paragraphs II.A.11.(e) and II.C.2.(i)(iv) in Part A of Schedule IV);

(f) effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example paragraphs II.A.11.(f) and IV.B.15 in Part A of Schedule IV and paragraph D.11. in Part B of that Schedule IV), and the soil ecology through the concentration of chemicals and toxins.

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

(a) the spread of the GMO in the environment;

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

(c) phenotypic and genetic instability;

(d) interactions with other organisms;

(e) 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 GMO is 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 GMO(s) is intended to be released, and the manner of the release.

4. *Estimation of the risk posed by each identified characteristic of the GMO*

An estimation of the risk to human health or the environment posed by each identified characteristic of the GMO 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 of the GMO or the marketing of the GMO product*

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 GMO*

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

PART D
Conclusions on the potential environmental impact from the release into the environment of the GMO or the placing on the market of the GMO product

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

D.1. In the case of GMOs other than higher plants

1. Likelihood of the GMO to become persistent and invasive in natural habitats under the conditions of the proposed release.

2. Any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised under the conditions of the proposed release.

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

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

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

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

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

8. Possible immediate 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.

9. Possible immediate or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the GMO where these are different from those used for non-GMOs.

D.2. In the case of genetically modified higher plants (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 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 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 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.

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

8. Possible immediate 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.

9. Possible immediate 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 place where the GMO is to be released into the environment.

SCHEDULE II
(Section 2(2)(b))

CONTAINMENT MEASURES

1. The principles of good microbiological practice as well as the following principles of good occupational safety and hygiene shall apply—

(a) to keep workplace and environmental exposure to any physical, chemical or biological agent to the lowest practicable level;

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

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

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

(e) to provide training of personnel;

(f) to establish biological safety committees or subcommittees as required;

(g) to formulate and implement local codes of practice for the safety of personnel.

2. In addition to the above principles, the containment measures set out below shall be applied, as appropriate, so as to ensure a high level of safety. The additional containment measures shall be chosen by the user from the following categories, depending on the specific organism and the specific category, in order to ensure the protection of health of the wider population and the environment.

The operations shall be considered in terms of their unit operations. The characteristics of each operation will dictate the physical containment to be used at that stage. This will allow selection and design of process, plant and operating procedures best fitted to assure adequate and safe containment. Two important factors to be considered when selecting the equipment needed to implement the containment are the risk of, and the effects consequent on, equipment failure. Engineering practice may require increasingly stringent standards to reduce the risk of failure as the consequence of that failure becomes less tolerable.

Specific containment measures for Type A operations shall be established taking into account the containment categories below and bearing in mind the specific circumstances of such operations.

Specifications	Containment Categories		
	1	2	3
1. Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system)	Yes	Yes	Yes
2. Exhaust gases from the closed system should be treated so as to:	Minimize release	Prevent release	Prevent release
3. Sample collection, addition of materials to a closed system and transfer of viable micro-organisms to another closed system, should be performed so as to:	Minimize release	Prevent release	Prevent release
4. Bulk culture fluids should not be removed from the closed system unless the viable micro-organisms have been:	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to:	Minimize release	Prevent release	Prevent release
6. Closed systems should be located within a controlled area	Optional	Optional	Yes, and purpose-built
(a) Biohazard signs should be posted	Optional	Yes	Yes
(b) Access should be restricted to nominated personnel only	Optional	Yes	Yes, via airlock
(c) Personnel should wear protective clothing	Yes, work clothing	Yes	A complete change

(d) Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
(e) Personnel should shower before leaving the controlled area	No	Optional	Yes
(f) Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes
(g) The controlled area should be adequately ventilated to minimize air contamination	Optional	Optional	Yes
(h) The controlled area should be maintained at an air pressure negative to atmosphere	No	Optional	Yes
(i) Input air and extract air to the controlled area should be HEPA filtered	No	Optional	Yes
(j) The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Yes	Yes
(k) The controlled area should be sealable to permit fumigation	No	Optional	Yes

SCHEDULE IIIA
(Section 2(3))
TECHNIQUES WHICH GIVE RISE TO GENETIC MODIFICATION
PART 1

The techniques referred to in section 2(3) as giving rise to the occurrence of genetic modification include the following—

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

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

(3) cell fusion or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2

The techniques referred to in section 2(3) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques or methods other than those which are excluded by Schedule IIIB are the following—

(1) in vitro fertilization;

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

(3) polyploidy induction.

SCHEDULE IIIB
(Section 4(b))
TECHNIQUES OF GENETIC MODIFICATION YIELDING ORGANISMS TO WHICH THIS ORDINANCE DOES NOT APPLY

The techniques of genetic modification yielding organisms to which this Ordinance does not apply, on condition that they do not involve the use of genetically modified micro-organisms as recipient or parental organisms are the following—

(1) mutagenesis;

(2) cell fusion (including protoplast fusion) of plant cells of organisms which exchange genetic material through traditional breeding methods.

SCHEDULE IV
(Sections 6, 10(1)(a)(i) and (iii), 11(1)(a), 16(1) and (2))

INFORMATION TO BE INCLUDED IN AN ENVIRONMENTAL RISK ASSESSMENT RELATING TO A DELIBERATE RELEASE INTO THE ENVIRONMENT OF A GMO OR THE PLACING ON THE MARKET OF A GMO PRODUCT

Notes

1. An application such as is referred to in section 11 for a deliberate release of a GMO or an application such as is referred to in section 20 for the placing on the market of a GMO product shall include, as appropriate, the information set out below in Parts A and B respectively.

2. Not all the points included will apply in every case. Thus each application must include such of the matters as is appropriate to it.

3. The degree of detail required in respect of each matter may vary according to the nature and scale of the proposed release.

Future developments in genetic modification may necessitate adapting this Schedule to technical progress or developing guidance notes on this Schedule. Once adequate experience has been acquired, further differentiation of information requirements may be possible for different types of GMOs, or for a particular use of GMOs, such as the development of vaccines through applications for the release of specific GMOs.

The application shall also include a description of methods used or a reference to standardised or internationally recognised methods, together with the name of the body responsible for carrying out the studies.

4. Part A applies to the release of all types of GMOs, other than higher plants. Part B applies to the release of genetically modified higher plants. Higher plants means plants belonging to the taxonomy of Spermatophyta (Gymnospermae and Angiospermae).

PART A

INFORMATION REQUIRED IN APPLICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

I. GENERAL INFORMATION

A. Name and address of the applicant (company or institute).

B. Name, qualifications and experience of the responsible scientist.

C. Title of the project.

II. INFORMATION RELATING TO THE GMO

A. Characteristics –

(a) of the donor,

(b) of the recipient, or

(c) (where appropriate) parental organisms:

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 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 GMO and to make the introduced vector and insert function in the GMO;

3. frequency of mobilisation of inserted vector 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 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) sequence, functional identity and location of the altered, inserted or deleted nucleic acid segment in question with particular reference to any known harmful sequence;

(f) methods and criteria used for selection.

2. Information on the final GMO:

(a) description of genetic trait or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

(b) structure and amount of any vector 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;

(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 GMO;

(i) considerations for human health and animal health, as well as plant health:

(i) toxic or allergenic effects of the GMOs 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 immuno-competent:

- 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 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 to be used for the release;
6. quantities of GMOs to be released;
7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities);
8. protection measures taken in respect of workers during the release;
9. post-release treatment of the site;
10. techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment;
11. information on, and results of, previous releases of the GMOs, 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 references of the sites (in case of notifications under Part III of this Ordinance the sites of release will be the foreseen areas of use of the GMO product);
2. physical or biological proximity to humans and other significant biota;
3. proximity to significant biotopes, protected areas or sources of supplies of drinking water;
4. climatic characteristics of the regions 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 sites of release;
9. any known planned developments or changes in land use in the region which could influence the environmental impact of the release;
10. particulars of related species which grow in the Island of Cyprus and their geographical distribution.

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs 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 GMOs;

2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms and greenhouses;

3. genetic transfer capability –

   (a) post-release transfer of genetic material from GMOs into organisms in affected ecosystems;

   (b) post-release transfer of genetic material from indigenous organisms to the GMOs;

4. likelihood of post-release selection leading to the expression of unexpected or undesirable traits in the modified organism;

5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify 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 GMOs could be disseminated.

C. Potential environmental impact

1. potential for excessive population increase in the environment;

2. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism;

3. identification and description of the target organisms if applicable;

4. expected mechanism and result of interaction between the released GMOs and the target organism if applicable;

5. identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the expected mechanisms of any identified adverse interaction;

6. likelihood of post-release shifts in biological interactions or in host range;

7. known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens;

8. known or predicted involvement in biogeochemical processes;

9. 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 GMOs, and for monitoring their effects;

2. specificity (to identify the GMOs, 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 or minimise the spread of the GMOs beyond the site of release or the designated area for use;

2. methods and procedures to protect the site from intrusion by unauthorised persons;

3. methods and procedures to prevent other organisms from entering the site.

C. Waste treatment

1. type of waste generated;

2. amount of waste expected;

3. possible risks;

4. description of treatment envisaged.

D. Emergency response plans

1. methods and procedures for controlling the GMOs in case of unexpected spread;

2. methods for decontamination of the areas affected, for example eradication of the GMOs;

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 B
INFORMATION REQUIRED IN APPLICATIONS RELATING TO RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)

A. GENERAL INFORMATION

1. Name and address of the applicant (company or institute).
2. Name, qualifications and experience of the responsible scientist.
3. Title of the project.

B. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

1. Complete name –

(a) family name,

(b) genus,

(c) species,

(d) subspecies,

(e) cultivar/breeding line,

(f) common name.

2. Information concerning –

(a) reproduction –

(i) modes of reproduction,

(ii) any specific factors affecting reproduction,

(iii) 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) any specific factors affecting survivability.

4. Dissemination –

(a) ways and extent of dissemination (for example an estimate of how viable pollen or seeds decline with distance);

(b) any specific factors affecting dissemination.

5. Geographical distribution of the plant.

6. In the case of plant species not normally grown in the Areas or the member States of the European Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

7. Potentially significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification.

2. Nature and source of the vector used.

3. Size, source (name of donor organisms) 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 traits and characteristics which have been introduced or modified.

2. Information on the sequences actually inserted or 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 GMHP or any carrier or foreign DNA remaining in the GMHP;

(b) in case of deletion, size and function of the deleted region;

(c) location of the insert in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination;

(d) copy number of the insert.

3. Information on the expression of the insert –

(a) information on the 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, stem, pollen, etc.).

4. Information on how the genetically modified plant differs from the recipient plant in –

(a) modes and rate of reproduction;

(b) dissemination;

(c) survivability.

5. Genetic stability of the insert and phenotypic stability of the GMHP.

6. Potential for transfer of genetic material from the genetically modified plants to other organisms.

7. Information on any toxic, allergenic or other harmful effects on human health and the environment arising from the genetic modification.

8. Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs.

9. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).

10. Potentially significant interactions with non-target organisms.

11. Potential interactions with the abiotic environment.

12. Description of detection and identification techniques for the genetically modified plant.

13. Information about any previous releases of the genetically modified plant.

E. INFORMATION RELATING TO THE SITE OF RELEASE (APPLICABLE ONLY IN RESPECT OF APPLICATIONS MADE UNDER PART II OF THIS ORDINANCE)

1. Location and size of the release sites.

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 biotopes or protected areas within the Island of Cyprus which may be affected by the release.

5. Proximity to organic farms and to hives of honey-producing bees.

F. INFORMATION RELATING TO THE RELEASE (APPLICABLE ONLY IN RESPECT OF APPLICATIONS MADE UNDER PART II OF THIS ORDINANCE)

1. Purpose of the release.

2. Expected date and duration of each release.

3. Method by which the genetically modified plants will be released.

4. Method for preparing and managing the release site, before, during and after the release, including cultivation practices and harvesting methods.

5. Approximate number of plants or of number of plants per square metre.

G. INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE TREATMENT PLANS (APPLICABLE ONLY IN RESPECT OF APPLICATIONS MADE UNDER PART II OF THIS ORDINANCE)

1. Any precautions taken –

   (a) distances from sexually compatible plant species, whether wild relatives or crops;

   (b) any measures to minimise or prevent dispersal of any reproductive organ of the GMHP (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 release site.

SCHEDULE V
(Sections 6(4), 20(1)(a), (e) and (f), 22(1)(e) and 27(3))

ADDITIONAL INFORMATION WHICH IS REQUIRED WITH AN APPLICATION TO PLACE A GMO PRODUCT ON THE MARKET

This Schedule describes in general terms the additional information required with an application to place a GMO product on the market and requirements concerning the labelling of GMO products. This Schedule may be supplemented by guidance notes published by the Chief Officer in such manner as he deems appropriate.

PART A

In addition to the information required under Schedule IV, the following information shall be provided with an application to place a GMO product on the market –

1. The proposed commercial name of the product and the name of the GMO it contains, and any specific identification, name or code used by the applicant to identify the GMO. If a licence is granted in respect of the product then any new commercial name given to the product must be notified to the Chief Officer.

2. The name and full address of the person established in the Areas who is responsible for placing the GMO product on the market, whether he is the manufacturer, the importer or the distributor.

3. The name and full address of the supplier of any control samples.

4. A description as to how the GMO product is intended to be used. Any differences between the use or management of the GMO product and that of a non-genetically modified product serving a similar use must be mentioned.

5. A description of the geographical area and types of environment where the product is intended to be used within the Areas, including, where possible, an estimate of the proposed scale of use in each area.

6. The categories of intended users of the product, for example, industrial, agricultural, skilled workers, general public.

7. Information on the genetic modification for the purposes of facilitating the control and inspection of the GMO product after it has been marketed. This information should include where appropriate the lodging of samples of the GMO or its genetic material, with the Chief Officer and details of nucleotide sequences or such other information as may be 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 the applicant considers to be a trade or industrial secret and thus to be kept in absolute confidence must be identified.

8. The information to be contained on any label attached to the GMO product or in any document accompanying it. This information must include, at least in summary, the commercial name of the product, a statement that "This product contains genetically modified organisms", the name of the GMO and the information referred to in paragraph 2 above and how further information concerning the product may be obtained from the register maintained under section 30.

PART B

The following information must be provided with the application, when relevant, in addition to that of in Part A above, in accordance with Section 26 of this Ordinance –

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 applicant and, if required, the Chief Officer, so that he can be fully informed of any adverse effect. Such instructions should be consistent with the requirements of Part C of Schedule VII;

4. proposed restrictions in the approved use of the GMO, for example where the product may be used and for what purposes;

5. proposed packaging;

6. estimated production in, or imports into the Areas and the territory of the European Community;

7. proposed additional labelling. This may include, at least in summary form, the information referred to in points paragraphs 4 and 5 of Part A and paragraphs 1, 2, 3 and 4 of this Part of this Schedule.

SCHEDULE VI
(Section 11(1)(f))

FORM OF SUMMARY OF DOSSIER TO BE SUBMITTED WITH AN APPLICATION FOR A LICENCE UNDER PART II OF THIS ORDINANCE

PART A

APPLICATION FOR THE RELEASE OF GENETICALLY MODIFIED HIGHER PLANTS (ANGIOSPERMAE AND GYMNOSPERMAE)

A. GENERAL INFORMATION

1. Details of application –

Reference number:

Date of acknowledgment of application:

Title of the project:

Proposed period of release:

2. Applicant –

Name of institute or company:

3. Is release of the same GMO planned also in any member State of the European Community?

Yes ☐ No ☐ Don't know ☐

If yes, give the name of the member State concerned

4. Has an application for the release of the same GMO in a member State of the European Community been made by the applicant?

Yes ☐ No ☐

If yes, give the reference number:

B. INFORMATION ON THE GENETICALLY MODIFIED PLANT

1. Complete name of the recipient or parental plant

(a)	Family name
(b)	Genus
(c)	Species
(d)	Subspecies
(e)	Cultivar/breeding line
(f)	Common name

2. Description of the traits and characteristics which have been introduced or modified, including marker genes and previous modifications.

3. Type of the genetic modification:

(a)	Insertion of genetic material	☐
(b)	Deletion of genetic material	☐
(c)	Base substitution	☐
(d)	Cell fusion	☐
(e)	Other, please specify	☐

4. In the case of insertion of genetic material, give the source and intended function of each constituent fragment of the region to be inserted.

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

6. Brief description of the method used for the genetic modification.

C. INFORMATION RELATING TO THE EXPERIMENTAL RELEASE

1. Purpose of the release.

2. Geographical location of the release site.

3. Area of the release site (in square metres).

4. Summary of the potential environmental impact from the release of the genetically modified plants.

5. Brief description of any measures taken for the management of risks.

PART B
APPLICATION FOR RELEASE OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

GENERAL INFORMATION

1. Details of application

Reference number:

Date of acknowledgment of application :

Title of the project:

Proposed period of release:

2. Applicant

Name of institution or company:

3. GMO characterization

(a) Indicate whether the GMO is a:

Viroid	☐
RNA virus	☐
DNA virus	☐
Bacterium	☐
Fungus	☐
Animal	☐
Other, please specify	☐

(b) Identity of the GMO:

4. Is release of the same GMO planned anywhere in the European Community?

Yes ☐ No ☐ Don't know ☐

If yes, insert the name of the country concerned

5. Has an application been made by the same applicant for release of the same GMO anywhere in the European Community?

Yes ☐ No ☐

If yes:

Name of member State of application:

Reference number of application:

INFORMATION RELATING TO SCHEDULE IV
A. Information relating to the recipient or parental organisms from which the GMO is derived

1. Indicate whether the recipient or parental organism is a:

Viroid	☐
RNA virus	☐
DNA virus	☐
Bacterium	☐
Fungus	☐
Animal	☐
Other, please specify	☐

2. Complete name

(i)	Order and higher taxon (for animals)
(ii)	Genus
(iii)	Species
(iv)	Subspecies
(v)	Pathovar (biotype, ecotype, race, etc.)
(vi)	Common name

3. Geographical distribution of the organism

(a) Is it indigenous to the Island of Cyprus?

Yes ☐ No ☐ Don't know ☐

(b) Is it indigenous to EC countries other than the Republic?

(i) Yes ☐

If yes, indicate the type of ecosystem in which it is found:

Atlantic	☐
Mediterranean	☐
Arctic	☐
Continental	☐

(ii) No ☐ Don't know ☐

(c) Is it regularly used in the Island of Cyprus?

Yes ☐ No ☐

(d) Is is regularly kept in the Island of Cyprus?

Yes ☐ No ☐

4. Natural habitat of the organism

(a) If the organism is a micro-organism

Water	☐
Soil, free-living	☐
Soil, in association with plant-root systems	☐
Soil, in association with plant leaf/stem systems	☐
Soil, in association with animals	☐
Other (specify)	☐

(b) If the organism is an animal:

natural habitat or usual agro-ecosystem:

5. (a) Detection techniques.

(b) Identification techniques.

6. Is the recipient organism classified under any European Community rules relating to the protection of human health or the environment?

Yes ☐ No ☐

If yes, specify them:

7. Is the recipient organism pathogenic or harmful in any other way (including its extra-cellular products), whether it is alive or dead?

Yes ☐ No ☐

If yes:

(a) to which of the following organisms:

Humans	☐
Animals	☐
Plants	☐

(b) give the relevant information specified in paragraph 11(d) of Chapter IIA of Part A of Schedule IV.

8. Information concerning reproduction:

(a) Generation time in natural ecosystems:

(b) Generation time in the ecosystem where the release will take place:

(c) Manner of reproduction:

Sexual	☐	Asexual	☐

(d) Factors affecting reproduction:

9. Survivability:

(a) Ability to form structures enhancing survival or dormancy:

i	Endospores	☐
ii	Cysts	☐
iii	Sclerotia	☐
iv	Asexual spores (fungi)	☐
v	Sexual spores (fungi)	☐
vi	Eggs	☐
vii	Pupae	☐

viii	Larvae	☐
ix	Other, please specify	☐

(b) Relevant factors affecting survivability:

10. Dissemination:

(a) Means of dissemination,

(b) Factors affecting dissemination.

11. Previous genetic modifications of the recipient or parental organism already released pursuant to a licence under this Ordinance (give reference number of previous application)

B. Information relating to the genetic modification

1. Type of genetic modification.

i	Insertion of genetic material	☐
ii	Deletion of genetic material	☐
iii	Base substitution	☐
iv	Cell fusion	☐
v	Other, please specify	☐

2. Intended result of the genetic modification.

3. (a) Has a vector been used in the process of modification?

Yes ☐ No ☐

If no, go straight to question 5.

(b) If yes, is the vector wholly or partially present in the modified organism?

Yes ☐ No ☐

If no, go straight to question 5.

4. If the answer to question 3(b) above is yes, give the following information:

(a) Type of vector.

Plasmid	☐
Bacteriophage	☐
Virus	☐
Cosmid	☐
Phasmid	☐
Transposable element	☐
Other, please specify	☐

(b) Identity of the vector.

(c) Host range of the vector.

(d) Presence in the vector of sequences giving a selectable or identifiable phenotype.

	Yes	No
Antibiotic resistance	☐	☐
Heavy metal resistance	☐	☐
Other, specify	☐	☐

(e) Constituent fragments of the vector.

(f) Method for introducing the vector into the recipient organism.

i	Transformation	☐
ii	Electroporation	☐
iii	Macroinjection	☐
iv	Microinjection	☐
v	Infection	☐
vi	Other, please specify	☐

5. If the answer to both question 3(a) and question 3(b) above is no, what was the method used to introduce the insert into the recipient/parental cell?

i	Transformation	☐
ii	Microinjection	☐
iii	Microencapsulation	☐
iv	Macroinjection	☐
v	Other, please specify	☐

6. Information on the insert.

(a) Composition of the insert.

(b) Source of each constituent part of the insert.

(c) Intended function of each constituent part of the insert in the GMO.

(d) Location of the insert in the host organism.

On a free plasmid	☐
Integrated in the chromosome	☐
Other, please specify	☐

(e) Does the insert contain parts whose product or function is not known?

Yes ☐ No ☐

If yes, please specify:

C. Information on the organism from which the insert is derived (Donor)

1. Indicate whether it is a:

Viroid	☐
RNA virus	☐
DNA virus	☐
Bacterium	☐
Fungus	☐
Plant	☐
Animal	☐
Other, please specify	☐

2. Complete name.

i	Order and higher taxon (for animals)
ii	Family name (for plants)
iii	Genus
iv	Species
v	Subspecies
vi	Strain
vii	Cultivar/breeding line
viii	Pathovar
ix	Common name

3. Is the organism pathogenic or harmful in any other way (including its extra-cellular products), whether alive or dead?

Yes	☐	No	☐	Don't know	☐

If, yes, specify the following:

(a) to which of the following organisms?

Humans	☐
Animals	☐
Plants	☐

(b) are the donated sequences involved in any way to the pathogenic or harmful properties of the organism?

Yes	☐	No	☐	Don't know	☐

If yes, give the relevant information specified in paragraph 11(d) of Chapter IIA of Part A of Schedule IV.

4. Is the donor organism classified under any European Community rules relating to the protection of human health or the environment?

Yes ☐ No ☐

If yes, specify them:

5. Do the donor and recipient organisms exchange genetic material naturally?

Yes	☐	No	☐	Don't know	☐

D. Information relating to the genetically modified organism

1. Genetic traits and phenotypic characteristics of the recipient or parental organism which have been changed as a result of the genetic modification.

(a) Is the GMO different from the recipient as far as survivability is concerned?

Yes	☐	No	☐	Don't know	☐

If yes, please specify:

(b) Is the GMO in any way different from the recipient as far as mode or rate of reproduction is concerned?

Yes	☐	No	☐	Don't know	☐

If yes, please specify:

(c) Is the GMO in any way different from the recipient as far as dissemination is concerned?

Yes	☐	No	☐	Don't know	☐

If yes, please specify:

2. Genetic stability of the genetically modified organism

3. Is the GMO pathogenic or harmful in any other way (including its extra-cellular products), whether alive or dead?

Yes	☐	No	☐	Don't know	☐

If yes,

(a) to which of the following organisms? :

Humans	☐
Animals	☐
Plants	☐

(b) give the relevant information specified in paragraph 11(d) of Chapter IIA of Part A of Schedule IV and in paragraph 2(i) of Chapter IIC of Part A of Schedule IV.

4. Description of identification and detection methods.

(a) Techniques used to detect the GMO in the environment:

(b) Techniques used to identify the GMO:

E. Information relating to the release

1. Purpose of the release.

2. Is the site of the release different from the natural habitat or from the ecosystem in which the recipient organism is regularly used, kept or found?

Yes ☐ No ☐

If yes, please describe in what way it is different.

3. Information concerning the release and the surrounding area.

(a) Geographical location (administrative region and where appropriate grid reference):

(b) Area (in square metres) –

(i) of actual release site:

(ii) of wider release area:

(c) Proximity to internationally recognized biotopes or protected areas (including drinking water reservoirs), which could be affected:

(d) Flora and fauna including crops, livestock and migratory species which may potentially interact with the GMO:

4. Method and amount of release.

(a) Quantities of GMOs to be released:

(b) Duration of the operation:

(c) Methods and procedures to avoid or minimize the spread of the GMOs beyond the site of the release:

F. Interactions of the GMO with the environment and potential impact on the environment

1. Complete name of target organisms.

i	Order and higher taxon (for animals)
ii	Family name (for plants)
iii	Genus
iv	Species
v	Subspecies
vi	Strain
vii	Cultivar
viii	Pathovar
ix	Common name

2. Expected mechanism and result of interaction between the released GMOs and the target organism.

3. Other potentially significant interactions with other organisms in the environment.

4. Is post-release selection for the GMO likely to occur?

Yes	☐	No	☐	Don't know	☐

If yes, give details:

5. Types of ecosystems to which the GMO could be disseminated from the site of release and in which it could become established:

6. Complete name of non-target organisms which may be affected unintentionally.

i	Order and higher taxon (for animals)
ii	Family name (for plants)
iii	Genus
iv	Species
v	Subspecies
vi	Strain
vii	Cultivar
viii	Pathovar
ix	Common name

7. Likelihood of live genetic exchange –

(a) from the GMO to other organisms in the release ecosystem:

(b) from other organisms to the GMO:

8. Give references to relevant results from studies of the behaviour and characteristic of the GMO and its ecological impact carried out in simulated natural environments (e.g. microcosms, etc.):

G. Information relating to monitoring

1. Methods for monitoring the GMO:

2. Methods for monitoring effects on ecosystem:

3. Methods for detecting transfer of the donated genetic material from the GMO to other organisms:

4. Area of monitoring site (in square metres):

5. Period of monitoring:

6. Frequency of monitoring:

H. Information on post-release and waste treatment

1. Post-release treatment of the site:

2. Post-release treatment of the GMOs:

3. Waste:

(a) Type and quantity of waste generated:

(b) Treatment of waste:

I. Information on emergency response plans

1. Methods and procedures for controlling GMOs in the event of their spreading unexpectedly:

2. Methods for decontamination of the areas affected by such spreading:

3. Methods for disposing of or decontaminating plants, animals, soils etc. affected by such spreading:

4. Plans for protecting human health and the environment in the event of any undesirable effect:

SCHEDULE VII

(Sections 20(1)(d), 22(1)(f) and 42)

MONITORING PLAN

This Schedule describes in general terms the objectives to be achieved and the general principles to be followed in preparing a monitoring plan such as is referred to in sections 20, 22 and 42.

A. Objective

The objective of a monitoring plan is to –

(a) confirm that any assumptions made in the environmental risk assessment regarding the occurrence and impact of potential adverse effects of the GMO product or its use are correct; and

(b) identify any adverse effects of the GMO product or its use on human health or the environment which were not foreseen when the environmental risk assessment was made.

B. General principles

Monitoring such as is referred to in sections 20, 22, and 26 is to be carried out after the grant of a licence to place a GMO product on the market.

The interpretation of the data collected in the course of such 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 GMO product or its use, as such changes may be the result of environmental factors other than the placing of the GMO product on the market.

Experience and data gained through the monitoring of experimental releases of GMOs may assist in designing the post-marketing monitoring regime required for the placing on the market of a GMO product.

C. Content of the monitoring plan

The monitoring plan should—

1. Be as detailed as the nature of the case requires having regard to the environmental risk assessment.

2. Take into account the characteristics of the GMO product, the characteristics and scale of its intended use and the range of relevant environmental conditions where the GMO product is expected to be placed on the market.

3. Incorporate general surveillance procedures for identifying unforeseen adverse effects and, if necessary, specific monitoring of adverse effects identified in the environmental risk assessment.

3.1. Such specific monitoring should be carried out for a sufficient period as to detect immediate and direct as well as delayed or indirect effects which have been identified in the environmental risk assessment.

3.2. Such surveillance procedures may make use of established routine surveillance procedures such as the monitoring of agricultural cultivars, plant protection or veterinary and medical

products. An explanation must be included as to how relevant information collected through such procedures becomes available to the holder of the licence.

4. Facilitate the observation, in a systematic manner, of the effects of the GMO product on the environment and on human health.

5. Identify the person who will carry out the various tasks that the monitoring plan requires and the person responsible for ensuring that the monitoring plan is carried out properly, and ensure that there is a clear means by which the holder of the licence will inform the Chief Officer of any observed adverse effects on human health or the environment. The plan shall include the times at which results are to be reported.

6. Give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and the environment and enable the holder of the licence or the Chief Officer, as appropriate, to take any measures necessary to protect human health and the environment.

SCHEDULE VIII

(Section 20)

FORM OF SUMMARY OF DOSSIER IN SUPPORT OF AN APPLICATION FOR A LICENCE TO PLACE A GMO PRODUCT ON THE MARKET

A. GENERAL INFORMATION

1. Details of the application.

(a) Name of the GMO product (commercial and other names).

(b) Date of acknowledgement of application.

2. Applicant

(a) Name of applicant.

(b) Address of applicant.

(c) The applicant is:

the manufacturer of the GMO product	☐
the importer of the GMO product	☐

(d) if the applicant is the importer of the GMO product:

(i) Name of manufacturer:

(ii) Address of manufacturer:

3. Characteristics of the GMO contained in the GMO product.

Indicate the name and nature of each GMO contained in the GMO product.

4. General description of the GMO product.

(a) Type of product

(b) Composition of the product

(c) Specificity of the product

(d) Types of users of the product

(e) Conditions for the use and handling of the product

(f) Geographical areas where it is intended that the product is to be used

(g) Description of environment suitable for use of the product

(h) Estimate of quantity to be produced or imported annually

5. Has a licence been applied for under Part II of this Ordinance in respect of the GMO contained in the GMO product?

Yes ☐ No ☐

(a) If yes, give country and reference number of the application:

(b) If no, give the risk analysis data on the basis of the elements of such data described in Part II of this Ordinance:

6. Is a licence in respect of the product being applied for also in any member State of the European Community?

Yes ☐ No ☐

If yes, please specify:

7. Has any other product containing the same GMO been placed on the market in the Areas or the European Community by any other person?

Yes ☐ No ☐

If yes, please give particulars:

8. Information on releases of the same GMO or of the same combination of GMOs previously or currently applied for or carried out by the applicant at any place whether in the Areas or elsewhere.

9. Specify instructions and or recommendations for storage and handling.

10. Proposed packaging.

11. Proposed labelling.

12. Measures to take in case of unintended release or misuse of the GMO or GMO product.

13. Measures for waste disposal and treatment.

B. NATURE OF THE GMO CONTAINED IN THE GMO PRODUCT AND INFORMATION RELATING TO THE RECIPIENT OR PARENTAL ORGANISM FROM WHICH THE GMO IS DERIVED

14. Scientific name and other names.

15. Phenotypic and genetic traits.

16. Geographical distribution and natural habitat of the organisms.

17. Genetic stability of the organism and factors affecting it.

18. Potential for genetic transfer and exchange with other organisms.

19. Information concerning reproduction and factors affecting it.

20. Information on survival and factors affecting it.

21. Ways of dissemination and factors affecting it.

22. Interactions with the environment.

23 (a) Detection techniques.

23 (b) Identification techniques.

24. Classification under European Community rules concerning the protection of human health and the environment.

25 (a) Pathogenic characteristics.

25 (b) Other harmful characteristics of the organism living or dead, including its extra-cellular products.

26. Nature and description of known extra-chromosomal genetic elements.

27. History of previous genetic modifications.

INFORMATION RELATING TO THE GENETIC MODIFICATION

28. Methods used for the genetic modification.

29. Characteristics of the vector.

(a) Nature and source of the vector

(b) Description of the vector construction

(c) Genetic map and (if any) restriction map of the vector

(d) Sequence data

(e) Information on the degree to which the vector contains sequences whose product or function area is not known

(f) Genetic transfer capabilities of the vector

(g) Frequency of mobilization of the vector

(h) Part of the vector which remains in the GMO

30. Information on the insert.

(a) Methods used to construct the insert

(b) Restriction sites

(c) Sequence of the insert

(d) Origin and function of each constituent part of the insert in the GMO

(e) Information on the degree to which the insert is limited to the required function

(f) Location of the insert in the GMO

INFORMATION ON THE ORGANISM FROM WHICH THE INSERT IS DERIVED (DONOR ORGANISM)

31. Scientific and other names.

32 (a) Pathogenic characteristics of the donor organism.

32 (b) Other harmful characteristics of the organism living or dead, including its extra-cellular products.

33. If the donor organism has any pathogenic or harmful characteristics, indicate whether the donated sequences are in any way involved in them.

34. Classification under European Community rules relating to the protection of human health and the environment.

35. Potential for natural exchange of genetic material between the donor and recipient organisms.

INFORMATION RELATING TO THE GMO CONTAINED IN THE GMO PRODUCT

36. Description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

37. Genetic stability of the GMO.

38. Rate and level of expression of the new genetic material.

39. Activity of the expressed proteins.

40 (a) Description of detection techniques for the GMO in the environment:

(b) Description of identification techniques:

41. Health considerations –

(a) toxic or allergenic effects of the non-viable GMOs and their metabolic products;

(b) product hazards;

(c) comparison of the GMO with the donor, recipient or parental organism regarding pathogenicity;

(d) capacity for colonization;

(e) if the organism is pathogenic to humans who are immuno-competent, supply the information specified in paragraph IIC2(i)(v) in Part A of Schedule IV.

INTERACTION OF THE GMO WITH THE ENVIRONMENT

42. Survival, multiplication and dissemination of the GMO in the environment.

43. Interaction of the GMO with the environment.

44. Environmental impact of the GMO.

C. EXPECTED EFFECTS OF THE GMO PRODUCT

1. Effects on the environment of the GMO product.

2. Effects on human health of the GMO product.

D. INFORMATION RELATING TO PREVIOUS RELEASES

I. History of releases carried out under Part II of this Ordinance.

1. Licence number:
2. Release site:
3. Scope of the release:
4. Duration of the release:
5. Duration of post-release monitoring:
6. Scope of post-release monitoring:
7. Conclusions of post-release monitoring:
8. Results submitted to the Chief Officer under section 14 with respect to the risks to human health and the environment arising from the release.

II. History of previous releases carried out outside of the Areas.

1. Country where GMO was released:
2. Authority overseeing the release:
3. Release site:
4. Scope of the release:
5. Duration of post-release monitoring:
6. Scope of post-release monitoring:
7. Conclusions of post-release monitoring:
8. Results of the release with respect to any risks to human health and the environment:

III. History of previous work relevant to risk assessment prior to placing GMO product on the market.

7th June 2006 P. D. Draycott

(SBA/AG /2/EN/268) Chief Officer.

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