Genetic Manipulation Regulations 1989 / Health and Safety Executive.

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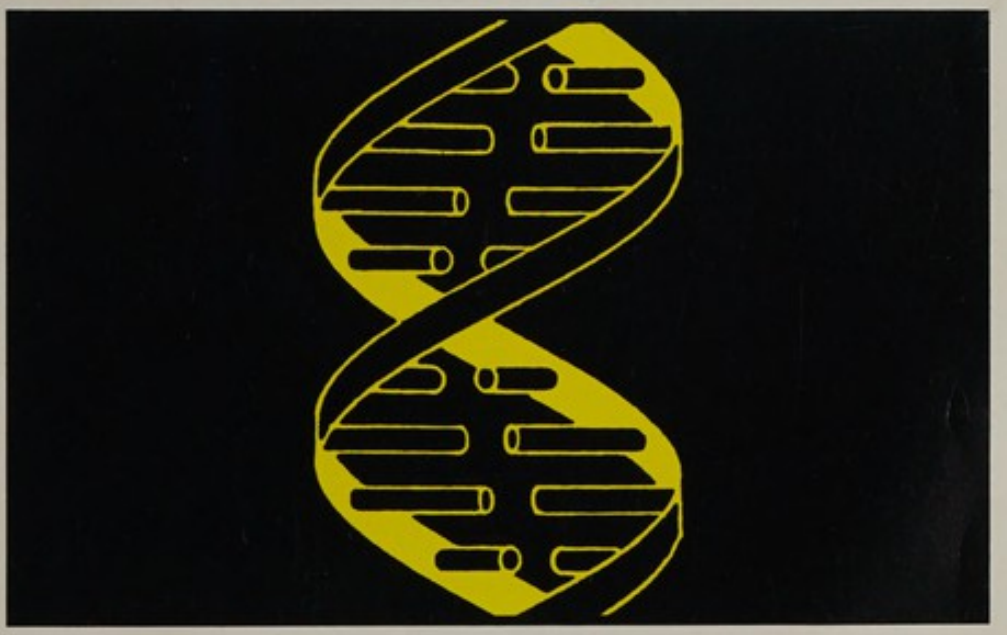

GUIDANCE ON REGULATIONS

Health and Safety
Executive

Genetic Manipulation Regulations 1989

London: Her Majesty's Stationery Office

First published 1989

This booklet gives guidance on the relevant regulations and, although the guidance is based on legal requirements, it is not intended to be an authoritative interpretation of the law; such interpretation can only be made by the Courts.

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ISBN 0 11 885513 1

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Note

1 Throughout this document, paragraphs are marked to indicate whether they are Regulations (also printed in italics) or Guidance. In addition the paragraphs are colour coded as follows:

Regulation

Guidance

2 Cross references in the Guidance which quote a paragraph number and no Regulation number refer to a paragraph under the same Regulation. In cases where a paragraph under a different Regulation is quoted, the cross reference also gives the number of the Regulation.

Preface

This booklet contains

(a) The Genetic Manipulation Regulations (SI No 1989/1810) which are operative from 1 November 1989.

(b) Guidance Notes.

The Regulations provide that persons should not carry out genetic manipulation unless they have previously notified the Health and Safety Executive.

The Regulations extend the meaning of work in Part I of the Health and Safety at Work etc Act 1974 to include an activity involving genetic manipulation. Non-employed persons engaged in genetic manipulation will have the same duties under the Act as self-employed persons.

The Guidance Notes offer practical guidance on the Regulations.

Introduction

1 The Genetic Manipulation Regulations 1989 made under the Health and Safety at Work etc Act 1974 (HSW Act) specify that no person shall carry out activities involving genetic manipulation unless notice of intention has been given to the Health and Safety Executive (HSE). This notice must be given at least 30 days in advance (90 days in the case of intentional introduction into the environment) unless a shorter period has been agreed by HSE.

Advice and enforcement

2 The Advisory Committee on Genetic Manipulation (ACGM) and the former Genetic Manipulation Advisory Group (GMAG) have issued series of guidance notes on individual subjects which are available to all centres of genetic manipulation work. Copies of this current guidance may be obtained from HSE (see paragraph 1 to guidance on regulation 5). In addition, people notifying "general intention" or particular activities in advance (see paragraph 2 to guidance on regulation 5) will receive an individual response from HSE after consultation with ACGM on their proposals. The HSE Inspectorate, when inspecting the workplaces concerned, may require precautions to be taken (see paragraph 3 below).

3 HSE will be the enforcing authority for all of the sites to which the requirements of the Regulations and the HSW Act apply. Enforcement will be made under the powers available under the HSW Act. The Regulations do not provide for the enforcement of health and safety standards, however when conducting site inspections the HSE Inspectorate may have observations and requirements under the HSW Act. HSE inspectors have extensive powers under this Act, including powers to require the provision of information relevant to their purposes and for the production of documents. They may also take formal action to achieve compliance with the Act by issuing improvement or prohibition notices. In England and Wales they may also institute legal proceedings for breaches of the Regulations. In Scotland breaches of the Regulations which come to the notice of inspectors may be referred to the Procurator Fiscal for consideration to be given to the institution of legal proceedings.

Biological safety officers and health surveillance

4 It is also appropriate for the employer to appoint a biological safety officer to give expert advice on a day to day basis while the work is in progress. Suitable health surveillance of the workers concerned may also be necessary (see ACGM/HSE/Note 4).

Regulation 1

Citation and commencement

Regulation 1

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

Guidance 1

Activities already notified under the previous Health and Safety (Genetic Manipulation) Regulations 1978 need not be re-notified (see guidance on regulation 9(2)).

Regulation 2

Interpretation

Regulation 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;

Regulation

"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[(a)]; or

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

(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 -

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(a) S.I. 1980/1212.
(b) S.I. 1987/1758.

Regulation

2

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.

Guidance

1 The definition of genetic manipulation given in regulation 2 is slightly wider than that contained in the 1978 Regulations and takes account of recent scientific developments. The revised definition covers direct introduction of recombinant nucleic acid but in other respects is as in the 1978 Regulations. Particular points to note are:

(a) combinations of heritable material have to be prepared outside the cell or organism;

(b) the definition does not cover the transfection of cells with total genomic DNA or the transformation of cells with viruses (unless the preparation or assembly of combinations of nucleic acid outside the cell or organism was involved);

(c) the definition does not cover cell fusion;

(d) gene deletion is covered when it is brought about by the process of genetic manipulation. Deletions can affect the properties of an organism but they occur naturally and widely and, artificially, can be brought about by processes other than genetic manipulation;

(e) the definition covers the insertion of additional copies of a gene;

(f) a "pathogen" is defined largely by reference to Schedule1 (see also regulation 5(6)). The categorisation in Schedule1 is based on the Categorisation report of the Advisory Committee on Dangerous Pathogens 1984 (ISBN 0 11 883761 3).

In addition, the new Regulations require the notification of:

(i) the *use* of a cell or organism constructed by genetic manipulation. This covers the large scale *use* or growth in a pilot plant or commercial manufacturing facility involving genetically manipulated organisms which has previously been notifiable to HSE under voluntary arrangements (ACGM/HSE/Note 6). Large scale use is not defined in Note 6, but is usually taken to refer to volumes of 10 litres or more and 10 litres remains the best "cut off" point. The principles for risk assessment in Note 6 may also be applied to fermentation in lower volumes. The notification requirement also covers the use in the laboratory or on a large scale of recombinants constructed elsewhere in the country or imported into Great Britain.

(ii) the *intentional introduction* of genetically manipulated organisms into the environment. This has previously been known as "planned release" and has also been notifiable to HSE under a voluntary scheme (ACGM/HSE/Note 3). For this particular use only the definition is extended to cover related in vitro techniques that would enable the construction of organisms with novel combinations of genes. In practical terms, intentional introduction means the use in the environment of an organism modified as above without provision for containment such as special procedures, equipment and installations or facilities that provide physical barriers to minimise its spread (and that of its nucleic acid to the environment).

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Guidance

2

2 The supply or application of a cell or organism as a *finished product* for routine use, eg medicines, drugs, fertilisers, is generally not within the scope of these Regulations. (The supply or use of such products may be governed by other legislation eg the Medicines Act 1968.) But the exclusion of finished products for routine use applies only if construction or modification has been notified under regulation 5. Essentially the Regulations are concerned with the construction and use of genetically manipulated organisms (including those that are imported). The emphasis is on their use *during the productive process*. This distinction between "use" in production and "use" of finished products should be carefully noted. HSE, guided as necessary by ACGM, will be prepared to advise in doubtful cases.

Regulation 3

Meaning of "work" and "at work"

Regulation

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.

Guidance

3

The Regulations extend the meaning of "work" and "at work" in the HSW Act so as to include all genetic manipulation, whether the person concerned is an employer, an employee, a self-employed person or is non-employed, for example, a research student.

Regulation 4

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

Regulation

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.

Guidance

4

The Regulations modify Section 3(2) of the HSW Act so that non-employed persons are treated as if they were self-employed. This places on them the duty to conduct their undertakings in such a way as to ensure, so far as is reasonably practicable, that persons other than employees are not exposed to risk to their health and safety.

Regulation 5

Notification of activities involving genetic manipulation

Regulation

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.

Regulation

(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 in anipulation 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.

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Guidance

1 Notification of proposals to carry on relevant activities involving genetic manipulation should be submitted to:

The Health and Safety Executive
Branch MDA3
Baynards House
1 Chepstow Place
Westbourne Grove
London W2 4TF
(Telephone 01-243 6000)

Responsibility for providing the appropriate information lies with the person carrying out any of the activities specified in regulation 5. In practice, the "person" will generally be a body corporate eg a company, university or institute. Proposals will be considered by the Advisory Committee on Genetic Manipulation (ACGM), which consists of representatives of employers, representatives of employees and medical and scientific specialists, with an independent chairman. The ACGM advises the Health and Safety Commission and Executive on genetic manipulation matters relating to health

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and safety at work, and the Health, Agriculture, Environment, Industry and Northern Ireland Ministers on other genetic manipulation matters.

2 Regulation 5(2) states that notification should be in a form approved by HSE and copies of notification forms can be obtained from the address given in paragraph 1 above. Notification arrangements fall into three categories:

(a) a notification of an intention to carry out activities involving genetic manipulation (regulation 5(2)(a) and Schedule 2);

(b) a notification of each individual activity involving genetic manipulation ie construction, use and intentional introduction (regulation 5(2)(b) and Schedule 3);

((a) and (b) should be made at least 30 days in advance of commencement of the activity (90 days in the case of intentional introductions), unless a shorter period is agreed by HSE.)

(c) a retrospective notification should be submitted as soon as is reasonably practicable at the end of each calendar year (regulation 5(4)(b) and Schedule 4). This applies only to experimental work falling into containment levels 1 and 2, or large-scale work in the category of good large-scale practice.

3 Significant changes in particulars notified (eg cessation of genetic manipulation work) in accordance with regulation 5(2)(a) (paragraph 2(a) above) should be supplied to HSE in writing under regulation 5(3) unless included in the course of notification of individual activities (see Schedule 3 paragraph 1(d) and Schedule 4). It would also be helpful if notifiers could advise HSE of any changes of the Biological Safety Officer or Supervisory Medical Officer.

4 (a) All experiments involving the genetic manipulation of plant pests, and the use of such genetically manipulated plant pests, must be notified to HSE in accordance with regulation 5 and will, in addition, require a licence from the Ministry of Agriculture, Fisheries and Food (MAFF), the Department of Agriculture and Fisheries for Scotland (DAFS), or the Forestry Commission Secretariat (FCS). To facilitate such licensing *all proposals involving genetically manipulated plant pests in contained conditions should be submitted* to:

Legislation Section
Plant Pathology Department
MAFF
Harpenden Laboratory
Hatching Green
Harpenden
Herts AL5 2BD (For England and Wales)

or

Head of Plant Health Section,
Agricultural Scientific Services,
East Craigs,
Edinburgh EH12 8NJ (For Scotland)

(b) Regulation 5(6) states that notification is not required where the only activities consist of self cloning activities (or "homogenic rearrangements"), except where these involve a pathogen or an intentional introduction into the environment. For the purpose of

Guidance
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defining a pathogen and an intentional introduction into the environment, reference should be made to regulation 2(1).

Regulation 6 Risk assessment

Regulation
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) .

Guidance
6

The Regulations expressly require that a group of persons, to be known as the genetic manipulation safety committee, should be set up. Ever since the Williams Report of 1976 it has been considered essential that there should be a properly constituted and representative safety committee at each centre where genetic manipulation experiments are carried out or where work is undertaken involving the use of genetically manipulated organisms. The ACGM has endorsed this principle, and, in considering notifications of particular activities under Schedules 2 and 3, ACGM and HSE will take into account comments made by the genetic manipulation safety committee. Advice on the constitution and functions of local safety committees has been issued and is available from HSE at the address given in paragraph 1 to the guidance on regulation 5. The 'approved method' referred to in regulation 6 is that laid down in writing by HSE and may be obtained from the address given as before.

Regulation 7 Application outside Great Britain

Regulation
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.

(a) S.I. 1989/840

Guidance
7

The Regulations apply to those premises and activities specified in the Health and Safety at Work etc Act 1974 (Application Outside Great Britain) Order 1989 (S.I. 1989/840) as they apply within Great Britain. Notification is therefore required of any activity (including intentional introduction into the environment) which takes place on an offshore installation which is in territorial waters or areas designated under the Continental Shelf Act 1964 which include the British North Sea oil fields. The Order, and therefore the Regulations, does not however apply to intentional introductions from vessels in or aircraft flying over territorial waters or designated areas and so does not require notification of those activities. However, any such releases at sea would require a licence from MAFF under Part 2 of the Food and Environment Protection Act 1985.

Regulation 8 — Exemption certificates

Regulation

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.

Guidance

8

Regulation 8(1) sets out the powers of HSE to make exemptions from the requirements of the Regulations. Before making any such exemption HSE will consider the circumstances of the case in accordance with regulation 8(2) and will consult the ACGM (see paragraph 1 of guidance to regulation 5).

Regulation 9 — Revocations and savings

Regulation

9

(1) The Health and Safety (Genetic Manipulation) Regulations 1978[(a)] 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.

(a) S.I. 1978/752.

Guidance

9

Regulation 9(1) revokes the Health and Safety (Genetic Manipulation) Regulations 1978 (see guidance on regulation 1). Regulation 9(2) contains savings for notifications made under the 1978 Regulations. Practitioners of genetic manipulation who have previously notified HSE of an intention to carry out activities involving genetic manipulation under the former Regulations need not make a fresh notification of intention and need only notify further individual activities not already notified to HSE under previous statutory or voluntary arrangements.

Schedule 1 Hazard groups for organisms

Regulation 2(1)

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

Particulars to be given in a notification of an intention to carry out activities involving genetic manipulation

Regulation 5(2)(a)

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

Particulars to be given in a notification of an activity involving genetic manipulation

Regulation 5(2)(b)

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 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 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

Particulars to be given of activities involving genetic manipulation in the annual return under regulation 5(4)

Regulation 5(4)(b)

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.

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