

1989 No. 1810

HEALTH AND SAFETY

The Genetic Manipulation Regulations 1989

<i>Made</i> - - - -	<i>3rd October 1989</i>
<i>Laid before Parliament</i>	<i>11th October 1989</i>
<i>Coming into force</i>	<i>1st November 1989</i>

The Secretary of State, in exercise of the powers conferred on him by sections 15(1), (2), (3)(b), (4)(a), (5)(b), and (9), 52(2) and (3), and 82(3)(a) of, and paragraphs 1(1)(b) and (c), 6(1) and 15(1) of Schedule 3 to, the Health and Safety at Work etc. Act 1974(a) ("the 1974 Act") and of all other powers enabling him in that behalf and for the purpose of giving effect without modifications to proposals submitted to him by the Health and Safety Commission under section 11(2)(d) of the 1974 Act after the carrying out by the said Commission of consultations in accordance with section 50(3) of that Act, hereby makes the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Genetic Manipulation Regulations 1989 and shall come into force on 1st November 1989.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

"approved" means approved for the time being in writing by the Health and Safety Executive for the purposes of these Regulations;

"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 (that is outside provision for containment) of a live cell or organism which was produced or modified by genetic manipulation, in vitro cell fusion or 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);

"pathogen" means any of the following—

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

(b) an animal pathogen within the meaning of Article 3 of the Importation of Animal Pathogens Order 1980(b); or

(c) a plant pest within the meaning of Article 3 of the Plant Health (Great Britain) Order 1987(c).

(a) 1974 c.37; sections 15, 50 and 52 were amended by Schedule 15 to the Employment Protection Act 1975 (c.71), paragraphs 6, 16 and 17 respectively.

(b) S.I. 1980/1212.

(c) S.I. 1987/1758.

(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 regulation 5.

(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).

(4) In these Regulations, unless the context otherwise requires—

- (a) a reference to a numbered regulation or Schedule is a reference to the regulation or Schedule in these Regulations so numbered; and
- (b) a reference to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule in which that reference appears.

Meaning of “ work ” and “ at work ”

3. For the purpose of these Regulations and Part I of the Health and Safety at Work etc. Act 1974 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 section 3(2) of the Health and Safety at Work etc. Act 1974

4. Section 3(2) of the Health and Safety at Work etc. Act 1974 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.

Notification of activities involving genetic manipulation

5.—(1) Subject to paragraphs (4) and (6), no person shall carry out an activity involving genetic manipulation unless, before commencing that activity, he has notified the Health and Safety Executive of his intention to do so at least—

- (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 Executive may agree.

(2) Subject to paragraph (4), the notification required by paragraph (1) shall be in an approved form 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 made 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 Executive of that change.

(4) In the case of an activity involving genetic manipulation specified in paragraph (5), it shall be sufficient compliance with paragraph (1) if the person who intends to carry out the activity—

- (a) notifies the Executive in accordance with paragraphs (1) and (2)(a); and
- (b) as soon as is reasonably practicable after the end of each calendar year sends the Executive a list of the 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 approved method.

(2) The person carrying out the activity shall establish a committee for the purpose of advising him in relation to any risk assessment mentioned in regulation 6(1).

Application outside Great Britain

7. These Regulations shall apply to any work outside Great Britain to which sections 1 to 59 and 80 to 82 of the Health and Safety at Work etc. Act 1974 apply by virtue of the Health and Safety at Work etc. Act 1974 (Application outside Great Britain) Order 1989(a) as they apply to work within Great Britain.

Exemption certificates

8.—(1) Subject to paragraph 2, the Health and Safety Executive 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 Executive shall not grant any such exemption unless, having regard to 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 enactments 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.

Revocations and savings

9.—(1) The Health and Safety (Genetic Manipulation) Regulations 1978(b) are hereby revoked.

(2) In the case of an activity involving genetic manipulation commenced—

- (a) before the date on which these Regulations come into force it shall be sufficient compliance with regulation 5(1) if the intention to carry out that activity was notified under the said Regulations of 1978;
- (b) on or after the date on which these Regulations come into force it shall be sufficient compliance with regulation 5(1) (in so far as it requires a notification referred to in regulation 5(2)(a)) if the intention to carry out that activity was notified under the said Regulations of 1978.

Signed by order of the Secretary of State.

Patrick Nicholls
Parliamentary Under Secretary of State,
Department of Employment

3rd October 1989

- (a) S.I. 1989/840.
- (b) S.I. 1978/752.

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 work is to be carried out.
3. The name and designation of the person responsible for the work.
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 person carrying out the work;
 - (b) the address of the premises or site where the work is to be carried out;
 - (c) particulars of the work to be undertaken;
 - (d) any variation of the particulars notified in accordance with Schedule 1;
 - (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 project;
 - (b) a list of staff to be involved in the project.
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 project;
 - (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;
 - (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 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 projects 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)

1. These Regulations supersede the Health and Safety (Genetic Manipulation) Regulations 1978 which they revoke.

2. The terms used in the Regulations including "genetic manipulation", "activities involving genetic manipulation" and "intentional introduction into the environment" are defined in regulation 2.

3. By regulations 3 and 4 the meaning of the word "work" for the purposes of these Regulations and Part I of the Health and Safety at Work etc. Act 1974 is extended to include an activity involving genetic manipulation and, in relation to such activities, section 3(2) of that Act (general duties of employers and self-employed persons to persons other than their employees) is modified to have effect as if the reference in that subsection to a self-employed person includes a reference to any person who is not an employer or an employee.

4. By regulation 5 no person may undertake an activity involving genetic manipulation unless he has notified the Health and Safety Executive of his intention to do so at least 30 days in advance, or in the case of an intentional introduction into the environment, at least 90 days in advance. The details that are required to be notified are specified in Schedules 2 and 3.

5. 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)).

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 Health and Safety Executive. The regulation also requires him to establish a committee for the purpose of advising him in relation to the assessment.

7. These Regulations are applied to certain activities outside Great Britain (regulation 7) and provide for exemptions to be granted by the Health and Safety Executive (regulation 8).

8. In addition to revoking the Health and Safety (Genetic Manipulation) Regulations 1978, regulation 9 provides that after their revocation notifications which had been made under them shall have effect for the purposes of regulation 5 (1) (although notifications of individual activities will still have to be made if they commence on or after the coming into force of these Regulations).

9. Copies of the method approved by the Health and Safety Executive for the risk assessment of activities involving genetic manipulation are obtainable from the Health and Safety Executive, Baynards House, 1 Chepstow Place, London W2 4TF.

£1.35 net

ISBN 0 11 097810 2

Printed in the United Kingdom by Her Majesty's Stationery Office

831/WO1641 C62 10/89 3190446