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STATUTORY RULES OF NORTHERN IRELAND

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**2015 No. 339**

**The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015**

**PART 4**

**Duties and Powers of the Competent Authority**

**Duties of competent authority on receiving a notification**

**23.** The competent authority shall examine a notification and accompanying documentation submitted under regulation 9(2), 10(2), 11(2), or 12(2) for—

- (a) conformity with the requirements of these Regulations;
- (b) the accuracy and completeness of the information provided;
- (c) the adequacy and correctness of the risk assessment or summary of the risk assessment;
- (d) the adequacy of the waste management and emergency response measures;
- (e) in the case of a notification submitted under regulation 10(2) or 11(2), the correctness of the class assigned to the contained use; and
- (f) the inclusion of an emergency plan where the risk assessment indicates that such a plan is necessary.

**Requests for additional information**

**24.—(1)** For the purpose of carrying out an examination of a notification in accordance with regulation 23 the Executive may, on behalf of the competent authority, request the notifier to provide such additional information relating to the notification as it may specify.

(2) If requested to do so by the Department of the Environment, the Executive shall request additional information under paragraph (1).

(3) A request for additional information shall be made in writing.

(4) The Executive shall send an acknowledgement of receipt to the notifier within 10 working days of receipt of all of the additional information.

(5) The period of time beginning with the date on which the Executive requests additional information and ending with the date on which the Executive receives all of that additional information will not be taken into account in calculating the period of days referred to in regulation 10(4), 10(7), 11 (4), 11(5) or 12(4).

(6) The competent authority may return a notification to the notifier where—

- (a) the Executive has requested additional information;
- (b) the notifier has not provided all the additional information requested within six months of the date on which the Executive sent the request; and

- (i) contained use has not commenced at the premises to which a notification made under regulation 9(2) relates; or
- (ii) the contained use referred to in the notification has not commenced.

#### **Powers of competent authority in relation to contained use**

**25.** The competent authority may at any time by notice in writing to a notifier—

- (a) set a time limit for, or impose conditions with regard to, a particular contained use;
- (b) require the notifier and any user to suspend, terminate or not to commence a particular contained use;
- (c) revoke or vary a consent granted to the notifier under regulation 11,

and the notifier and any user undertaking the contained use shall comply with that notice.

#### **Exemption certificates**

**26.—**(1) The competent authority may, by a certificate in writing, exempt—

- (a) any person or class of persons; or
- (b) any genetically modified organism or class of genetically modified organisms,

from all or any of the requirements of, or prohibitions imposed by, these Regulations.

(2) An exemption may be granted subject to conditions and to a time limit and may be revoked by a certificate in writing at any time.

(3) The competent authority shall not grant an exemption unless, having regard to the circumstances of the case and in particular to—

- (a) the conditions, if any, that it proposes to attach to the exemption; and
- (b) any relevant requirements imposed by or under any enactments,

it is satisfied about the matters referred to in paragraph (4).

(4) The matters are—

- (a) that the health or safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it; and
- (b) where the exemption relates to a contained use involving a micro-organism, that the environment will not be prejudiced in consequence of the exemption.

#### **Duties of competent authority on receipt of information about accidents**

**27.** Where the competent authority is informed of an accident in accordance with regulation 22, it shall—

- (a) ensure that any necessary measures are taken;
- (b) immediately inform those EEA States which could be affected by the accident;
- (c) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit their effects; and
- (d) send to the European Commission—
  - (i) the information provided under regulation 22(a), (b) and (d);
  - (ii) information on the effectiveness of the measures taken in response to the accident; and

- (iii) an analysis of the accident, including recommendations to limit its effects and to avoid similar accidents in the future.

### **Register of notifications**

- 28.**—(1) This regulation is subject to regulation 29.
- (2) The competent authority shall maintain a register of every notification submitted under regulations 9 to 12.
- (3) Subject to paragraph (4) the register shall contain—
- (a) in relation to each notification submitted under regulations 9(2), 10(2), 11(2) or 12(2)—
    - (i) the name, address and telephone number and any fax number and any e-mail address of the notifier;
    - (ii) the date on which the Executive acknowledged receipt of the notification; and
    - (iii) where the competent authority receives details of a matter referred to in subparagraphs (a) to (g) of regulation 14(1), or in regulation 15(1), confirmation that such details have been received;
  - (b) in relation to each notification submitted under regulation 10(2), 11(2) or 12(2), the date of any cessation of the contained use to which the notification related;
  - (c) in relation to each notification submitted under regulation 9(2)—
    - (i) the information specified in paragraphs (d) to (g) and (h)(ii) and (iii) of Schedule 5;
    - (ii) if applicable, the fact that the competent authority has been informed of an accident at those premises under regulation 22;
  - (d) in relation to each notification submitted under regulation 10(2), the information specified in paragraphs (e) to (k) and (m)(i) and (ii) of Schedule 6;
  - (e) in relation to each notification submitted under regulation 11(2)—
    - (i) the information specified in paragraphs (e) to (j), (l), (m)(i),(iii) and (iv) and (r) of Schedule 6;
    - (ii) if applicable, confirmation that consent for the contained use has been granted under regulation 11(4) or 11(5);
  - (f) in relation to each notification submitted under regulation 12(2), the information specified in paragraphs (e) to (j) and (m)(i) of Schedule 6.
- (4) The competent authority shall omit information from the register where—
- (a) the information falls within one of the exceptions to disclosure in regulation 12(5) or 13(1) of the Environmental Information Regulations 2004(1);
  - (b) the notifier has requested that the competent authority treat the information as confidential; and
  - (c) the competent authority has decided that the information is to be kept confidential.
- (5) The competent authority may not keep the following information confidential if it was submitted in accordance with the requirements of regulation 9(2), 10(2) or 11(2)—
- (a) the general characteristics of any genetically modified micro-organisms, the name and address of the notifier, and the location of use;
  - (b) the class of contained use and the containment measures;

- (c) the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.
- (6) Information shall be entered in the register within 14 days of its receipt by the competent authority.
- (7) The competent authority may remove from the register details of—
  - (a) premises which are no longer used for contained use, ten years after being informed of this under regulation 14(1)(c);
  - (b) premises where all contained use has ceased for the time being, ten years after being informed of this under regulation 14(1)(d), provided that no notice of recommencement under regulation 14(1)(f) has been received;
  - (c) a contained use that has ceased, ten years after being informed of this under regulation 14(1)(e).
- (8) A copy of the register shall be made available for inspection to members of the public by the Executive, by such means as it considers appropriate, which may include publication on its website.

**Information not to be included in the register**

**29.**—(1) No information shall be included in the register if and so long as, in the opinion of the Department of Enterprise, Trade and Investment, the inclusion in the register of that information, or information of that description, would be a breach of confidentiality.

(2) For the purpose of securing the exclusion from the register of information to which paragraph (1) applies, the Department of Enterprise, Trade and Investment may give the competent authority directions—

- (a) specifying information, or descriptions of information, to be excluded from the register; or
- (b) specifying descriptions of information to be referred to the Department of Enterprise, Trade and Investment for its determination.

(3) No information referred to the Department of Enterprise, Trade and Investment under paragraph (2)(b) shall be included in the register unless the Department of Enterprise, Trade and Investment determines that it should be included.

(4) The competent authority shall notify the Department of Enterprise, Trade and Investment of any information it excludes from the register in accordance with directions given to it under paragraph (2).

(5) A person may give a written notice to the Department of Enterprise, Trade and Investment specifying information which appears to that person to be information to which paragraph (1) may apply and stating why it should not be included in the register.

(6) If a person gives a written notice under paragraph (5), at the same time that person shall give written notice to the competent authority that they have done so.

(7) No information notified under paragraph (5) shall be included in the register unless the Department of Enterprise, Trade and Investment determines that it should be included.