SECOND SUPPLEMENT TO THE GIBRALTAR GAZETTE

No. 2,889 of 28th December, 1995

LEGAL NOTICE NO.154 OF 1995.

INTERPRETATION AND GENERAL CLAUSES ACT

PUBLIC HEALTH ACT

PUBLIC HEALTH (GENETICALLY MODIFIED ORGANISMS) REGULATIONS 1995

In exercise of the powers conferred on it by section 23 of the Interpretation and General Clauses Act, and of all other enabling powers, and for the purpose of transposing into the national law of Gibraltar Council Directive 90/219/EEC, as amended by Council Directive 94/51/EEC, and Council Directive 90/220/EEC, as amended by Council Directive 94/15/EEC, the Government has made the following regulations —

Title and commencement.

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

(2) Where a person is carrying out an activity to which Part IVA of the Act (as contained in regulation 2) applies at the coming into effect of these regulations the provisions of that Part shall not apply to such person for a period of 90 days commencing on the day on which these regulations shall have come into effectAmendment to the Public Health Act.

The Public Health Act is amended by inserting after section 180 the following new Part —

"PART IVA - GENETICALLY MODIFIED ORGANISMS

Interpretation of Part IVA.

180A. (1) In this Part, unless the context shall otherwise require, —

"acquire", in relation to genetically modified organisms, includes any method by which such organisms may come to be in a person's possession, other than by their being imported;

"competent authority" means the person or body designated by the Government from time to time by notice in the Gazette as the competent authority for the purposes of implementing the Directives in Gibraltar;

"consent" means a consent granted under section 180F, and a reference to the limitations or conditions to which a consent is subject is a reference to the limitations or conditions subject to which the consent for the time being has effect;

"descendant", in relation to a genetically modified organism, means any other organism whose genes or other genetic material is derived, through any number of generations, from that organism by any process of reproduction;

"import" means import into Gibraltar;

"premises" includes any land;

"Directives" means Council Directives 90/219/EEC, as amended by Council Directive 94/51/EEC, and 90/220/EEC, as amended by Council Directive 94/15/EEC, and includes any amendments made to those Directives under Articles 20 of those Directives to reflect technical or scientific changes;

"inspector" in sections 180K and 180M includes any inspector appointed by the competent authority in accordance with section 180J;

"modifications" includes additions, alterations and omissions;

"prohibition notice" means a notice under section 180E;

"prescribed" means prescribed in regulations made under this Part; and

"related right", in relation to an obligation, includes any derogation or other right to make more onerous provisions available in respect of that obligation.

(2) Unless otherwise provided for in this Part, words and terms used in Council Directives 90/219/EEC, 90/220/EEC, 94/15/EEC and 94/51/EEC shall, in this Part, have the meaning given to them in those Directives.

(3) In this Part the term "organism" means any acellular, unicellular or multicellular entity (in any form), other than humans or human embryos and, unless the context otherwise requires, the term also includes any article or substance consisting of or including biological matter.

(4) For the purpose of sub-section (3) "biological matter" means anything (other than an entity mentioned in that sub-section) which consists of or includes —

(a) tissue or cells (including gametes or propagules) or subcellular entities, of any kind, capable of replication or of transferring genetic material; or

(b) genes or other genetic material, in any form, which are so capable;

and it is immaterial, in determining if something is or is not an organism or biological matter, whether it is the product of natural or artificial processes of reproduction and, in the case of biological matter, whether it has ever been part of a whole organism.

(5) For the purposes of this Part an organism is "genetically modified" if any of the genes or other genetic material in the organism —

(a) have been modified by means of an artificial technique prescribed in directions by the competent authority; or

(b) are inherited or otherwise derived, through any number of replications, from genes or other genetic material (from any source) which were so modified.

(6) The techniques which may be prescribed for the purposes of sub-section (5) include —

(a) any technique for the modification of any genes or other genetic material by the recombination, insertion or deletion of, or of any component parts of, that material from its previously occurring state; and

(b) any other technique for modifying genes or other genetic material which in the opinion of the competent authority would produce organisms which should for the purposes of this Part be treated as having been genetically modified;

but do not include techniques which involve no more than, or no more than the assistance of, naturally occurring processes of reproduction (including selective breeding techniques or in vitro fertilisation).

(7) It is immaterial for the purposes of sub-sections (5) and (6) whether the modifications of genes or other genetic material effected by a prescribed technique are produced by direct operations on that genetic material or are induced by indirect means (including in particular the use of viruses, microbial plasmids or other vector systems or of mutation inducing agents).

(8) In this Part, where the context permits, a reference to "reproduction", in relation to an organism, includes a reference to its replication or its transferring genetic material.

(9) This Part, except in so far as it relates to the importation of genetically modified organisms, applies to the territorial sea adjacent to Gibraltar.

Meaning of "damage to the environment", "control" and related expressions in this Part.

180B.(1) The provisions of sub-sections (2) to (11) have effect for the interpretation of this Part.

(2) The "environment" consists of land, air and water or any of those media.

(3) "Damage to the environment" is caused by the presence in the environment of genetically modified organisms which have (or of a single such organism which has) escaped or been released from a person's control and are (or is) capable of causing harm to the living organisms supported by the environment.

(4) An organism shall be regarded as present in the environment notwithstanding that it is present in or on any human or other organism, or any other thing, which is itself present in the environment.

(5) Genetically modified organisms present in the environment are capable of causing harm if —

(a) they are individually capable, or are present in numbers such that together they are capable, of causing harm; or

(b) they are able to produce descendants which will be capable, or which will be present in numbers such that together they will be capable, of causing harm;

and a single organism is capable of causing harm either if it is itself capable of causing harm or if it is able to produce descendants which will be so capable.

(6) "Harm" means harm to the health of humans or other living organisms or other interference with the ecological systems of which they form part and, in the case of man, includes offence caused to any of his senses or harm to his property.

(7) "Harmful" and "harmless" mean respectively, in relation to genetically modified organisms, their being capable or their being incapable of causing harm.

(8) The Government may by regulations provide, in relation to genetically modified organisms of any description specified in the regulations, that —

(a) the capacity of those organisms for causing harm of any description so specified; or

(b) harm of any description so specified;

shall be disregarded for such purposes of this Part as may be so specified.

(9) Organisms of any description are under the "control" of a person where he keeps them contained by any system of physical, chemical or

biological barriers (or combination of such barriers) used for either or both of the following purposes, namely —

(a) for ensuring that the organisms do not enter the environment or produce descendents which are not so contained; or

(b) for ensuring that any of the organisms which do enter the environment, or any descendents of the organisms which are not so contained, are harmless.

(10) An organism under a person's control is "released" if he deliberately causes or permits it to cease to be under his control or the control of any other person and to enter the environment, and such an organism “escapes" if, otherwise than by being released, it ceases to be under his control or that of any other person and enters the environment.

(11) Genetically modified organisms of any description are "marketed" when products consisting of or including such organisms are placed on the market.

Risk Assessment and notification requirements.

180C.(1) Subject to sub-sections (2) and (7), no person shall import or acquire, release or market any genetically modified organisms unless, before doing that act —

(a) he has carried out an assessment of any risks there are (by reference to the nature of the organisms and the manner in which he intends to keep them after their importation or acquisition or, as the case may be, to release or market them) of damage to the environment being caused as a result of doing that act; and

(b) in such cases and circumstances as may be prescribed, he has given the competent authority such notice of his intention of doing that act and such information as may be prescribed.

(2) Sub-section (1) does not apply to a person proposing to do an act mentioned in that sub-section who is required under section 180F(1)(a) to have a consent before doing that act.

(3) Subject to sub-section (4) and (7), a person who is keeping genetically modified organisms shall, in such cases or circumstances and at such times or intervals as may be prescribed —

(a) carry out an assessment of any risks there are of damage to the environment being caused as a result of his continuing to keep them;

(b) give the competent authority notice of the fact that he is keeping the organisms and such information as may be prescribed.

(4) Sub-section (3) does not apply to a person who is keeping genetically modified organisms and is required under section 180F(2) to have a consent authorising him to continue to keep the organisms.

(5) It shall be the duty of a person who carries out an assessment under sub-section (1)(a) or (3)(a) to keep, for the prescribed period, such a record of the assessment as may be prescribed.

(6) A person required by sub-section (1)(b) or (3)(b) to give notice to the competent authority shall give the competent authority such further information as the competent authority may by notice in writing require.

(7) Any regulations under this Part may provide for exemptions, or for the granting by the competent authority of exemptions to particular persons or classes of person, from the requirements of sub-section (1) or (3) in such cases or circumstances, and to such extent, as may be prescribed.

(8) The competent authority may at any time —

(a) give directions to a person falling within sub-section (1) requiring that person to apply for a consent before doing the act in question; or

(b) give directions to a person falling within sub-section (3) requiring that person, before such date as may be specified in the direction, to apply for a consent authorising him to continue keeping the organisms in question;

and a person given directions under paragraph (a) shall then, and a person given directions under paragraph (b) shall from the specified date, be subject to section 180H in place of the requirements of this section.

(9) Regulations under this Part may —

(a) prescribe the manner in which assessments under sub-section (1) or (3) are to be carried out and the matters which shall be investigated and assessed;

(b) prescribe minimum periods of notice between the giving of a notice under sub-section (1)(b) and the doing of the act in question;

(c) make provision allowing the competent authority to shorten or to extend any such period;

(d) prescribe maximum intervals at which assessments under sub-section (3)(a) shall be carried out;

and the regulations may make different provision for different cases and different circumstances.

General duties relating to importation, acquisition, keeping, release or marketing of organisms.

180D.(1) A person who —

(a) is proposing to import or acquire any genetically modified organisms; or

(b) is keeping any such organisms; or

(c) is proposing to release or market any such organisms;

shall, subject to sub-section (5), be subject to the duties specified in sub-sections (2), (3) or (4), as the case may be.

(2) A person who proposes to import or acquire genetically modified organisms —

(a) shall take all reasonable steps to identify, by reference to the nature of the organisms and the manner in which he intends to

keep them (including any precautions to be taken against their escaping or causing damage to the environment), what risks there are of damage to the environment being caused as a result of their importation or acquisition; and

(b) shall not import or acquire the organisms if it appears that, despite any precautions which may be taken, there is a risk of damage to the environment being caused as a result of their importation or acquisition.

(3) A person who is keeping genetically modified organisms —

(a) shall take all reasonable steps to keep himself informed of any damage to the environment which may have been caused as a result of his keeping the organisms and to identify what risks there are of damage to the environment being caused as a result of his continuing to keep them;

(b) shall cease keeping the organisms if, despite any additional precautions which may be taken, it appears, at any time, that there is a risk of damage to the environment being caused as a result of his continuing to keep them; and

(c) shall use the best available techniques not entailing excessive cost for keeping the organisms under his control and for preventing any damage to the environment being caused as a result of his continuing to keep the organisms;

and where a person is required by paragraph (b) to cease keeping the organisms he shall dispose of them as safely and as quickly as practicable and paragraph (c) shall continue to apply until he has done so.

(4) A person who proposes to release genetically modified organisms —

(a) shall take all reasonable steps to keep himself informed, by reference to the nature of the organisms and the extent and manner of the release (including any precautions to be taken against their causing damage to the environment), what risks there are of damage to the environment being caused as a result of their being released;

(b) shall not release the organisms if it appears that, despite the precautions which may be taken, there is a risk of damage to the environment being caused as a result of their being released; and

(c) subject to paragraph (b), shall use the best available techniques not entailing excessive cost for preventing any damage to the environment being caused as a result of their being released;

and this sub-section applies, with the necessary modifications, to a person proposing to market organisms as it applies to a person proposing to release organisms.

(5) This section does not apply —

(a) to persons proposing to import or acquire, to release or to market any genetically modified organisms, in cases or circumstances where, under section 180C, they are not required to carry out a risk assessment before doing that act;

(b) to persons who are keeping any genetically modified organisms and who —

(i) were not required under section 180C to carry out a risk assessment before importing or acquiring them;

(ii) have not been required under that regulation to carry out a risk assessment in respect of the keeping of those organisms since importing or acquiring them; or

(c) to holders of consents, in the case of acts authorised by those consents.

Prohibition notices.

180E. (1) The competent authority may serve a notice under this Part (a "prohibition notice") on any person it has reason to believe —

(a) is proposing to import or acquire, release or market any genetically modified organisms; or

(b) is keeping any such organisms;

if it is of the opinion that doing any such act in relation to those organisms or continuing to keep them, as the case may be, would involve a risk of causing damage to the environment.

(2) A prohibition notice may prohibit a person from doing an act mentioned in sub-section (1)(a) in relation to any genetically modified organisms or from continuing to keep them and the prohibition may apply in all cases or circumstances or in such cases or circumstances as may be specified in the notice.

(3) A prohibition notice shall —

(a) state that the competent authority is, in relation to the person on whom it is served, of the opinion mentioned in sub-section (1);

(b) specify what is, or is to be, prohibited by the notice; and

(c) if the prohibition is not to be effective on being served, specify the date on which the prohibition is to take effect;

and a notice may be served on a person notwithstanding that he may have a consent authorising any act which is, or is to be, prohibited by the notice.

(4) Where a person is prohibited by a prohibition notice from continuing to keep any genetically modified organisms, he shall dispose of them as quickly and safely as practicable or, if the notice so provides, as may be specified in the notice.

(5) The competent authority may at any time withdraw a prohibition notice served on any person by notice given to that person.

Consents required by certain persons.

180F. (1) Subject to sub-section (8), no person shall import or acquire, release or market any genetically modified organisms —

(a) in such cases or circumstances as may be prescribed in relation to that act; or

(b) in any case where he has been given directions under section 180C(8)(a);

except in pursuance of a consent granted by the competent authority and in accordance with any limitations and conditions to which the consent is subject.

(2) Subject to sub-section (8), no person who has imported or acquired any genetically modified organisms (whether under a consent or not) shall continue to keep the organisms —

(a) in such cases or circumstances as may be prescribed, after the end of the prescribed period; or

(b) if he has been given directions under sub-section 180C(8)(b), after the date specified in the directions;

except in pursuance of a consent granted by the competent authority and in accordance with any limitations or conditions to which the consent is subject.

(3) A person who is required under sub-section (2) to cease keeping any genetically modified organisms shall dispose of them as quickly and safely as practicable.

(4) An application for a consent shall contain such information and be made and advertised in such manner as may be prescribed and shall be accompanied by the fee required under section 180H.

(5) The applicant shall, in prescribed circumstances, give such notice of his application to such persons as may be prescribed.

(6) The competent authority may by notice to the applicant require him to furnish such further information specified in the notice, within such period as may be so specified, as he may require for the purpose of determining the application and if the applicant fails to furnish the information within the specified period the competent authority shall not be required to proceed with the application.

(7) Where an applicant for consent for releasing or marketing genetically modified organisms becomes aware, before his application is either granted or rejected, of any new information with regard to any risks there are of damage to the environment being caused as a result of the

organisms being released or marketed, he shall notify the competent authority of that new information forthwith.

(8) Regulations under this section may provide for exemptions, or for the granting by the competent authority of exemptions to particular persons or classes of person, from —

(a) any requirement under sub-sections (1) or (2) to have a consent; or

(b) any of the requirements to be fulfilled under the regulations by an applicant for a consent;

in such cases or circumstances as may be prescribed.

(9) Where an application for a consent is duly made to it, the competent authority may grant the consent subject to such limitations and conditions as may be imposed under section 180G or it may refuse the application.

(10) The conditions attached to a consent may include conditions which are to continue to have effect notwithstanding that the holder has completed or ceased the act or acts authorised by the consent.

(11) The competent authority may at any time, by notice given to the holder of a consent, revoke the consent or vary the consent (whether by attaching new limitations and conditions or by revoking or varying any limitations and conditions to which it is at that time subject).

(12) Regulations under this section may make different provision for different cases and different circumstances.

Consents: limitations and conditions.

180G. (1) The competent authority may include in a consent such limitations and conditions as it may think fit.

(2) Without prejudice to the generality of sub-section (1), the conditions included in a consent may —

(a) require the giving of notice of any fact to the competent authority; or

(b) prohibit or restrict the keeping, releasing or marketing of genetically modified organisms under the consent in specified cases or circumstances;

and where, under any condition, the holder of a consent is required to cease keeping any genetically modified organisms, he shall dispose of them, if no manner is specified in the conditions, as quickly and safely as practicable.

(3) Subject to sub-section (6), there is implied in every consent for the importation or acquisition of genetically modified organisms a general condition that the holder of the consent shall —

(a) take all reasonable steps to keep himself informed (by reference to the nature of the organisms and the manner in which he intends to keep them after their importation or acquisition) of any risks there are of damage to the environment being caused as a result of their importation or acquisition; and

(b) if at any time it appears that any such risks are more serious than were apparent when the consent was granted, notify the competent authority forthwith.

(4) Subject to sub-section (6), there is implied in every consent for keeping genetically modified organisms a general condition that the holder of the consent shall —

(a) take all reasonable steps to keep himself informed of any damage to the environment which may have been caused as a result of his keeping the organisms and of any risks there are of such damage being caused as a result of his continuing to keep them;

(b) if at any time it appears that any such risks are more serious than were apparent when the consent was granted, notify the competent authority forthwith; and

(c) use the best available techniques not entailing excessive cost for keeping the organisms under his control and for preventing any damage to the environment being caused as a result of his continuing to keep them.

(5) Subject to sub-section (6), there is implied in every consent for releasing or marketing genetically modified organisms a general condition that the holder of the consent shall —

(a) take all reasonable steps to keep himself informed (by reference to the nature of the organisms and the extent and manner of the release or marketing) of any risks there are of damage to the environment being caused as a result of their being released or, as the case may be, marketed;

(b) notify the competent authority of —

(i) any new information which becomes available with regard to any risks there are of damage to the environment being so caused, and

(ii) the effects of any releases by him for the assessment of any risks there are of damage to the environment being so caused by such organisms being released or marketed;

(c) use the best available techniques not entailing excessive cost for preventing any damage to the environment being caused as a result of their being released or, as the case may be, marketed.

(6) The general condition implied into a consent under sub-sections (3), (4) or (5) has effect subject to any conditions imposed under sub-section (1) and the obligations imposed by virtue of sub-section (4) (c) or (5) (c) shall not apply to any aspect of an act authorised by a consent which is regulated by such a condition.

(7) Subject to any conditions imposed under sub-section (1), there shall be implied in every consent for keeping, releasing or marketing genetically modified organisms of any description a general condition that the holder of the consent —

(a) shall take all reasonable steps to keep himself informed of developments in the techniques which may be available in his case for preventing damage to the environment being caused as a result of the doing of the act authorised by the consent in relation to organisms of that description; and

(b) if it appears at any time that any better techniques are available to him than is required by any condition included in the consent under sub-section (1), shall notify the competent authority of that fact forthwith.

Fees and charges.

180H. (1) The competent authority may make and from time to time devise a scheme prescribing —

(a) fees payable in respect of applications for consents; and

(b) charges payable by persons holding consents in respect of the subsistence of their consents;

and it shall be a condition of any such consent that any applicable prescribed charge is paid in accordance with that scheme.

(2) A scheme under this section may, in particular —

(a) provide for different fees or charges to be payable in different cases or circumstances;

(b) provide for the times at which and the manner in which payments are to be made; and

(c) make such incidental, supplementary and transitional provision as appears to the competent authority to be appropriate.

(3) The competent authority shall so frame a scheme under this section as to secure, so far as practicable, that the amounts payable under it will be sufficient, taking one financial year with another, to cover the expenditure of the competent authority in discharging its functions under this Part in relation to consents.

Appointment etc of inspectors.

180J. (1) The competent authority may appoint as inspectors, for carrying this Part into effect, such number of persons appearing to it to be qualified for the purpose as it may consider necessary.

(2) The competent authority may make to or in respect of any person so appointed such payments by way of remuneration, allowances or otherwise as it may determine.

(3) An inspector shall not be personally liable in any civil or criminal proceedings for anything done in the purported exercise of any power under section 180K or 180M if the court is satisfied that the act was done in good faith and that there were reasonable grounds for doing it.

(4) In Gibraltar an inspector, if authorised to do so by the competent authority with the consent of the Government, may, although not of counsel or a solicitor, prosecute before the magistrates' court proceedings for an offence under section 180N.

Rights of entry and inspection.

180K. (1) An inspector may, on production (if so required) of his authority, exercise any of the powers specified in sub-section (3) for the purposes of the discharge of the functions of the competent authority under this Part.

(2) Those powers are exercisable —

(a) in relation to premises —

(i) on which the inspector has reason to believe a person is keeping or has kept any genetically modified organisms; or

(ii) from which he has reason to believe any such organisms have been released or have escaped; and

(b) in relation to premises on which the inspector has reason to believe there may be harmful genetically modified organisms or evidence of damage to the environment caused by genetically modified organisms;

but they are not exercisable in relation to premises used wholly or mainly for domestic purposes.

(3) The powers of an inspector are —

(a) at any reasonable time (or, in a situation in which in his opinion there is an immediate risk of damage to the environment, at any time) —

(i) to enter premises which he has reason to believe it is necessary for him to enter and to take with him any person duly authorised by the Government or the competent authority and, if the inspector has reasonable cause to apprehend any serious obstruction in the execution of his duty, a police officer; and

(ii) to take with him any equipment or materials required for any purpose for which the power of entry is being exercised;

(b) to carry out such tests and inspections (and to make such recordings), as may in any circumstances be necessary;

(c) to direct that any, or any part of, premises which he has power to enter, or anything in or on such premises, shall be left undisturbed (whether generally or in particular respects) for so long as is reasonably necessary for the purpose of any test or inspection;

(d) to take samples of any organisms, articles or substances found in or on any premises which he has power to enter, and of the air, water or land in, on, or in the vicinity of, the premises;

(e) in the case of anything found in or on any premises which he has power to enter, which appears to him to contain or to have contained genetically modified organisms which have caused or are likely to cause damage to the environment, to cause it to be dismantled or subjected to any process or test (but not so as to damage or destroy it unless this is necessary);

(f) in the case of anything mentioned in paragraph (e) or anything found on premises which he has power to enter which appears to be a genetically modified organism or to consist of or include genetically modified organisms, to take possession of it and detain it for so long as is necessary for all or any of the following purposes, that is to say —

(i) to examine it and do to it anything which he has power to do under that paragraph;

(ii) to ensure that it is not tampered with before his examination of it is completed; and

(iii) to ensure that it is available for use as evidence in any proceedings for an offence under section 180N;

(g) to require any person whom he has reasonable cause to believe to be able to give any information relevant to any test or inspection under this section to answer (in the absence of persons other than a person nominated to be present and any persons whom the inspector may allow to be present) such questions as the inspector thinks fit to ask and to sign a declaration as to the truth of his answers;

(h) to require the production of, or where the information is recorded in computerised form, the furnishing of extracts from, any records which are required to be kept under this Part or it is necessary for him to see for the purposes of any test or inspection under this section and to inspect, and take copies of, or of any entry in, the records;

(j) to require any person to afford him such facilities and assistance with respect to any matters or things within that person's control or in relation to which that person has responsibilities as are necessary to enable the inspector to exercise any of the powers conferred on him by this section;

(k) any other power for the purpose mentioned in sub-section (1) which is conferred by regulations made by the Government.

(4) The Government may by regulations make provision as to the procedure to be followed in connection with the taking of, and the dealing with, samples under sub-section (3)(d).

(5) Where an inspector proposes to exercise the power conferred by sub-section (3) (e), he shall, if so requested by a person who at the time is present on and has responsibilities in relation to those premises, cause anything which is to be done by virtue of that power to be done in the presence of that person.

(6) Before exercising the power conferred by sub-section (3)(e), an inspector shall consult such persons as appear to him appropriate for the purpose of ascertaining what dangers, if any, there may be in doing anything which he proposes to do under the power.

(7) Where under the power conferred by sub-section (3)(f) an inspector takes possession of anything found on any premises, he shall leave there, either with a responsible person or, if that is impracticable, fixed in a conspicuous position, a notice giving particulars sufficient to identify what he has seized and stating that he has taken possession of it under that power; and before taking possession under that power of —

(a) any thing that forms part of a batch of similar things; or

(b) any substance;

an inspector shall, if it is practical and safe for him to do so, take a sample of it and give to a responsible person at the premises a portion of the sample marked in a manner sufficient to identify it.

(8) No answer given by a person in pursuance of a requirement imposed under sub-section (3)(g) shall be admissible in evidence in any proceedings against that person

(9) The powers conferred by sub-sections (3)(a), (b), (c), (d), (e) and (h) shall also be exercisable (subject to sub-sections (4), (5) and (6)) by any person authorised for the purpose in writing by the Government.

(10) Nothing in this section shall be taken to compel the production by any person of a document of which he would on grounds of legal professional privilege be entitled to withhold production on an order for discovery in an action in the Supreme Court.

(11) Every person being employed in the administration of this Part or any regulations made hereunder shall regard information obtained in the exercise of the powers contained in this Part as entirely confidential.

Obtaining of information from persons.

180L. (1) For the purposes of the discharge of its functions under this Part, the competent authority may, by notice in writing served on any person who appears to it —

(a) to be involved in the importation, acquisition, keeping, release or marketing of genetically modified organisms; or

(b) to be about to become, or to have been, involved in any of those activities;

require that person to furnish such relevant information available to it as is specified in the notice, in such form and within such period following service of the notice as is so specified.

(2) For the purposes of this section "relevant information" means information concerning any aspects of the activities in question, including any damage to the environment which may be or have been caused thereby and the discharge by the Government of an obligation under the Community Treaties or any international agreement concerning the protection of the environment from harm caused by genetically modified organisms shall be treated as a function of his under this Part.

Power to deal with cause of imminent danger of damage to the environment.

180M. (1) Where, in the case of anything found by him on any premises which he has power to enter, an inspector has reason to believe that it is a genetically modified organism or that it consists of or includes genetically modified organisms and that, in the circumstances in which he finds it, it is a cause of imminent danger of damage to the environment, he may seize it and cause it to be rendered harmless (whether by destruction, by bringing it under proper control or otherwise).

(2) Before there is rendered harmless under this section —

(a) any thing that forms part of a batch of similar things, or

(b) any substance,

the inspector shall, if it is practicable and safe for him to do so, take a sample of it and give to a responsible person at the premises a portion of the sample marked in a manner sufficient to identify it.

(3) As soon as may be after anything has been seized and rendered harmless under this section, the inspector shall prepare and sign a written report giving particulars of the circumstances in which it was seized and so dealt with by him, and shall —

(a) give a signed copy of the report to a responsible person at the premises where it was found by him; and

(b) unless that person is the owner of it, also serve a signed copy of the report on the owner;

and if, where paragraph (b) applies, the inspector cannot after reasonable inquiry ascertain the name or address of the owner, the copy may be served on him by giving it to the person to whom a copy was given under paragraph (a).

Offences.

180N. (1) It is an offence for a person —

(a) to do anything in contravention of section 180C(1) in relation to something which is, and which he knows or has reason to believe is, a genetically modified organism;

(b) to fail to comply with section 180C(3) when keeping something which is, and which he knows or has reason to believe is, a genetically modified organism;

(c) to do anything in contravention of section 180F(1) or (2) in relation to something which is, and which he knows or has reason to believe is, a genetically modified organism;

(d) to fail to comply with any requirement of sub-section (2), (3) (a), (b) (c) or (4) of section 180D in relation to something which is, and which he knows or has reason to believe is, a genetically modified organism;

(e) to fail, without reasonable excuse, to comply with section 180C(5) or (6) or section 180F(7);

(f) to contravene any prohibition imposed on him by a prohibition notice;

(g) without reasonable excuse, to fail to comply with any requirement imposed under section 180K;

(h) to prevent any other person from appearing before or from answering any question to which an inspector may, by virtue of section 180K(3), require an answer;

(j) intentionally to obstruct an inspector in the exercise or performance of his powers or duties, other than his powers or duties under section 180M;

(k) intentionally to obstruct an inspector in the exercise of his powers or duties under section 180M;

(l) to fail, without reasonable excuse, to comply with any requirement imposed by a notice under section 180L;

(m) to make a statement which he knows to be false or misleading in a material particular, or recklessly to make a statement which is false or misleading in a material particular, where the statement is made —

(i) in purported compliance with a requirement to furnish any information imposed by or under any provision of this Part; or

(ii) for the purpose of obtaining the grant of a consent to himself or any other person or the variation of a consent;

(n) intentionally to make a false entry in any record required to be kept under section 180C or 180F;

(p) with intent to deceive, to forge or use a document purporting to be issued under section 180F or required for any purpose thereunder or to make or have in his possession a document so closely resembling any such document as to be likely to deceive;

(q) falsely to pretend to be an inspector.

(2) It shall be a defence for a person charged with an offence under sub-section (1)(a), (b), (c), (d) or (f) to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

(3) A person convicted of an offence under sub-section (1) or under any regulation made under this Part shall be liable, on summary conviction, to a fine not exceeding level 3 of the standard scale or to imprisonment for a term not exceeding 3 months, or to both.

(4) Where a person is convicted of an offence under sub-section (1)(b) in respect of the keeping by him of any genetically modified organism the court shall, upon conviction, order that any such genetically modified organisms be forfeit to the Crown.

(5) If the contravention in respect of which a person was convicted is continued after he was convicted he shall be guilty of a further offence and liable on summary conviction to a fine of one fifth of the amount at level 3 on the standard scale for each day on which the contravention is so continued.

Onus of proof as regards techniques and evidence.

180P. (1) In any proceedings for either of the following offences, that is to say —

(a) an offence under section 180N(1)(c) consisting in a failure to comply with the general condition implied by section 180G(4)(c) or 180G(5)(c); or

(b) an offence under section 180N(1)(d) consisting in a failure to comply with section 180D(3)(c) or 180D(4)(c);

it shall be a defence for the accused to prove that there was no better available technique not entailing excessive cost than was in fact used to satisfy the condition or to comply with that section.

(2) Where an entry is required by a condition in a consent to be made in any record as to the observance of any other condition and the entry has not

been made, that fact shall be admissible as evidence that that other condition has not been observed.

Power of court to order cause of offence to be remedied.

180Q. (1) Where a person is convicted of an offence under section 180N(1)(a), (b), (c), (d), (e) or (f) in respect of any matters which appear to the court to be matters which it is in his power to remedy, the court shall, in addition to or instead of imposing any punishment, order him, within such time as may be fixed by the order, to take such steps as may be specified in the order for remedying those matters.

(2) The time fixed by an order under sub-section (1) may be extended or further extended by order of the court on an application made before the end of the time as originally fixed or as extended under this sub-section, as the case may be.

(3) Where a person is ordered under sub-section (1) to remedy any matters, that person shall not be liable under section 180N in respect of those matters, in so far as they continue during the time fixed by the order or any further time allowed under sub-section (2).

Power of competent authority to remedy harm.

180R. (1) Where there is a failure by any person to fulfil an obligation under this Part and that failure causes any harm which it is possible to remedy, the competent authority may, subject to sub-section (2) —

(a) arrange for any reasonable steps to be taken towards remedying the harm; and

(b) recover the cost of taking those steps from any person having that obligation.

(2) The competent authority shall not exercise its powers under this section where any of the steps are to be taken on or will affect land in the occupation of any person other than the person having the obligation in question, except with the permission of that person.

The competent authority.

180S. (1) Neither the competent authority nor any of its members, officers or servants shall be liable in damages for anything done or omitted in the discharge or purported discharge of any powers or functions conferred on the competent authority by this Part or rules or regulations made hereunder.

(2) The Government may prescribe fees to be charged by the competent authority in respect of the carrying out of its functions under this Part.

Offences by bodies corporate.

180T. (1) Where an offence under any provision of this Part committed by a body corporate is proved to have been committed with the consent or connivance of, or to have been attributable to any neglect on the part of any director, manager, secretary or other similar officer of the body corporate or a person who was purporting to act in any such capacity, he as well as the body corporate shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

(2) Where the affairs of a body corporate are managed by its members, sub-section (1) shall apply in relation to the acts or defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(3) A fine imposed on an unincorporated association on its conviction for an offence shall be paid out of the funds of the association.

(4) Where an offence under this Part committed by a partnership is proved to have been committed with the consent or connivance of or to have been attributable to any neglect on the part of a partner he as well as the partnership is guilty of the offence and liable to be proceeded against and punished accordingly.

Offences under these regulations due to fault of others.

180U. Where the commission by any person of an offence under this Part is due to the act or default of some other person, that other person may be charged with and convicted of the offence by virtue of this section whether or not proceedings for the offence are taken against the first-mentioned person.

Application to Crown.

180V. (1) Subject to the provisions of this section and subject to the provisions of the Crown Proceedings Act, the provisions of this Part and of regulations made under it shall bind the Crown.

(2) No contravention by the Crown of any provision of this Part or of any regulations made under it shall make the Crown criminally liable, but the Supreme Court may, on the application of any body charged with enforcing that provision, declare unlawful any act or omission of the Crown which constitutes such a contravention.

(3) Notwithstanding anything in sub-section (2), the provisions of this Part and of regulations and rules made under it shall apply to persons in the public service of the Crown as they apply to other persons.

(4) If the Government certifies that it appears to it, as respects any Crown premises and any powers of entry exercisable in relation to them specified in the certificate that it is requisite or expedient that, in the interests of national security, the powers should not be exercisable in relation to the premises, those powers shall not be exercisable in relation to those premises, and in this sub-section "Crown premises" means premises held or used by or on behalf of the Crown.

(5) Nothing in this section shall be taken as in any way affecting servants or agents of the Government in their private capacity.

Public Register.

180W. (1) The competent authority shall keep a public record of all notifications made to it and of any consents or prohibitions issued by it under the provisions of this Part or any regulations made thereunder.

(2) The competent authority shall from time to time cause to be advertised by notice in the Gazette the time and place where the public record shall be open for inspection upon payment of a prescribed fee.

(3) Any information required to be notified to the competent authority will be removed from the public record and treated as confidential if the notifier indicates the information in the notification submitted by him contains information that might harm his competitive position.

(4) Verifiable justification shall be given in any case to which sub-section (3) applies, and it shall be entirely a matter within the discretion of

the competent authority, after consultation with the notifier, which information will be kept confidential.

(5) The competent authority shall inform the notifier of its decision made under sub-section (4).

Power to make regulations to give effect to Community obligations.

180X. The Government may by regulations provide that the provisions of this Part shall have effect with such modifications as may be therein prescribed for the purpose of enabling the Government to give effect to any Community obligation or exercise any related right provided for in the Directives and may so provide for matters incidental and supplementary thereto and for any matter which may be prescribed by virtue of the provisions of this Part and for any matter in respect of which there is provision in this Part for the making of regulations.".

Dated this 28th day of December, 1995.

J. Pilcher,
Minister for the Environment and Tourism.

LEGAL NOTICE NO. 155 OF 1995.

PUBLIC HEALTH ACT

PUBLIC HEALTH (GENETICALLY MODIFIED ORGANISMS) (CONTAINED USE) REGULATIONS 1995

ARRANGEMENT OF REGULATIONS

Regulation

PART VI

MISCELLANEOUS AND GENERAL

LEGAL NOTICE NO.155 OF 1995.

PUBLIC HEALTH ACT

PUBLIC HEALTH (GENETICALLY MODIFIED ORGANISMS) (CONTAINED USE) REGULATIONS 1995

In exercise of the powers conferred on it by section 180X of the Public Health Act, and of all other enabling powers, and for the purpose of transposing into the national law of Gibraltar Council Directives 90/219/EEC and 94/51/EEC the Government has made the following regulations —

Title and commencement.

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

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

PART I

GENERAL

Interpretation.

2. (1) In these regulations, unless the context shall otherwise require —

"accident" means any incident involving a significant and unintended release of genetically modified organisms in the course of an activity involving genetic modification which presents an immediate or delayed hazard to human health or to the environment;

"approved" means approved in writing for the time being by the Competent Authority;

"activity involving genetic modification" means any operation involving the contained use of a genetically modified organism;

"Competent Authority" means the person or body designated as the Competent Authority by the Government from time to time by notice in the Gazette under section 180A;

"a competent authority of a member State" means a competent authority of the United Kingdom or of another member State appointed by the United Kingdom or that State, as the case may be, for the purposes of the Contained Use Directive;

"contained use" means any operation in which organisms are genetically modified or in which such genetically modified organisms are

cultured, stored, used, transported, destroyed or disposed of and for which physical barriers or a combination of physical barriers with chemical or biological barriers or both, are used to limit their contact with the general population and the environment;

"the Contained Use Directive" means Council Directive 90/219/EEC, as amended by Council Directive 94/51/EEC, on the contained use of genetically modified micro-organisms and includes any changes made to that Directive under Article 20 thereof to reflect technical or scientific change and any further Directives made for that purpose;

"genetic modification" in relation to an organism means the altering of the genetic material in that organism by a way that does not occur naturally by mating or natural recombination or both and within the terms of this definition —

(a) genetic modification occurs at least through the use of the techniques listed in Part I of Schedule 1; and

(b) the techniques listed in Part II of that Schedule are not considered to result in genetic modification, and

"genetically modified" shall be construed accordingly;

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

"micro-organism" means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material including animal or plant cell cultures;

"organism" means a biological entity capable of replication or of transferring genetic material and includes a micro-organism;

"self-cloning" means the removal of nucleic acid from a cell or organism, followed by the re-insertion of all or part of that nucleic acid with or without further enzymic, chemical or mechanical steps-into the same cell type (or cell-line) or into a phylogenetically closely related species which can naturally exchange genetic material with the donor species;

"Type A operation" means any activity involving genetically modified micro-organisms for the purposes of teaching, research, development, or for non-industrial or non-commercial purposes on a scale at which the practices and conditions of the operations relative to the culture, volume and numbers of organisms involved is such that —

(a) the system used to keep the organisms under containment reflects good microbiological practice and good occupational safety and hygiene; and

(b) it is possible easily to render the organisms inactive by standard laboratory decontamination techniques;

"Type B operation" means any activity involving the genetic modification of micro-organisms other than a Type A operation.

(2) Genetically modified organisms shall be classified —

(a) in the case of micro-organisms —

(i) as Group I micro-organisms if they comply with such of the criteria set out in Part I of Schedule 2 as are applicable to the particular case, determined in accordance with the guidelines set out in Part II of that Schedule which gives effect to Commission Decision 91/448/EEC; or

(ii) as Group II micro-organisms if they do not comply with the said criteria; or

(b) in the case of genetically modified organisms other than micro-organisms, in accordance with the criteria set out in Part III of Schedule 2.

Application.

3. (1) These regulations shall have effect with a view to protecting persons against risks to their health, whether immediate or delayed, and for the protection of the environment, arising from activities involving genetically modified organisms.

(2) Regulations 7 to 11 shall not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(3) These regulations shall not apply to the genetic modification of organisms solely by any of the techniques referred to in Part III of Schedule I or to any organisms so modified.

(4) Insofar as these regulations relate to the protection of the environment, they shall only apply to genetically modified micro-organisms.

(5) Nothing in these regulations shall prejudice any requirement imposed by or under any enactment which relates to public health or the protection of the environment.

Meaning of "work" and "at work".

4. For the purpose of these regulations the meaning of "work" shall be extended to include any activity involving genetic modification and the meaning of "at work" shall be extended accordingly.

PART II

NOTIFICATION OF AND CONSENT FOR ACTIVITIES INVOLVING GENETIC MODIFICATION

Prohibition of certain work with genetically modified organisms outside containment.

5. (1) Subject to sub-regulation (2), any operation in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of is prohibited unless it is undertaken in conditions of contained use in accordance with these regulations.

(2) Sub-regulation (1) shall not apply to any operation in which —

(a) genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of where such organisms are or are contained in a product marketed in pursuance of —

(i) a consent granted by the Competent Authority under section 180F; or

(ii) a written consent given by a competent authority of a member State in accordance with Article 13(4) of Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms,

and in either case, the operation is conducted is accordance with any conditions or limitations attached to that consent;

(b) genetically modified organisms are released or marketed in circumstances in which the consent of the Competent Authority is required under section 180F.

(3) In this regulation, "product" means a product consisting of or containing a genetically modified organism or a combination of genetically modified organisms.

Risk assessment.

6. (1) A person shall not —

(a) use any premises for activities involving genetic modification for the first time; or

(b) undertake any activity involving genetic modification,

unless he has ensured that, before commencing that use or activity, as the case may be, a suitable and sufficient assessment of the risks created thereby to human health and the environment has been made.

(2) Without prejudice to the generality of sub-regulation (1), the purposes of the assessment undertaken under that sub-regulation shall include —

(a) classifying any genetically modified organisms involved in the activity in accordance with the provisions of Schedule 2; and

(b) where appropriate, making decisions about the levels of containment required for the activity concerned.

(3) In making the assessment required by sub-regulation (1) the person undertaking that assessment shall —

(a) in particular, take due account of the parameters set out in Schedule 3 in as far as they are relevant; and

(b) in a case in which the Competent Authority has approved a method in relation to the activity involving genetic modification concerned or in relation to a particular element of that assessment, undertake the assessment in accordance with that method.

(4) The assessment shall be reviewed forthwith if —

(a) there is reason to suspect that the assessment is no longer valid; or

(b) there has been a significant change in the activity to which the assessment relates.

(5) The person making the assessment shall make a record of it and of any subsequent review and shall keep that record for at least 10 years from the date on which use of the premises or the activity, as the case may be, to which the assessment related, ceased.

Notification of the intention to use premises for activities involving genetic modification for the first time.

7. (1) Subject to sub-regulations (2) to (6) and regulation 9, no person shall undertake any activity involving genetic modification at any premises for the first time, unless he has notified the Competent Authority of his intention to do so at least 90 days in advance or before such shorter time as the Competent Authority may approve and with that notification has furnished the particulars specified in Schedule 4.

(2) In the case of activities involving the genetic modification of micro-organisms, separate notifications shall be made of an intention to use the premises for activities involving genetically modified micro-organisms of Group I or Group II.

(3) In the case of activities involving genetically modified micro-organisms of Group II, the premises shall only be used for those activities after the Competent Authority has given its consent.

(4) In any other case, the use of the premises for the activity may be commenced at or after the end of the period of 90 days, or such shorter period as the Competent Authority may have approved in pursuance of sub-regulation (1), unless the Competent Authority objects in writing before the end of the relevant period.

(5) In any case in which a consent is required under sub-regulation (3), the Competent Authority shall communicate its decision on the application in writing within 90 days after the application was received.

(6) Nothing in this regulation shall prevent a person from notifying under regulation 8 an individual activity which he intends to undertake in the premises at the same time as making a notification under this regulation and in such a case he shall not commence the activity except in accordance with the time periods specified in this regulation.

Notification of individual activities involving genetic modification.

8. (1) Subject to sub-regulations (2) to (7) and regulation 9, no person shall undertake any activity involving genetic modification unless he has notified the Competent Authority of his intention to do so at least 60 days in advance or before such shorter time as the Competent Authority may approve and has furnished the particulars specified in sub-regulations
(2) to (7) and, except in the case of an activity to which sub-regulation (5) applies, the activity may be commenced after the expiry of the relevant period if by then the Competent Authority has not objected in writing.

(2) In the case of an activity which is —

(a) a Type A operation involving only micro-organisms classified as Group I; or

(b) an activity involving genetically modified organisms other than micro-organisms and which satisfy the criteria set out in Part III of Schedule 2,

it shall be a sufficient compliance with sub-regulation (1) if the person undertaking the activity keeps a record of such activities and forthwith after the end of each calendar year notifies the Competent Authority —

(c) of the total number of risk assessments under regulation 6 undertaken during that year;

(d) where appropriate, that he is intending to continue to undertake such activities; and

(e) that the information notified to the Competent Authority in accordance with regulation 7 remains correct.

(3) In the case of an activity which is a Type B operation involving only micro-organisms classified as Group 1, the specified particulars for the purposes of sub-regulation (1) shall be those specified in Part I of Schedule 5.

(4) In the case of an activity which is —

(a) a Type A operation involving genetically modified micro-organisms classified as Group II; or

(b) an activity involving genetically modified organisms other than micro-organisms and which do not satisfy the criteria set out in Part III of Schedule 2,

the specified particulars for the purposes of sub-regulation (1) shall be those specified in Parts I and II of Schedule 5.

(5) In the case of an activity which is a Type B operation involving genetically modified micro-organisms classified as Group II, the specified particulars for the purposes of sub-regulation (1) shall be those specified in Parts I, II and III of Schedule 5 and the activity shall only be commenced with the consent of the Competent Authority.

(6) In any case in which a consent is required under sub-regulation (5), the Competent Authority shall communicate its decision on the application in writing within 90 days after the application was received.

(7) The Competent Authority may accept as a single notification a connected programme of work covering more than one activity involving

genetic modification at one site, or a single activity carried on by the same person at more than one site.

Additional provisions relating to notifications and consents.

9.(1) Where necessary for the purpose of evaluating a notification made under regulation 7 or 8, the Competent Authority may require in writing the person making the notification to give such additional information relating to the proposal as it may specify and, in such a case, the person making the notification shall not proceed with the activity involving genetic modification, until the Competent Authority gives its approval, and the period between the time when the Competent Authority requires the information and the notifier responds to the satisfaction of the Competent Authority shall not be taken into account in calculating the periods of days referred to in the provisions concerned.

(2) Any consent granted by the Competent Authority under regulation 7 or 8 may be granted subject to conditions or to a limit of time and may be revoked or varied at any time and in such a case the person undertaking the activity shall comply with those conditions.

(3) Where a person making a notification in pursuance of regulation 7 or 8 subsequently makes a significant change in any premises or activity to which the notification relates or becomes aware of any new information which would affect the particulars previously notified, he shall forthwith notify the Competent Authority thereof.

(4) If information subsequently becomes available to the Competent Authority which could have significant consequences for the risks to health or the environment created by an activity involving genetic modification which has been notified to it, it may require the notifier to modify the conditions under which the activity is carried out, or to suspend or terminate the activity.

(5) Notifications made in pursuance of regulations 7 and 8 shall be in a form approved by the Competent Authority.

Advisory power of Competent Authority.

10. The Competent Authority shall advise any person or body that undertakes an assessment made for the purposes of regulation 6(1) in relation to that assessment.

PART III

CONDUCT OF ACTIVITIES INVOLVING GENETIC MODIFICATION

Standards of occupational and environmental safety and containment.

11.(1) For any activity involving genetically modified micro-organisms of Group I, the principles of good microbiological practice and the following principles of good occupational safety and hygiene shall apply, that is to say —

(a) keeping workplace and environmental exposure to any physical, chemical and biological agent adequately controlled;

(b) exercising engineering control methods at source and supplementing these with appropriate personal protective clothing and equipment where necessary;

(c) testing and maintaining control measures and equipment;

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

(e) providing training of personnel; and

(f) formulating and implementing local rules for the safety of personnel.

(2) For the purpose of sub-regulation (1) "adequate" in relation to the control of an agent means adequate having regard only to the nature of the agent and the nature and degree of exposure to such an agent and "adequately" shall be construed accordingly.

(3) For any activities involving genetically modified micro-organisms of Group II in Type A operations, in addition to the principles set out in sub-regulation (1) the containment measures shall be determined by a method approved by the Competent Authority.

(4) For any activities involving genetically modified micro-organisms of Group II in Type B operations, in addition to the principles set out in sub-regulation (1) the containment measures set out in Schedule 6 shall be applied at an appropriate level so as to ensure a high level of health and safety and environmental protection.

(5) For any activities involving genetically modified organisms other than micro-organisms, the principles set out in sub-regulation (1) shall be applied in as far as they are appropriate.

Emergency plans.

12. (1) Where the assessment made in accordance with regulation 6(1) shows that as a result of any reasonably foreseeable accident the health or safety of persons outside the premises in which an activity involving genetic modification is carried on is liable to be affected or there is a risk of damage to the environment, the person undertaking the activity shall ensure that a suitable emergency plan is prepared with a view to securing the health and safety of those persons and the protection of the environment.

(2) The person preparing the plan shall consult such persons, bodies and authorities as are appropriate and shall inform the emergency services in writing of the plan and of the hazards to which the plan relates.

(3) The person undertaking the activity involving genetic modification which is the subject of the emergency plan shall take appropriate measures to inform persons who are liable to be affected by an accident of the safety measures and the correct behaviour to adopt in the event of an accident.

(4) The information required to be given in pursuance of sub-regulation (3) shall be repeated and brought up to date at appropriate intervals and shall be made publicly available.

Notification of accidents.

13. (1) Where an accident occurs, the person undertaking the activity involving genetically modified organisms shall forthwith notify the Competent Authority of it and shall provide the following information —

(a) the circumstances of the accident;

(b) the identity and quantity of genetically modified organisms released;

(c) any information necessary to assess the effects of the accident on the health of the general population and on the environment; and

(d) the emergency measures taken.

(2) Where the Competent Authority receives a notification in pursuance of sub-regulation (1), the Competent Authority shall —

(a) ensure that any emergency, medium and long term measures are taken;

(b) immediately inform any member State that could be affected by the accident;

(c) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit their effects; and

(d) send to the European Commission the information provided for under sub-regulation (1), together with an analysis of the accident and details of any recommendations made to avoid similar accidents in the future and to limit their effects.

PART IV

DISCLOSURE OF INFORMATION NOTIFIED AND PUBLICITY

Disclosure of information notified.

14. (1) Where a person making a notification in pursuance of regulations 7, 8 and 9 indicates that it contains certain information the disclosure of which might harm his competitive position and should be kept confidential, full justification for that indication shall be given and in such a case after consulting the notifier the Competent Authority shall decide which

information shall be kept confidential and shall inform the notifier of its decision.

(2) Nothing in sub-regulation (1) shall apply to the following information which shall not be kept confidential —

(a) the name and address of the notifier and the location of the activity involving genetic modification;

(b) the purpose of the activity;

(c) the description of the genetically modified organism involved;

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

(e) the evaluation of foreseeable effects and in particular pathogenic effects and ecologically disruptive effects.

(3) Notwithstanding sub-regulation (2), where the Competent Authority is satisfied on the basis of detailed evidence submitted to it by the notifier and where appropriate, after consultation with the notifier, that it is necessary to withhold, for the time being, certain of the information specified in sub-regulation (2) in order to protect his intellectual property rights, the Competent Authority shall withhold that information to the extent and for so long as it is necessary to protect those rights.

(4) Information which is kept confidential in accordance with sub-regulation (1) or withheld in accordance with sub-regulation (3) shall be disclosed only —

(a) to the Government;

(b) to the European Commission or the competent authority of a member State;

(c) for the purpose of any legal proceedings;

(d) with the consent of the notifier; or

(e) to the extent necessary to evaluate the notification.

(5) A person who receives information in accordance with sub-regulation (4)(e) shall not use that information except for a purpose of the Competent Authority or the Government.

(6) Where the notifier has requested that certain information in the notification shall be kept confidential in accordance with sub-regulation (1) or withheld in accordance with sub-regulation (3), the Competent Authority shall not disclose any of that information (except in accordance with sub-regulation (4)) until at least 14 days after it has reached a decision under the relevant sub-regulation.

(7) After consulting the notifier, the Competent Authority may review any decision made under sub-regulation (1) or (3) and shall inform the notifier of the result of that review.

(8) Where, for whatever reason, the notifier withdraws the notification, the Competent Authority shall not thereafter disclose any of the information supplied.

Register of notifications.

15. (1) The Competent Authority shall maintain a register of notifications to which regulation 7(3) or 8(5) relates (for which the consent of the Competent Authority is required) and that register shall be open to inspection by members of the public at any reasonable time.

(2) The register referred to in sub-regulation (1) shall contain in relation to each such notification —

(a) such of the information referred to in sub-regulation (3) of regulation 14 as has not been withheld in accordance with sub-regulation (4) of that regulation; and

(b) a statement as to whether or not the consent of the Competent Authority has been granted.

(3) The information referred to in sub-regulation (2)(a) shall be entered in the register within 14 days of its receipt by the Competent Authority and the information referred to in sub-regulation (2)(b) within 14 days of the decision whether to grant the consent or not having been made, except that where the notifier has requested that certain information specified in

regulation 14(3) be withheld in accordance with regulation 14(4), that information shall only be entered in the register not less that 14 days but not more than 28 days after the Competent Authority has made a decision not to withhold that information.

PART V

ADDITIONAL DUTIES PLACED ON THE COMPETENT AUTHORITY

Duties on receiving notifications.

16. The Competent Authority shall examine a notification under regulations 7 or 8 for —

(a) the conformity with the requirements of these regulations;

(b) the accuracy and completeness of the information given;

(c) the correctness of the classification of the organisms to which the notification relates in accordance with Schedule 2; and

(d) where appropriate, the adequacy of the waste management, safety and emergency response measures.

Information to be sent to the Government.

17 Forthwith after receipt, the Competent Authority shall send to the Government a copy in each case of —

(a) any notification received under regulations 7 or 8;

(b) any requirement for further information under regulation 9(1) and the response thereto; and

(c) any notification relating to an accident under regulation 13, and if requested to do so by the Government shall require additional information under regulation 9(1).

Reports to the European Commission.

18. The Competent Authority shall send to the European Commission reports of notifications for which a consent is required under regulation 8(5) and summary reports of the application of these regulations in accordance with Article 18 of the Contained Use Directive.

PART VI

MISCELLANEOUS AND GENERAL

Exemption certificates.

19.(1) Subject to sub-regulation (2) and to any provisions imposed by the Communities in respect of the control and regulation of genetically modified organisms, the Competent Authority may, with the agreement of the Government in so far as the exemption relates to the environment, by a certificate in writing, exempt any person or class of persons, genetically modified organism or class of genetically modified organisms from all or any of the requirements or prohibitions imposed by these regulations and any such exemption may be granted subject to conditions and to a time limit and may be revoked by a certificate in writing at any time.

(2) The Competent Authority shall not grant any such exemption unless, having regard to the circumstances of the case and in particular to —

(a) the conditions, if any, that it proposes to attach to the exemption; and

(b) any requirements imposed by or under any enactments which apply to the case, likely to be affected by the exemption,

the protection of the environment will not be prejudiced in consequence of it.

Enforcement and civil liability.

20.(1) It is an offence for a person —

(a) to fail to discharge a duty to which he is subject by virtue of the provisions of these regulations;

(b) to contravene any requirement or prohibition imposed by these regulations;

(2) In the event of a breach of duty imposed by regulations 5 to 13 the Competent Authority shall have a right of action in civil proceedings if that breach of duty causes damages.

Fees for notifications.

21. (1) Fees shall be payable in accordance with sub-regulation (2) by a notifier to the Competent Authority in relation to any matter referred to in that sub-regulation.

(2) The fees referred to in sub-regulation (1) shall be —

(a) subject to paragraph (b), on each notification of the intention to use premises for activities involving genetic modification for the first time under regulation 7, £100;

(b) on each notification of the intention to use premises for activities involving genetic modification for the first time where a consent is required under regulation 7(3), £130;

(c) subject to paragraph (d), on each notification of individual activities involving genetic modification under regulation 8, £180;

(d) on each notification of individual activities involving genetic modification for which a consent is required under regulation 8(5), £270.

SCHEDULE 1

Regulations 2(1) and 3(3)

DEFINITION OF GENETIC MODIFICATION

PART I

Examples of techniques constituting genetic modification

1. Examples of the techniques which constitute genetic modification which are referred to in paragraph (a) of the definition of genetic modification in regulation 2(1) are —

(a) recombinant DNA techniques consisting of 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 occur naturally but in which they are capable of continued propagation;

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

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

PART II

Techniques which are not considered to result in genetic modification

2. The following techniques are not considered to result in genetic modification if they do not involve the use of recombinant-DNA molecules or genetically modified organisms —

(a) in vitro fertilisation;

(b) conjugation, transduction, transformation or any other natural process; and

(c) polyploidy induction.

PART III

Techniques to which these regulations do not apply

3. These regulations shall not apply to the following techniques of genetic modification if they do not involve the use of genetically modified organisms as recipient or parental organisms —

(a) mutagenesis;

(b) the construction and use of somatic hybridoma cells (for example for the production of monoclonal antibodies);

(c) cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods;

(d) self-cloning of non-pathogenic naturally occurring micro-organisms which fulfil the criteria of Group I for recipient micro-organisms; and

(e) self-cloning of non-pathogenic naturally occurring organisms other than micro-organisms which fulfil the criteria of Part III of Schedule 2.

SCHEDULE 2

Regulation 2(2)

CRITERIA FOR THE CLASSIFICATION OF ORGANISMS

PART I

Criteria for classifying genetically modified micro-organisms into Group I

4. A genetically modified micro-organism is classified as falling within Group I when all the following criteria are fulfilled —

(a) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants;

(b) the nature of the vector and the insert is such that they do not endow the genetically modified micro-organism with a

phenotype likely to cause disease to humans, anmilas or plants, or likely to cause adverse effects in the environment;

(c) the genetically micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to cause adverse effects in the environment.

PART II

Guidelines as applicable for classification of micro-organisms in Group I

For classification into Group I the following guidelines should be used to further interpret Part I of this Schedule

5. Characteristics of the recipient or parental organism(s)

(1) Non-pathogenic

The recipient or parental organisms can be classified as non-pathogenic if they satisfy the conditions of one of the following clauses —

(a) the recipient or parental strain should have an established record of safety in the laboratory and/or industry, with no adverse effects on human health and the environment;

(b) the recipient or parental strain does not meet the conditions of clause (a) but it belongs to a species for which there is a long record of biological work including safety in the laboratory and/or industry, showing no adverse effects on human health and the environment;

(c) if the recipient or parental organism is a strain which does not satisfy the conditions of clause (a) and belongs to a species for which there is no record of biological work including safe use in the laboratory and/or industry, appropriate testing (including, if necessary, animals) shall be carried out, in order to establish non-pathogenicity and safety in the environment;

(d) if a non-virulent strain of an acknowledged pathogenic species is used, the strain should be as deficient as possible in genetic material that determines virulence so as to ensure no reversion

to pathogenicity. In the case of bacteria, special attention should be given to plasmid or phage-borne virulence determinants.

(2) No adventitious agents; the recipient or parental strain/cell line should be free of known biological contaminating agents (symbionts, mycoplasms, viruses, viroids, etc.), which are potentially harmful.

(3) The recipient or parental strain/cell line should have proven and extended history of safe use or built-in biological barriers, which, without interfering with optimal growth in the reactor or fermenter, confer limited survivability and replicability, without adverse consequences in the environment (applicable only for Type B operations).

6. Characteristics of the vector

(1) The vector should be well characterised. For this purpose the following characteristics should be taken into account —

(a) information on composition and construction —

(i) the type of the vector should be defined (virus, plasmid, cosmid, phasmid, transposable element, minichromosome, etc.);

(ii) the following information on the constituent fragments of the vector should be available —

(aa) the origin of each fragment (progenitor genetic element, strain of organism in which the progenitor genetic element naturally occurred),

(bb) if some fragments are synthetic, their functions should be known;

(iii) the methods used for construction should be known;

(b) information on vector structure —

(i) the size of the vector should be known and expressed in basepairs or D;

(ii) the function and relative positions of the following should be known —

(aa) structural genes,

(bb) marker genes for selection (antibiotic resistance, heavy metal resistance, phage immunity, genes coding for degradation of xenobiotics, etc.),

(cc) regulatory elements,

(dd) target sites (nic-sites, restriction endonuclease sites, Tinkers, etc.),

(ee) transposable elements (including provirus sequences),

(ff) genes related to transfer and mobilisation function (e.g. with respect to conjugation, transduction or chromosomal integration),

(gg) replicon(s).

(2) The vector should be free from harmful sequences. The vector should not contain genes coding for potentially harmful or pathogenic traits (e.g. virulence determinants, toxins, etc.) unless for Type A operations, such genes constitute an essential feature of the vector without, under any conditions or circumstances, resulting in a harmful or pathogenic phenotype of the genetically modified micro-organism.

(3) The vector should be limited in size as much as possible to the genetic sequences required to perform the intended function.

(4) The vector should not increase the stability of the genetically modified micro-organism in the environment (unless that is a requirement of the intended function).

(5) The vector should be poorly mobilisable —

(a) if the vector is a plasmid —

(i) it should have a restricted host-range;

(ii) it should be defective in transfer-mobilisation factors e.g. Tra, MobS. 036, for Type A operations or Tra, Mob, for Type B operations;

(b) if the vector is a virus, cosmid or phasmid —

(i) it should have a restricted host-range;

(ii) it should be rendered non-lysogenic when used as a cloning vector (e.g. defective in the ci-lambda repressor).

(6) It should not transfer any resistance markers to micro-organisms not known to acquire them naturally (if such acquisition could compromise use of drugs to control disease agents).

7. Required characteristics of the insert

(1) The insert should be well characterised. For this purpose, the following characteristics should be taken into account —

(a) the origin of the insert should be known (genus, species, strain);

(b) the following information on the library from which the insert originated, should be known —

(i) the source and method for obtaining the nucleic acid of interest (CDNA, chromosomal, mitochondrial, etc.);

(ii) the vector in which the library was constructed (e.g. lambda gt 11, pBR372, etc.) and the site in which the DNA was inserted;

(iii) the method used for identification (colony, hybridization, immuno-blot, etc.);

(iv) the strain used for library construction;

(c) if the insert is synthetic, its intended function should be identified;

(d) the following information on the structure of the insert is required —

(i) information on structural genes, regulatory elements;

(ii) size of the insert;

(iii) restriction endonuclease sites flanking the insert;

(iv) information on transposable elements and provirus sequences.

(2) The insert should be free from harmful sequences —

(a) the function of each genetic unit in the insert should be defined (not applicable for Type A operations);

(b) the insert should not contain genes coding for potentially harmful or pathogenic traits (e.g. virulence determinants, toxins, etc.), (unless for Type A operations, such genes constitute an essential part of the insert without, under any circumstances, resulting in a harmful or pathogenic phenotype of the genetically modified micro-organism).

(3) The insert should be limited in size as much as possible to the genetic sequences required to perform the intended function.

(4) The insert should not increase the stability of the construct in the environment (unless that is a requirement of intended function).

(5) The insert should be poorly mobilisable. For instance, it should not contain transposing or transferable provirus sequences and other functional transposing sequences.

8. Required characteristics of the genetically modified micro-organism

(1) The genetically modified micro-organism should be non-pathogenic. This requirement is reasonably assured by compliance with all the requirements above.

(2) The genetically modified micro-organisms should be as safe —

(a) to man and the environment as the recipient or parental strains (applicable only for Type A operations);

(b) in the reactor or fermentor as the recipient or parental strains, but with limited survivability and/or replicability outside the reactor or fermenter without adverse consequences in the environment (applicable only for Type B operations).

9. Other genetically modified micro-organisms that could be included in Group I if they meet the conditions in paragraph 8

(1) Those constructed entirely from a single prokaryotic recipient (including its indigenous plasmids and viruses) or from a single eukaryotic recipient (including its chloroplasts, mitochondria, plasmids, but excluding viruses).

(2) Those that consist entirely of genetic sequences from different species that exchange these sequences by known physiological processes.

PART III

Criteria for the classification of organisms other than micro-organisms

10. An organism which satisfies the criteria of this Part is a genetically modified organism —

(a) which is not a genetically modified micro-organism; and

(b) which is as safe in the containment facility as any recipient or parental organism.

SCHEDULE 3

Regulation 6(3)

PARAMETERS TO BE TAKEN INTO ACCOUNT IN RISK ASSESSMENTS, AS FAR AS THEY ARE RELEVANT, UNDER REGULATION 6

Characteristics of the donor, recipient or (where appropriate) parental organism

1. The following matters shall be investigated and assessed in relation to any organism which is or will be a donor, recipient or parental organism —

(a) the name, species, subspecies and strain of the organism;

(b) the degree of relatedness between the donor, recipient (and where appropriate the parental) organism in relation to which the assessment is being carried out;

(c) the sources of the organism;

(d) the reproductive cycle of the organism;

(e) history of prior genetic modifications to the organism;

(f) the stability of the genetic traits of the organism;

(g) the nature of the pathogenicity, virulence, infectivity, toxicity, and vectors of disease transmission of the organism;

(h) the base sequence, frequency of mobilisation and specificity of the organisms indigenous vectors;

(j) the presence in the organism of genes which confer resistance;

(k) the host range of an organism which is a parasite or pathogen;

(l) the organisms other potentially significant physiological traits, and the stability of those traits;

(m) the organisms natural habitat and geographic distribution;

(n) the climatic characteristics of the organisms natural habitat;

(p) the significant involvement of the organism in environmental processes, including nitrogen fixation and pH rule;

(q) the interaction of the organism with other organisms in the environment and its effect on those organisms, including its likely competitive or symbiotic properties;

(r) the ability of the organism to form survival structures, including seeds, spores or sclerotia.

2. Characteristics of the modified organism

The following matters shall be investigated and assessed in relation to an organism in relation to which a risk assessment under regulation 6 is carried out —

(a) the description of the modification, including the technique used or proposed to be used to introduce a vector or insert into the organism;

(b) the nature and source of the vector introduced into the organism;

(c) the function of the genetic modification and/or of the new nucleic acid;

(d) the structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organism;

(e) the stability of the genetic traits introduced into the organism;

(f) the frequency of mobilisation of inserted vector or genetic transfer capability;

(g) the rate and level of expression of the new genetic material in .the organism, and the method and sensitivity of measurement of that rate and level;

(h) the activity of the expressed protein.

3. Health considerations

The following matters shall be investigated and assessed in relation to an organism in relation to which a risk assessment under regulation 6 is carried out —

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

(b) product hazards;

(c) comparison of the modified micro-organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(d) capacity for colonisation;

(e) if the organism is pathogenic to humans who are immunocompetent —

(i) diseases caused and mechanism of pathogenicity including invasiveness and virulence,

(ii) communicability,

(iii) infective dose,

(iv) host range, possibility of alteration,

(v) possibility of survival outside of human host,

(vi) presence of vectors or means of dissemination,

(vii) biological stability,

(viii) antibiotic-resistance patterns,

(ix) allergenicity,

(x) availability of appropriate therapies.

4. Environmental considerations

The following matters shall also be investigated and assessed in relation to an organism in relation to which a risk assessment under regulation 6 is carried out —

(a) the factors affecting survival, multiplication and dissemination of the modified organism in the environment;

(b) the available techniques for detection, identification, and monitoring of the modified organism in the environment;

(c) the available techniques for detecting transfer of the new genetic material to other organisms;

(d) the known and predicted habitats of the modified organism;

(e) the ecosystems to which the modified organism could be disseminated as a result of an escape;

(f) the anticipated mechanism and result of interaction between the modified organism and the organisms which might be exposed in case of the escape of the organism;

(g) the known or predicted effects of the organism on plants and animals, including pathogenicity, infectivity, toxicity virulence, vector or pathogen allergenicity colonisation, predation, parasitism, symbiosis and competition;

(h) the known or predicted involvement of the organism in biogeochemical processes, including nitrogen fixation and pH rule;

(j) the availability of methods for decontamination of the area in case of release to the environment.

SCHEDULE 4

Regulation 7(1)

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 7(1)

A notification required for the purposes of regulation 7(1) shall include the following information —

(a) the name and address of the person responsible for carrying out the activity and the names of persons responsible for

supervision, monitoring and safety together with details of their training and qualifications;

(b) address of the premises where the activity is to be carried on and its grid reference and, where appropriate, a description of the sections of the installation;

(c) a description of the nature of the activity to be undertaken, the likely scale of the operation and in particular, in the case of micro-organisms, their classification (whether in Group I or Group II);

(d) a summary of the risk assessment undertaken in accordance with regulation 6;

(e) the names and capacities of the members of the genetic modification safety committee;

(f) comments made by the genetic modification safety committee on the local arrangements for risk assessment;

(g) the names of the biological and deputy biological safety officers concerned with the intended activities (if any);

(h) the name of the supervisory medical officer (if any);

(j) the arrangements for health surveillance (if any); and

(k) any other information the Competent Authority needs for the purpose of maintaining the register referred to in regulation 15.

SCHEDULE 5

Regulation 8

INFORMATION REQUIRED FOR A NOTIFICATION UNDER REGULATION 9

PART I

1. Information required under regulation 8(3)

A notification required for the purposes of regulation 8(3) shall include the following information —

(a) the name and address of the person responsible for carrying out the activity;

(b) address of the premises where the activity is to be carried out;

(c) the date of the notification referred to in regulation 7(1);

(d) the parental organism used, or where applicable the host-vector system used;

(e) the source and the intended function of the genetic material involved in the modification;

(f) the identity and characteristics of the genetically modified organism;

(g) the purpose of the activity including the expected results;

(h) where appropriate the culture volumes to be used or the scale of the activity;

(j) details of waste treatment including levels of live genetically modified micro-organisms in the waste; and

(k) a summary of the risk assessment required in accordance with regulation 6 and of the comments of the genetic modification safety committee on it.

PART II

2. Additional information required under regulation 8(4)

In addition to the information required under Part I a notification made for the purposes of regulation 8(4) shall contain the following information —

(a) a description of the sections of the installation involved and the methods for handling the organisms;

(b) a description of the predominant meteorological conditions and the potential sources of danger arising from the location of the installation;

(c) a description of the protective and supervisory methods to be applied throughout the duration of the activity; and

(d) in the case of micro-organisms, the containment level to which the micro-organism has been allocated in accordance with the risk assessment made in accordance with regulation 6(1) and in any case the safety precautions to be observed.

PART III

Additional information required under regulation 8(5)

3. In addition to the information required under Parts I and II a notification made for the purposes of regulation 8(5) shall contain the information specified in paragraph 5.

4. If it is not technically possible, or if it does not appear necessary to give the information specified in paragraph 5, the reason shall be stated. The level of detail required in response to each subset of considerations is likely to vary according to the nature and scale of the proposed activity . In the case of information already submitted to the Competent Authority by the notifier under these regulations reference can be made to that information by him.

5. The additional information required is —

(a) information about the genetically modified micro-organisms —

(i) the identity and characteristics of the genetically modified micro-organisms,

(ii) the purpose of the contained use or the nature of the product,

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

(iv) the culture volume to be used,

(v) behaviour and characteristics of the micro-organisms in the case of changes in the conditions of containment or release into the environment,

(vi) overview of the potential hazards associated with the release of the micro-organisms into the environment, and

(vii) substances which are or may be produced in the course of use of the micro-organisms other than the intended product;

(b) information about personnel —

(i) the maximum number of persons working in the installation, and

(ii) the number of persons who will work directly with the micro-organisms;

(c) information about the installation —

(i) the activity in which the micro-organisms are to be used,

(ii) the technological processes used,

(iii) a description of the sections of the installation involved, and

(iv) the predominant meteorological conditions and specific hazards arising from the location of the installation;

(d) information about waste management —

(i) types, quantities and potential hazards arising from the use of the micro-organisms,

(ii) waste management techniques used including recovery of liquid or solid wastes and the inactivation techniques used, and

(iii) ultimate form and destination of inactivated wastes;

(e) information about accident prevention and emergency response plans —

(i) the sources of hazards and conditions under which accidents might occur,

(ii) the preventive measures applied such as safety equipment, alarm systems, containment methods and procedures and available resources,

(iii) a description of information given to workers, and

(iv) the information necessary for the Competent Authority to evaluate any emergency plan prepared in accordance with regulation 12;

(f) the full risk assessment referred to in regulation 6; and

(g) any other information the Competent Authority needs for the purpose of maintaining the register referred to in regulation 15.

SCHEDULE 6

Regulation 11(4)

CONTAINMENT MEASURES FOR MICRO-ORGANISMS OF GROUP II

1. The containment measures for Type B operations using micro-organisms from Group II shall be chosen by the user from the levels in the Table below as appropriate to the micro-organism and the operation in question in order to ensure the protection of health of the general population and the environment.

2. Type B operations shall be considered in terms of their unit Operations. The characteristics of each operation will dictate the physical containment to

be used at that stage. This will allow the selection and design of process, plant and operating procedures best fitted to ensure 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 risks of failure as the consequence of that failure becomes less tolerable.

Dated this 28th day of December , 1995

J. Pilcher,
Minister for the Environment and Tourism.