1994 No. 143

HEALTH AND SAFETY

Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 1994

Made . . . . . *12th April 1994*

Coming into operation . . *1st June 1994*

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The Department of Economic Development, the Department of Agriculture and the Department of the Environment being Departments designated(**a**) for the purpose of section 2(2) of the European Communities Act 1972(**b**) in relation to the control and regulation of genetically modified organisms, acting jointly in the exercise of the powers conferred on them by the said section 2, and the Department of Economic Development, acting as the Department concerned(**c**), in exercise of the powers conferred by Articles

(**a**) S.I. 1991/775
(**b**) 1972 c. 68
(**c**) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)

2(5), 17(1) to (5), 40(2), (4) and (6) and 55(2) of, and paragraphs 1(1) and (5), 3(1), 5(1), 7, 8, 9, 10, 12(1), 13, 14(1), 15 and 19 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978(**a**) and of every other power enabling them in that behalf, after consultation in accordance with Article 46(1) of that Order with the Health and Safety Agency for Northern Ireland and such other bodies as appeared to them to be appropriate, hereby make the following Regulations:—

PART I

INTERPRETATION AND GENERAL

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 1994 and shall come into operation on 1st June 1994.

Interpretation

2.—(1) In these Regulations—

"the 1991 Regulations" shall be construed in accordance with regulation 23;

"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 Department;

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

"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 Department" means the Department of Economic Development;

"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 examples of which are listed in Part I of Schedule 1; and

(**a**) S.I. 1978/1039 (N.I. 9)

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

"genetic modification safety committee" means the committee established in accordance with regulation 11;

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

"the notifier" shall be construed in accordance with regulation 10(1);

"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 are 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(**a**), 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.

(3) The Interpretation Act (Northern Ireland) 1954(**b**) shall apply to these Regulations as it applies to a Measure of the Northern Ireland Assembly.

(**a**) O.J. No. L239, 28.8.91, p. 23
(**b**) 1954 c. 33 (N.I.)

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 8 to 12 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 1 or to any organisms so modified.

(4) In so far as these Regulations relate to the protection of the environment, they shall only apply to genetically modified micro-organisms.

(5) These Regulations shall have effect without prejudice to any requirement imposed by or under any statutory provision which relates to public health or the protection of the environment.

Meaning of "work" and "at work"

4. For the purpose of these Regulations and Parts I and II of the Health and Safety at Work (Northern Ireland) Order 1978(**a**) the meaning of the word "work" shall be extended to include any activity involving genetic modification and the meaning of "at work" shall be extended accordingly.

Modification of Article 5(2) of the Health and Safety at Work (Northern Ireland) Order 1978

5. Article 5(2) of the Health and Safety at Work (Northern Ireland) Order 1978 shall be modified in relation to an activity involving genetic modification so as to have effect as if the reference to a self-employed person were a reference to any person who is not an employer or an employee and the reference to his undertaking included a reference to such an activity.

PART II

NOTIFICATION OF AND CONSENT FOR ACTIVITIES INVOLVING GENETIC MODIFICATION

Prohibition of certain work with genetically modified organisms outside containment

6.—(1) Subject to paragraph (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) Paragraph (1) shall not apply to an operation in which—

(a) S.I. 1978/1039 (N.I. 9); Article 5(2) was modified by S.R. 1982 No. 273