L.N. 194 of 2002

ENVIRONMENT PROTECTION ACT, 2001 (ACT NO. XX OF 2001)

Contained Use of Genetically Modified Micro-Organisms (Amendment) Regulations, 2002

BY VIRTUE of the powers conferred by Article 9 of the Environment Protection Act, the Minister for Home Affairs and the Environment has made the following regulations :-

Citation.

L.N. 169 of 2002

1. The title of these regulations is Contained Use of Genetically modified Micro-Organisms (Amendment) Regulations, 2002, and shall be read and construed as one with the Contained Use of Genetically Modified Micro-Organisms Regulations, 2002, hereinafter referred to as "the principal regulations".

Amends Annexes I to V of the principal regulations.

2. Annexes I to V attached to the English text of the "principal regulations", shall be substituted by Annexes I to V attached to the English text of these regulations.

ANNEX I

PART A

Techniques of genetic modification referred to in Article 3 paragraph 2 (i) are, inter alia:

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

2. Techniques involving the direct introduction into a micro-organism of heritable material prepared outside the micro-organism including micro-injection, macro-injection and micro-encapsulation.

3. Cell fusion or hybridisation 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 B

Techniques referred to in Article 4(b)(ii) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs made by techniques/methods other than techniques/methods excluded by Annex II, PART A:

(1) in vitro fertilisation;

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

(3) polyploidy induction.

ANNEX II

PART A

Techniques or methods of genetic modification yielding micro-organisms to be excluded from the Directive on the condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs other than those produced by one or more of the techniques/methods listed below:

1. Mutagenesis.

2. Cell fusion (including protoplast fusion) of prokaryotic species that exchange genetic material by known physiological processes.

3. Cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions.

4. Self-cloning consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent) with or without prior enzymic or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants. Self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular micro-organisms.

ANNEX III

PRINCIPLES TO BE FOLLOWED FOR THE ASSESSMENT REFERRED TO IN ARTICLE 5(1)

This Annex describes in general terms the elements to be considered and the procedure to be followed to perform the assessment referred to in Article 5(1). It may be supplemented, as regards in particular section B, by guidance notes which may be issued by the Authority .

A. ELEMENTS OF ASSESSMENT

1. The following should be considered as potentially harmful effects:
- disease to humans including allergenic or toxic effects,
- disease to animals or plants,
- deleterious effects due to the impossibility of treating a disease or providing an effective prophylaxis,
- deleterious effects due to establishment or dissemination in the environment,
- deleterious effects due to the natural transfer of inserted genetic material to other organisms.

2. The assessment referred to in Article 5(1) should be based on the following:
(a) the identification of any potentially harmful effects, in particular
those associated with:
(i) the recipient micro-organism;
(ii) the genetic material inserted (originating from the donor organism);
(iii) the vector;
(iv) the donor micro-organism (as long as the donor micro-organism is used during the operation);
(v) the resulting GMM;
(b) the characteristics of the activity;
(c) the severity of the potentially harmful effects;
(d) the likelihood of the potentially harmful effects being realised.

B. PROCEDURE

3. The first stage in the assessment process should be to identify the harmful properties of the recipient and, where appropriate, the donor micro-organism, any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties.

4. In general, only GMMs which show the following characteristics would be considered appropriate for inclusion in class 1 as defined in Article 5:

(i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants (1);

(1) This would only apply to animals and plants in the environment likely to be exposed.

(ii) the nature of the vector and the insert is such that they do not endow the GMM with a phenotype likely to cause disease to humans, animals or plants, or likely to cause deleterious effects in the environment;

(iii) the GMM is unlikely to cause disease to humans, animals or plants and is unlikely to have deleterious effects on the environment.

5. In order to obtain the necessary information to implement this process the user may firstly take into account relevant Community legislation (in particular Council Directive 90/679/EEC). International or national classification schemes (e.g. WHO, NIH, etc.) and their revisions due to new scientific knowledge and technical progress may also be considered.

These schemes concern natural micro-organisms and as such are usually based on the ability of micro-organisms to cause disease to humans, animals or plants and on the severity and transmissibility of the disease likely to be caused. Directive 90/679/EEC classifies micro-organisms, as biological agents, into four classes of risk on the basis of potential effects on a healthy human adult. These classes of risk can be used as guidance to the categorisation of the contained use activities in the four classes of risk referred to in Article 5(2). The user may also take into consideration classification schemes referring to plant and animal pathogens (which are usually established on a national basis). The abovementioned classification schemes give only a provisional indication of the risk class of the activity and the corresponding set of containment and control measures.

6. The hazard identification process carried out in accordance with paragraphs 3 to 5, should lead to the identification of the level of risk associated with the GMM.

7. Selection of the containment and other protective measures should then be made on the basis of the level or risk associated with the GMMs together with consideration of:

(i) the characteristics of the environment likely to be exposed (e.g. whether in the environment likely to be exposed to the GMMs there are known biota which can be adversely affected by the micro-organisms used in the contained use activity);

(ii) the characteristics of the activity (e.g. its scale; nature);

(iii) any non-standard operations (e.g. the inoculation of animals with GMMs; equipment likely to generate aerosols).

Consideration of items (i) to (iii) for the particular activity may increase, reduce or leave unaltered the level of risk associated with the GMM as identified under paragraph 6.

8. The analysis carried out as described above will finally lead to the assignment of the activity to one of the classes described in Article 5(2).

9. The final classification of the contained use should be confirmed byreviewing the completed assessment referred to in Article 5(2).

ANNEX IV

CONTAINMENT AND OTHER PROTECTIVE MEASURES

General principles

1. These tables present the normal minimum requirements and measures necessary for each level of containment.

Containment is also achieved through the use of good work practices, training, containment equipment and special installation design. For all activities involving GMMs the principles of good microbiological practice and the following principles of good occupational safety and hygiene, shall apply:

(i) to keep workplace and environmental exposure to any GMM to the lowest practicable level;

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

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

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

(v) to provide appropriate training of personnel;

(vi) to establish biological safety committees or subcommittees, if required;

(vii) to formulate and implement local codes of practice for the safety of personnel, as required;

(viii) where appropriate to display biohazard signs;

(ix) to provide washing and decontamination facilities for personnel;

(x) to keep adequate records;

(xi) to prohibit eating, drinking, smoking, applying cosmetics or the storing of food for human consumption in the work area;

(xii) to prohibit mouth pipetting;

(xiii) to provide written standard operating procedures where appropriate to ensure safety;

(xiv) to have effective disinfectants and specified disinfection procedures available in case of spillage of GMMs;

(xv) to provide safe storage for contaminated laboratory equipment and materials, when appropriate.

2. The titles of the tables are indicative:

Table I A presents minimum requirements for laboratory activities.

Table I B presents additions to and modifications of Table I A for glasshouse/growth-room activities involving GMMs.

Table I C presents additions to and modifications of Table I A for activities with animals involving GMMs.

Table II presents minimum requirements for activities other than laboratory activities.

In some particular cases, it might be necessary to apply a combination of measures, from Table I A and Table II, of the same level. In some cases users may, with the agreement of the Authority, not apply a specification under a particular containment level or combine specifications from two different levels.

In these tables "optional" means that the user may apply these measures on a case-by-case basis, subject to the assessment referred to in Article 5(1).

ANNEX V

PART A

Information required for the notification referred to in Article 6:

- name of user(s) including those responsible for supervision and safety,
- information on the training and qualifications of the persons responsible for supervision and safety,
- details of any biological committees or subcommittees,
- address and general description of the premises,
- a description of the nature of the work which will be undertaken,
- the class of the contained uses,
- only for class 1 contained uses, a summary of the assessment referred to in Article 5(1) and information on waste management.

PART B

Information required for the notification referred to in Article 8:

- the date of submission of the notification referred to in Article 6,
- the name of the persons responsible for supervision and safety and information on the training and qualification,
- the recipient, donor and/or parental micro-organism(s) used and, where applicable, the host-vector system(s) used,
- the source(s) and the intended function(s) of the genetic material(s) involved in the modification(s),
- identity and characteristics of the GMM,
- the purpose of the contained use including the expected results,
- approximate culture volumes to be used,
- description of the containment and other protective measures to be applied, including information about waste management including the wastes to be generated, their treatment, final form and destination,
- a summary of the assessment referred to in Article 5(1),
- the information necessary for the Authority to evaluate any emergency response plans if required under Article 13.

PART C

Information required for the notification referred to in Article 9:

(a) - the date of submission of the notification referred to in Article 6,
- the name of the persons responsible for supervision and safety and information on the training and qualification;

(b) - the recipient or parental micro-organism(s) to be used,
- the host-vector system(s) to be used (where applicable),
- the source(s) and intended functions(s) of the genetic material(s) involved in the modification(s),
- identity and characteristics of the GMM,

- the culture volumes to be used;

(c) - description of the containment and other protective measures to be applied, including information about waste management including the type and form of wastes to be generated, their treatment, final form and destination,

- the purpose of the contained use including the expected results,

- description of the parts of the installation;

(d) information about accident prevention and emergency response plans, if any:

- any specific hazards arising from the location of the installation,

- the preventive measures applied such as safety equipment, alarm systems and containment methods,

- procedures and plans for verifying the continuing effectiveness of the containment measures,

- a description of information provided to workers,

- the information necessary for the Authority to evaluate any emergency response plans if required under Article 13;

(e) a copy of the assessment referred to in Article 5(1).