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STATUTORY RULES OF NORTHERN IRELAND

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**2001 No. 295**

**Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001**

**Part II**

**Risk assessment and notification of activities involving Genetic Modification**

**Risk assessment of activities involving genetically modified micro-organisms**

6.—(1) A person shall not undertake any activity involving genetic modification of micro-organisms unless, before commencing that activity, he has ensured that a suitable and sufficient assessment of the risks created thereby to human health and the environment has been carried out.

(2) The person carrying out an assessment required by paragraph (1) shall take into account the matters set out in Part I of, and include the steps set out in Part II of, Schedule 3.

**Risk assessment of activities involving genetically modified organisms other than micro-organisms**

7.—(1) A person shall not undertake any activity involving genetic modification of organisms other than micro-organisms unless, before commencing that activity, he has ensured that a suitable and sufficient assessment of the risks created thereby to human health has been carried out.

(2) The person carrying out an assessment required by paragraph (1) shall take into account the matters set out in Part I of, and include the steps set out in Part II of, Schedule 4.

**Review and recording of risk assessments**

8.—(1) Where—

- (a) there is reason to suspect that an assessment is no longer valid; or
- (b) there has been a significant change in the activity involving genetic modification to which an assessment relates,

the person undertaking the activity involving genetic modification to which the assessment relates shall ensure that the assessment is reviewed forthwith.

(2) The person undertaking an activity involving genetic modification—

- (a) shall keep a record of the assessment relating to that activity, and any review of that assessment, for at least 10 years from the date of the cessation of that activity; and
- (b) shall make such record available to the competent authority when requested to do so.

(3) In this regulation, “assessment” means an assessment carried out for the purposes of regulation 6 or regulation 7.

### **Notification of the intention to use premises for the first time for activities involving genetic modification**

**9.—(1)** A person shall not use premises for the first time for the purpose of undertaking an activity involving genetic modification, unless—

- (a) he has submitted to the competent authority a notification informing it of his intention to do so and containing the information specified in Schedule 5; and
- (b) he has received an acknowledgement from the Executive of receipt of that notification.

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

### **Notification of class 2 activities involving genetic modification of micro-organisms**

**10.—(1)** Subject to the following paragraphs, a person shall not undertake an activity involving genetic modification of micro-organisms in class 2 unless he has submitted a notification to the competent authority informing it of his intention to do so and containing the information specified in Part I of Schedule 6.

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

(3) The competent authority shall ensure that any emergency plan has been prepared.

(4) A person shall not undertake—

(a) for the first time an activity referred to in paragraph (1) at the premises referred to in a notification submitted in accordance with that paragraph unless—

- (i) at least 45 days, or such shorter period of time as the competent authority may approve in writing, have elapsed since the date on which the acknowledgement was sent in accordance with paragraph (2) and the competent authority has not within the said period of 45 days or the shorter period of time approved by the competent authority, as the case may be, informed the notifier that he shall not undertake the activity in question, or
- (ii) he has received the acknowledgement required by paragraph (2) and consent for activities involving genetic modification in class 3 or 4 has already been granted in respect of the premises to which the notification submitted in accordance with paragraph (1) refers;

(b) for the second or subsequent times an activity referred to in paragraph (1) at the premises referred to in a notification submitted in accordance with that paragraph unless he has received the acknowledgement required by paragraph (2).

(5) Where a person submits a notification in accordance with paragraph (1) in respect of an activity referred to in that paragraph which is not to be undertaken for the first time at the premises referred to in the notification, with the notification that person may request that the competent authority makes a decision whether or not to agree to his undertaking the activity in question.

(6) The competent authority shall make a decision requested in accordance with paragraph (5) within 45 days of the date on which the acknowledgement was sent in accordance with paragraph (2).

### **Notification of class 3 or class 4 activities involving genetic modification of micro-organisms**

**11.—(1)** Subject to the following paragraphs, a person shall not undertake an activity involving genetic modification of micro-organisms in class 3 or class 4 unless he has—

- (a) submitted to the competent authority a notification informing it of his intention to do so and containing the information specified in Part II of Schedule 6; and
- (b) received the written consent of the competent authority to undertake the activity in question.

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

(3) Where a person proposes to undertake an activity referred to in paragraph (1) for the first time at the premises referred to in a notification submitted in accordance with that paragraph, the competent authority shall inform that person in writing of its decision to grant or refuse consent to undertake the activity in question not more than 90 days after the acknowledgement was sent in accordance with paragraph (2).

(4) Where a person proposes to undertake an activity referred to in paragraph (1) for the second or subsequent times at the premises referred to in a notification submitted in accordance with that paragraph, the competent authority shall inform that person in writing of its decision to grant or refuse consent to undertake the activity in question not more than 45 days after the acknowledgement was sent in accordance with paragraph (2).

(5) Before granting a consent under either paragraph (3) or paragraph (4), the competent authority shall ensure that any emergency plan has been prepared.

(6) Before deciding whether to grant or refuse a consent under either paragraph (3) or paragraph (4), the competent authority shall take into account any representations made to it by any person within 30 days of the date on which the Executive sent the acknowledgement of receipt in accordance with paragraph (2).

(7) A consent granted pursuant to this regulation may be granted subject to conditions.

### **Notification of activities involving genetic modification of organisms other than micro-organisms**

**12.**—(1) Subject to the following paragraphs, a person shall not undertake an activity involving genetic modification of organisms other than micro-organisms unless he has submitted to the competent authority a notification informing it of his intention to do so and containing the information specified in Part III of Schedule 6.

(2) Paragraph (1) shall not apply to an activity involving genetic modification of organisms where that genetic modification results in a genetically modified organism (other than a micro-organism) which poses no greater risk to humans than its unmodified parental organism.

(3) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

(4) A person shall not undertake any activity referred to in paragraph (1), unless at least 45 days, or such shorter period of time as the competent authority may approve in writing, have elapsed since the date on which the acknowledgement was sent in accordance with paragraph (3) and the competent authority has not within the said period of 45 days or the shorter period of time approved by the competent authority, as the case may be, informed the notifier that he shall not undertake the activity in question.

### **Notification of connected programmes of work**

**13.**—(1) The competent authority may accept a single notification submitted under regulation 10(1), 11(1) or 12(1) in respect of a connected programme of work undertaken by the same person at—

- (a) one site; or
  - (b) more than one site.
- (2) The competent authority may accept a single notification submitted under regulation 10(1), 11(1) or 12(1) in respect of a single activity involving genetic modification undertaken by the same person at more than one site.
- (3) In this regulation—
- (a) “connected programme of work” means a series of activities involving genetic modification which form a coherent and integrated programme;
  - (b) “site” means premises of which the competent authority has been notified in accordance with regulation 9(1).

### **Duties on receiving notifications and additional information**

**14.**—(1) The competent authority shall examine a notification submitted under regulation 9(1), 10(1), 11(1) or 12(1) for—

- (a) conformity with the requirements of these Regulations;
- (b) the accuracy and completeness of the information provided;
- (c) the correctness of the assessment carried out pursuant to regulation 6(1) or 7(1) and submitted to the competent authority with the notification;
- (d) the adequacy of the waste management and emergency response measures submitted with the notification; and
- (e) in the case of a notification submitted under regulation 10(1) or regulation 11(1), the correctness of the class assigned to the activity involving genetic modification of micro-organisms.

(2) For the purpose of carrying out an examination of a notification in accordance with paragraph (1), the Executive may in writing request the notifier to provide such additional information relating to the notification as it may specify, and, in such a case, when so requested by the Executive, the notifier shall not begin nor, subject to paragraph (3), continue, as the case may be, the activity involving genetic modification until the competent authority has given its approval in writing.

(3) Where the person who submitted a notification pursuant to regulation 9(1), 10(1), or 12(1) has commenced the activity involving genetic modification before the Executive requests additional information in accordance with paragraph (2)—

- (a) the Executive may give to that person instructions concerning the cessation of the activity involving genetic modification;
- (b) that person shall comply with any such instructions;
- (c) subject to any such instructions, that person shall continue the activity involving genetic modification only to the extent necessary in order to store or destroy all genetically modified organisms resulting from the activity since its commencement.

(4) If requested to do so by the Department of the Environment, the Executive shall request additional information under paragraph (2).

(5) Within 10 working days, the Executive shall acknowledge receipt of all additional information provided in response to a request made by the Executive under paragraph (2).

(6) The period of time between the date when the Executive requests additional information in accordance with paragraph (2) and the date when the Executive receives that additional information shall not be taken into account in calculating the period of days referred to in regulations 10(4), 10(6), 11(3), 11(4) or 12(4), as the case may be.

(7) Where—

- (a) a notifier under regulation 9(1) has not commenced any activity involving genetic modification, or a notifier under regulation 10(1), 11(1) or 12(1), has not commenced the activity relating to genetic modification to which his notification relates; and
- (b) the Executive requests additional information pursuant to paragraph (2); and
- (c) the notifier in question does not provide that information within a period of six months of the date on which the Executive sent the request,

the competent authority may return the notification to that notifier.

### **Additional provisions relating to notifications**

**15.**—(1) The competent authority may at any time by notice in writing to the person undertaking or proposing to undertake an activity involving genetic modification—

- (a) set a limit of time for, or impose conditions with regard to, that activity;
- (b) require that person to suspend, to terminate or not to commence that activity, as the case may be;
- (c) revoke or vary a consent granted to that person under regulation 11,

and the person to whom the notice is addressed shall comply with that notice.

(2) A notifier shall forthwith send to the competent authority full details in writing of—

- (a) any change in the information specified in paragraphs (a), (d) or (e) of Schedule 5 and provided by him in accordance with regulation 9(1);
- (b) any new building—
  - (i) added by the notifier to the premises notified by him in accordance with regulation 9(1), and
  - (ii) under his control;
- (c) any decision by him no longer to use premises notified by him in accordance with regulation 9(1) for the purposes of undertaking any activity involving genetic modification;
- (d) any cessation for the time being of all activity involving genetic modification at premises notified by him in accordance with regulation 9(1);
- (e) any cessation of an activity involving genetic modification notified by him in accordance with regulation 10(1), 11(1) or 12(1);
- (f) any re-commencement by him of an activity involving genetic modification at premises in respect of which details of a cessation had previously been given by him under subparagraph (d);
- (g) any change in the information specified in—
  - (i) paragraphs (b) and (c) of Schedule 5 and provided by him in accordance with regulation 9(1), or
  - (ii) paragraph 1(c) or (d) of Part I of Schedule 6 and provided by him in accordance with regulation 10(1).

(3) Without prejudice to regulation 9(1) a notifier shall, in addition to the details referred to in paragraph (2), send full details in writing of any use by him of additional premises in connection with a single activity involving genetic modification carried on solely by him at more than one site, on condition that a notification has been submitted by him in accordance with regulation 9(1) in respect of the additional premises;

(4) Subject to paragraphs (5) and (6), where a notifier subsequently—

- (a) makes a change in the premises or the activity involving genetic modification to which his notification relates which may have significant consequences for the risks arising from that activity; or
- (b) becomes aware of any new information which may have significant consequences for the risks arising from that activity,

he shall forthwith send to the competent authority in writing full details of the change or the new information, as the case may be.

(5) Subject to paragraph (6), where a change referred to in paragraph (3)(a) would require a person to submit a notification in accordance with regulation 11(1), that person shall not make the change until—

- (a) he has submitted a notification in accordance with that regulation; and
- (b) he has received the written consent of the competent authority pursuant to regulation 11(1)(b).

(6) Paragraph (5) shall not apply where a person undertakes an activity involving genetic modification with the written consent of the competent authority granted pursuant to regulation 11(1)(b) and the change referred to in paragraph (4) would require that person to make a further notification under regulation 11(1).

(7) A notifier may withdraw his notification by giving written notice to the competent authority, provided that the notifier has not commenced the activity involving genetic modification to which the notification relates.

(8) In this regulation, the word “site” has the same meaning as it has in regulation 13.

(9) Anything required to be submitted or sent to the competent authority pursuant to these Regulations shall be submitted or sent in writing to the competent authority at 83 Ladas Drive, Belfast BT6 9FR.