

GENETICALLY MODIFIED ORGANISMS (AMENDMENT) REGULATIONS 1996

The Minister for the Environment, in exercise of the powers conferred on him by sections 6 of the Environmental Protection Agency Act, 1992 (No. 7 of 1992), hereby makes the following Regulations:

REG 1

1. These Regulations may be cited as the Genetically Modified Organisms (Amendment) Regulations, 1996.

REG 2

2. These Regulations shall come into operation on 2nd day of December 1996.

REG 3

3. The Genetically Modified Organisms Regulations, 1994 (S.I. No. 345 of 1994) are hereby amended:

(a) by the substitution for the Second Schedule thereto of the following Schedule:

"

ARTICLE 3

SECOND SCHEDULE

CLASSIFICATION OF GENETICALLY MODIFIED MICRO-ORGANISMS

PART I

CRITERIA FOR CLASSIFYING GENETICALLY MODIFIED MICRO-ORGANISMS INTO GROUP I

A genetically modified micro-organism shall be classified as falling within Group I when all the following criteria are fulfilled:

- (i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants,
- (ii) 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, animals or plants, or likely to cause adverse effects in the environment, and
- (iii) the genetically modified micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to have adverse effects on the environment.

PART II

GUIDELINES FOR THE CLASSIFICATION OF GENETICALLY MODIFIED MICRO-ORGANISMS INTO GROUP I

For classification of genetically modified micro-organisms into Group I, the following guidelines shall apply for the further interpretation of the criteria in Part I of this Schedule:

- 1. Criteria (i) - (iii) refer to immunocompetent humans and healthy animals or plants.
- 2. For criterion (i), the following guidelines shall apply:
 - (1) In deciding whether the recipient or parental micro-organism is likely to cause disease to animals or plants, consideration should be given to the environment likely to be exposed to the recipient or parental micro-organism.

(2) (a) Non-virulent strains of acknowledged pathogenic species could be considered as unlikely to cause disease and as satisfying criterion (1), provided that:

- (i) the: non-virulent strain has an established record of safety in the laboratory and/or industry with no adverse effects on human, animal or plant health, and/or
- (ii) the strain is stably deficient in genetic material that determines virulence, or has stable mutations known to sufficiently reduce virulence.

(b) When it is not essential to remove all virulence determinants from a pathogen, particular attention should be paid to any toxin genes, plasmid- or phageborne virulence determinants and harmful adventitious agents; on such occasions a case by case evaluation will be needed.

3. For criterion (ii), the following guidelines shall apply:

(1) (a) The vector/insert should not contain genes expressing an active protein or transcript (e.g. virulence determinants, toxins, etc.) at a level and in a form which endow the genetically modified micro-organism with a phenotype likely to cause disease humans, animals or plants.

(b) in any case, when the vector/insert contains sequences which are involved in the expressions of harmful traits in certain micro-organisms, but which do not endow the genetically modified micro-organism with a phenotype likely to cause disease to humans, animals or plants, or likely to cause adverse effects on the environment, then the vector/insert should not be self-transmissible and should be poorly mobilisable.

(2) In the case of Type B operations, special consideration should be given to the following:

(a) vectors should not be self-transmissible or contain functional sequences, and should be poorly mobilisable, and

(b) in deciding whether the vector/insert are likely to endow the genetically modified micro-organism with a phenotype likely to cause disease to humans, animals or plants or to cause adverse effects in the environment, it is important to ensure that the vector/insert are well characterised or limited in size as much as possible to the genetic sequences required to perform the intended function.

4. For criterion (iii), the following guidelines shall apply:

(1) In deciding whether the genetically modified micro-organism is likely to cause adverse effects on the environment or disease to animals or plants, consideration should be given to the environment likely to be exposed to the genetically modified micro-organisms.

(2) In the case of Type B operations, in addition to criterion (iii), consideration should be given to the following:

(a) the genetically modified micro-organism should not transfer any resistance markers to micro-organisms, if such transfer could compromise disease treatment, and

(b) the genetically modified micro-organism should be as safe in the industrial setting as the recipient or parental micro-organism, or have characteristics that limit survival and gene transfer.

(3) (a) Other genetically modified micro-organisms which could be included in Group I if they are without adverse effects on the environment and meet the conditions in criterion (i) are those that are constructed entirely from a single prokaryotic recipient

(including its indigenous plasmids transposons and viruses), or from a single eukaryotic recipient (including its chloroplasts, mitochondria, plasmids, but excluding viruses), or consist entirely of genetic sequences from different species that exchange these sequences by known physiological processes.

(b) Before deciding if these genetically modified micro-organisms are to be included in Group I it should be considered whether they are excluded from the Regulations under the provisions of article 11 (1) (d), taking into account that self-cloning means the removal of nucleic acid from a cell of an organism, followed by reinsertion 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 cells of phylogenetically closely related species which can naturally exchange genetic material with the donor species.", and

(b) by the substitution for Part II, Section A, paragraph 3 of the Ninth Schedule thereto of the following:

"3. Geographical distribution of the organism

(a) Indigenous to the country where the notification is made:

YESNONOT KNOWN

(b) indigenous to other European Community countries:

YES

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

AtlanticMediterraneanContinental

ArcticBoreal

(ii)NONOT KNOWN

(c) Is it regularly used in the country where the notification is made:

YESNO

(d) Is it regularly kept in the country where the notification is made:

YESNO

GIVEN under the official Seal of the
Minister for the Environment this

29th day of November, 1996.

BRENDAN HOWLIN

Minister for the Environment.

EXPLANATORY NOTE

These Regulations amend the Genetically Modified Organisms Regulations, 1994 (S.I. No. 343 of 1994), by introducing revised criteria and guidelines for the classification of genetically modified micro-organisms for contained use purposes.