1991 No. 238

HEALTH AND SAFETY

Genetic Manipulation Regulations (Northern Ireland) 1991

Made	*6th June 1991*
Coming into operation . .	*12th August 1991*

The Department of Agriculture, the Department of Economic Development, the Department of the Environment and the Department of Health and Social Services acting jointly as the Department concerned(**a**), in exercise of the powers conferred by Articles 2(5), 17(1) to (5) and 55(2) of, and paragraphs 1(1), 5(1), 7(1) and 14(1) of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978(**b**) 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:—

Citation and commencement

1. These Regulations may be cited as the Genetic Manipulation Regulations (Northern Ireland) 1991 and shall come into operation on 12th August 1991.

Interpretation

2.—(1) In these Regulations—

"approved" means approved for the time being in writing by the Department;

"Department" means the Department of Economic Development;

"genetic manipulation" means the propagation of combinations of heritable material by the insertion of that material, prepared by whatever means outside a cell or organism, into a cell or organism in which it does not occur naturally; either—

(*a*) directly; or

(*b*) into a virus, microbial plasmid or other vector system which can then be incorporated in the cell or organism;

"genetic manipulation safety committee" means a committee established under regulation 6(2);

"intentional introduction into the environment" means the intentional introduction into the environment (without provision for containment)

(**a**) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)
(**b**) S.I. 1978/1039 (N.I. 9)

of a live cell or organism which was produced or modified by genetic manipulation, in vitro cell fusion or any other in vitro technique, to form combinations of heritable material which do not occur naturally in that cell or organism;

"organism" means any biological entity capable of replication (whether microscopic or not); and

"pathogen" means—

(*a*) any organism which falls into one of the hazard groups numbered 2, 3 and 4 in Schedule 1;

(*b*) a pest within the meaning of Article 3(1) of the Plant Health Order (Northern Ireland) 1988(**a**); or

(*c*) any collection or culture of organisms or any derivative either on its own or in recombinant form of such collection or culture of organisms which may cause disease in animals or poultry.

(2) In these Regulations a reference to "an activity involving genetic manipulation" shall be taken as a reference to an activity involving—

(*a*) the construction or modification of a cell or organism by genetic manipulation;

(*b*) the use of a cell or organism constructed or modified by genetic manipulation; or

(*c*) intentional introduction into the environment,

but shall not include a reference to the supply or use of a cell or organism as a finished product for routine use if the construction or modification of that cell or organism by genetic manipulation has been notified under regulations 5 or 8.

(3) In these Regulations, references to "containment levels" and to "good large-scale practice" shall be treated as references to those terms as further described in the method of risk assessment approved for the purpose of regulation 6(1).

Meaning of "work" and "at work"

3. For the purpose of these Regulations and Parts I and II of the Health and Safety at Work (Northern Ireland) Order 1978(**b**) the meaning of the word "work" shall be extended to include an activity involving genetic manipulation 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

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

(**a**) S.R. 1988 No. 175 to which there are amendments not relevant to the subject of these Regulations
(**b**) S.I. 1978/1039 (N.I. 9). Article 5(2) was modified by S.R. 1982 No. 273

Notification of activities involving genetic manipulation

5.—(1) Subject to regulation 8 and to paragraphs (4) and (6), a person shall not carry out an activity involving genetic manipulation unless, before commencing that activity, he gives notice in writing to the Department of his intention to do so not less than—

(*a*) in the case of an activity involving an intentional introduction into the environment, 90 days in advance;

(*b*) in any other case, 30 days in advance; or

(*c*) in either case, such shorter time in advance as the Department may agree.

(2) Subject to paragraph (4), the notice required by paragraph (1) shall be in a form approved for the purpose and shall comprise—

(*a*) a notification of an intention to carry out activities involving genetic manipulation which shall contain the particulars specified in Schedule 2; and

(*b*) a notification of each individual activity involving genetic manipulation which shall contain the particulars specified in Schedule 3.

(3) Where a person has given a notification in accordance with paragraph (2)(*a*) and subsequently makes a significant change in the activities to which the notification relates which would affect the particulars notified (including the cessation of those activities), he shall forthwith notify the Department of that change.

(4) Subject to regulation 8, in the case of an activity involving genetic manipulation to which this paragraph applies, it shall be sufficient compliance with paragraphs (1) and (2) if the person who carries out the activity—

(*a*) notifies the Department in accordance with paragraphs (1) and (2)(*a*); and

(*b*) as soon as is reasonably practicable after the end of each calendar year gives the Department a list of the individual activities carried out during that year containing the particulars specified in Schedule 4.

(5) Paragraph (4) shall apply to an activity involving genetic manipulation (other than intentional introduction into the environment) which, when assessed for risk in accordance with regulation 6(1), is assigned to containment levels 1 or 2 or as warranting only the use of good large-scale practice, as the case may be.

(6) Paragraph (1) shall not apply where the only activities involving genetic manipulation consist of self-cloning activities (namely the application of genetic manipulation to rearrange the genome of an individual species) except where they involve a pathogen or an intentional introduction into the environment.

Risk assessment

6.—(1) For the purpose of notifying an individual activity involving genetic manipulation under regulation 5(2)(*b*) or determining whether the activity is to be assessed as falling into containment levels 1 or 2 or as

warranting only the use of good large-scale practice, as the case may be (and is therefore an activity to which regulation 5(4) applies) the person carrying out the activity shall carry out a risk assessment of the intended activity by the method approved for the purpose.

(2) The person carrying out an activity referred to in paragraph (1) shall establish a committee for the purpose of advising him in relation to any risk assessment mentioned in that paragraph.

Exemption certificates

7.—(1) Subject to paragraph (2), the Department may, by a certificate in writing, exempt any person or class of person or any activity or class of activities 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 limit of time and may be revoked by a certificate in writing at any time.

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

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

(*b*) any other requirements imposed by or under any statutory provisions which apply to the case,

it is satisfied that the health and safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it.

Transitional provisions

8. Where a person carries out an activity involving genetic manipulation to which regulation 5(1) applies and which commenced before 12th August 1991, it shall be sufficient compliance with—

(*a*) regulation 5(4)(*a*) if, in the case of an activity to which that paragraph applies, he gives to the Department the notification referred to in regulation 5(2)(*a*) on or before 10th September 1991; and

(*b*) regulation 5(1) and (2) if, in any other case, he gives to the Department the notifications referred to in regulation 5(2) on or before 10th September 1991.

Sealed with the Official Seal of the Department of Agriculture on 6th June 1991.

(L.S.) *I. C. Henderson*
Assistant Secretary

Sealed with the Official Seal of the Department of Economic Development on 5th June 1991.

(L.S.) *Suzanna Cooper*
Assistant Secretary

Sealed with the Official Seal of the Department of the Environment on 4th June 1991.

(L.S.) *R. W. Rogers*
Assistant Secretary

Sealed with the Official Seal of the Department of Health and Social Services on 4th June 1991.

(L.S.) *J. Scott*
Assistant Secretary

SCHEDULE 1 Regulation 2(1)

HAZARD GROUPS FOR ORGANISMS

GROUP 1 An organism that is most unlikely to cause human disease.

GROUP 2 An organism that may cause human disease and which might be a hazard to laboratory workers but it is unlikely to spread in the community. Laboratory exposure rarely produces infection and effective prophylaxis or effective treatment is usually available.

GROUP 3 An organism that may cause severe human disease and present a serious hazard to laboratory workers. It may present a risk of spread in the community but there is usually effective prophylaxis or treatment available.

GROUP 4 An organism that causes severe human disease and is a serious hazard to laboratory workers. It may present a high risk of spread in the community and there is usually no effective prophylaxis or treatment.

SCHEDULE 2 Regulation 5(2)(*a*)

PARTICULARS TO BE GIVEN IN A NOTIFICATION OF AN INTENTION TO CARRY OUT ACTIVITIES INVOLVING GENETIC MANIPULATION

1. The name of the person who will carry out activities involving genetic manipulation.

2. The address or location of the premises or site where the activities are to be carried out.

3. The name and designation of the person responsible for the activities.

4. Into which of the following categories the activities fall—
   (*a*) the construction or modification of a cell or organism by genetic manipulation;
   (*b*) the use of a cell or organism constructed or modified by genetic manipulation; or
   (*c*) intentional introduction into the environment.

5. The arrangements for physical containment (unless the work is assigned to containment level 1 or good large-scale practice).

6. The names and capacities of members of the genetic manipulation safety committee.

7. Comments made by the genetic manipulation safety committee on the local arrangements for risk assessment.

8. The names of the biological and deputy biological safety officers concerned with the work (if any).

9. The name of the supervisory medical officer concerned with the work (if any).

10. The arrangements for health surveillance (if any).

SCHEDULE 3 Regulation 5(2)(*b*)

PARTICULARS TO BE GIVEN IN A NOTIFICATION OF AN ACTIVITY INVOLVING GENETIC MANIPULATION

1. In all cases—
   (*a*) the name of the person carrying out the activity;
   (*b*) the address of the premises or site where the activity is to be carried out;
   (*c*) particulars of the activity;
   (*d*) any variation of the particulars notified in accordance with Schedule 2;
   (*e*) comments by the genetic manipulation safety committee;
   (*f*) the proposals for physical containment (if any);
   (*g*) the subsequent use or distribution of nucleic acid;
   (*h*) the risk assessment and the categorisation data on which it is based.

2. In the case of the construction or modification of a cell or organism by genetic manipulation—
   (*a*) the proposed containment level of the activity;
   (*b*) a list of staff to be involved in the activity.

3. In the case of the use of a cell or organism constructed or modified by genetic manipulation—
   (*a*) the nature of the gene product;
   (*b*) the host vector system to be used;
   (*c*) the scale of operation proposed;
   (*d*) the safety precautions proposed;
   (*e*) the proposed process containment;
   (*f*) whether any part of the construction involves the use of a pathogen.

4. In the case of intentional introduction into the environment—
   (*a*) the objectives of the activity;
   (*b*) the nature of the cell or organism to be released;
   (*c*) the procedure used to introduce the genetic modification;
   (*d*) the nature of any altered nucleic acid and its source, its intended function and the extent to which it has been characterised;
   (*e*) verification of the genetic structure of the novel organism;
   (*f*) the genetic stability of the novel organism;
   (*g*) the ability of the organism to give rise to long-term survival forms and the effect the altered nucleic acid may have on this ability;
   (*h*) in the case of a pest control agent, details of the target biota;
   (*i*) the geographical location, size and nature of the site of release;
   (*j*) the physical and biological proximity of the site to man and other significant biota;
   (*k*) details of the ecosystem into which the organism is to be released;
   (*l*) the method and amount of release, rate, frequency and duration of application;
   (*m*) monitoring capabilities and intentions;

(*n*) the on-site worker safety procedures and facilities;

(*o*) the contingency plans in the event of unanticipated effects of the novel organism;

(*p*) an assessment of the environmental consequences of the release including—

(i) survival and persistence of the novel organism,

(ii) susceptibility to temperature, humidity, desiccation, ultra-violet light and other ecological stresses,

(iii) details of any modification of the organism designed to affect its ability to survive and to transfer genetic material,

(iv) potential for transfer of inserted polynucleotides to other organisms including methods for monitoring survival and transfer,

(v) methods to control or eliminate any superfluous organism or nucleic acid surviving in the environment or possibly in a product,

(vi) an assessment of the effects of the manipulation on the ecological behaviour of the organism in its natural habitat;

(*q*) details of any local consultation undertaken; and

(*r*) method of termination of the project.

SCHEDULE 4 Regulation 5(4)(*b*)

PARTICULARS TO BE GIVEN OF ACTIVITIES INVOLVING GENETIC MANIPULATION IN THE ANNUAL RETURN UNDER REGULATION 5(4)

1. The name of the person carrying out activities involving genetic manipulation.

2. The address or location of the premises or site where the work was carried out.

3. Any variation in the particulars notified in accordance with Schedule 2.

4. The numbers of all projects assigned to containment levels 1 and 2 respectively.

5. The numbers of activities involving the use of a cell or organism constructed or modified by genetic manipulation warranting only the use of good large-scale practice.

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations make provision relating to genetic manipulation (as defined in regulation 2(1)).

By regulations 3 and 4 the meaning of the word "work" for the purposes of these Regulations and Parts I and II of the Health and Safety at Work (Northern Ireland) Order 1978 is extended to include an activity involving genetic manipulation and, in relation to such activities, Article 5(2) of that Order (general duties of self-employed persons to persons other than their employees) is modified to have effect as if the reference in that paragraph to a self-employed person includes a reference to any person who is not an employer or an employee.

By regulation 5 a person may not undertake certain types of activity involving genetic manipulation unless he has notified the Department of Economic Development of his intention to do so at least 30 days in advance, or in the case of an intentional introduction into the environment (as defined in regulation 2(1)), at least 90 days in advance, unless the Department agrees, in either case, to a shorther notification period. The details that are required to be notified are specified in Schedules 2 and 3.

Regulation 5 also provides for a simplified notification procedure for activities which are assessed to create a low risk (regulation 5(4) and (5) and Schedule 4) and provide exemption for certain other activities (regulation 5(6)).

By regulation 6, for the purpose of making a notification of an activity involving genetic manipulation, the person carrying out the activity is required to make a risk assessment of that activity by a method that has been approved by the Department of Economic Development. The regulation also requires him to establish a committee for the purpose of advising him in relation to the assessment.

Regulation 7 provides for exemptions to be granted by the Department of Economic Development.

Regulation 8 provides for the notification of existing activities involving genetic manipulation.

Copies of the method approved by the Department of Economic Development for the risk assessment of activities involving genetic manipulation are obtainable from the Department of Economic Development, Health and Safety Division, 83 Ladas Drive, Belfast BT6 9FJ.

A person who contravenes the Regulations is guilty of an offence under Article 31 of the Health and Safety at Work (Northern Ireland) Order 1978 and is liable on summary conviction to a fine not exceeding £2,000 or, on conviction on indictment, to a fine.