
STATUTORY RULES OF NORTHERN IRELAND

2001 No. 295

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

Part IV

Disclosure of Information and Publicity

Disclosure of information provided pursuant to regulations 9 to 15

22.—(1) The information provided pursuant to regulations 9 to 15 shall not be treated as relevant information for the purposes of Article 30 of the 1978 Order⁽¹⁾.

(2) Subject to paragraph (3), where, either in a notification submitted under regulation 9(1), 10(1), 11(1) or 12(1), or in response to a request made in pursuance of regulation 14(2) or when providing information in accordance with regulation 15(2), 15(3) or 15(4), a person indicates that he is providing information which should be kept confidential on one or more of the grounds set out in regulation 5(2)(a) to (c) and (e) of the Environmental Information Regulations (Northern Ireland) 1993⁽²⁾—

- (a) that person shall give full justification for that indication to the competent authority; and
- (b) after consulting that person, the competent authority shall decide which, if any, information shall be kept confidential and shall inform him of its decision.

(3) Subject to paragraph (8), paragraph (2) shall not apply to the following information, which shall not be kept confidential—

- (a) the name and address of the notifier;
- (b) in the case of a notification relating to an activity involving genetic modification of a micro-organism—
 - (i) the location of the activity,
 - (ii) the general characteristics of the genetically modified micro-organism,
 - (iii) the class of the activity involving genetic modification of the micro-organism,
 - (iv) the containment measures, and
 - (v) the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

(4) Information which a notifier has indicated should be kept confidential and in relation to which the competent authority has not yet made a decision under paragraph (2)(b) and information which the competent authority has decided shall be kept confidential shall not be disclosed except—

- (a) to the extent necessary to evaluate the notification;
- (b) to the Department of Agriculture and Rural Development;

(1) S.I.1978/1039 (N.I. 9); Article 30 was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraph 1

(2) S.R. 1993 No. 45

- (c) to the Department of Enterprise, Trade and Investment;
- (d) to the Great Britain competent authority; and
- (e) to the European Commission.

(5) Where the competent authority has made a decision under paragraph (2)(b) that certain information shall not be kept confidential, that information shall not be disclosed until there has elapsed a period of 14 days following the day on which the competent authority informed the person providing the information of its decision except—

- (a) to the extent necessary to evaluate the notification;
- (b) to the Department of Agriculture and Rural Development;
- (c) to the Department of Enterprise, Trade and Investment;
- (d) to the Great Britain competent authority; or
- (e) to the European Commission.

(6) A person who receives information by virtue of paragraph (4)(a) or (5)(a) shall not use that information except for the purposes of the competent authority.

(7) Information contained in a notification which has been withdrawn shall not be disclosed after the competent authority has received written notice in accordance with regulation 15(7).

(8) Notwithstanding paragraph (3), where the competent authority is satisfied on the basis of evidence submitted to it by the notifier and, where appropriate, after consultation with the notifier, that it is necessary to withhold, for the time being, certain of the information specified in paragraph (3) in order to protect his intellectual property rights, the competent authority shall withhold that information to the extent that, and for so long as, it is necessary to protect those rights.

(9) Subject to paragraph (10), where, pursuant to paragraph (2) or (8), a notifier has indicated that—

- (a) he has provided confidential information; or
- (b) withholding information is necessary in order to protect his intellectual property rights,

he shall forthwith inform the competent authority in writing of any change in circumstances which may affect the justification given under paragraph (2)(a) or the evidence submitted under paragraph (8), as the case may be.

(10) Paragraph (9) shall not apply if the competent authority has informed the notifier that the information in question is not to be kept confidential or withheld.

(11) Where—

- (a) the competent authority has decided to keep information confidential pursuant to paragraph (2)(b) or has withheld information pursuant to paragraph (8); and
- (b) the notifier has informed the competent authority of any change in circumstances pursuant to paragraph (9),

the competent authority shall, after consulting the notifier where appropriate, review whether the information in question should continue to be kept confidential or withheld and shall inform the notifier of the result of that review.

(12) For the purposes of this regulation, “general characteristics” in relation to a genetically modified micro-organism, means characteristics other than genus, species, genotype, serotype and strain.

Disclosure of information provided pursuant to regulation 21

23.—(1) The information provided pursuant to regulation 21 shall not be treated as relevant information for the purposes of Article 30 of the 1978 Order.

(2) Subject to paragraph (3), where a person indicates that information provided by him pursuant to regulation 21 should be kept confidential on one or more of the grounds set out in regulation 5(2) (a) to (c) and (e) of the Environmental Information Regulations (Northern Ireland) 1993—

- (a) he shall give full justification for that indication to the competent authority; and
- (b) after consulting that person, the competent authority shall decide which, if any, information shall be kept confidential and shall inform that person of its decision.

(3) Subject to paragraph (7), paragraph (2) shall not apply to the following information, which shall not be kept confidential—

- (a) the name and address of the person providing the information;
- (b) in the case of an accident relating to an activity involving genetic modification of a micro-organism—
 - (i) the location of the accident,
 - (ii) the general characteristics of genetic modification of the micro-organism,
 - (iii) the class of the activity involving genetic modification of the micro-organism,
 - (iv) the containment measures, and
 - (v) the evaluation of actual and foreseeable effects, in particular any harmful effects on human health and the environment.

(4) Information which the person providing that information has indicated should be kept confidential and in relation to which the competent authority has not yet made a decision under paragraph (2)(b) and information which the competent authority has decided shall be kept confidential shall not be disclosed except to the extent necessary to enable the competent authority to comply with its obligations under regulation 21(2).

(5) Where the competent authority has made a decision under paragraph (2)(b) that certain information shall not be kept confidential, that information shall not be disclosed until there has elapsed a period of 14 days following the day on which the competent authority informed the person providing the information of its decision, except to the extent necessary to enable the competent authority to comply with its obligations under regulation 21(2).

(6) A person who receives information by virtue of paragraph (4) or (5) shall not use that information except for the purposes of the competent authority.

(7) Notwithstanding paragraph (3), where the competent authority is satisfied on the basis of detailed evidence submitted to it by the person providing the information and, where appropriate, after consultation with that person, that it is necessary to withhold, for the time being, certain of the information specified in paragraph (3) in order to protect his intellectual property rights, the competent authority shall withhold that information to the extent that, and for so long as, it is necessary to protect those rights.

(8) Subject to paragraph (9), where, pursuant to paragraph (2) or (7), a person has indicated—

- (a) that certain information is confidential; or
- (b) withholding information is necessary in order to protect his intellectual property rights,

he shall forthwith inform the competent authority in writing of any change in circumstances which may affect the justification given under paragraph (2)(a) or the evidence submitted under paragraph (7), as the case may be.

(9) Paragraph (8) shall not apply if the competent authority has informed the person providing the information that the information in question is not to be kept confidential or withheld.

(10) Where—

- (a) the competent authority has decided to keep information confidential pursuant to paragraph (2)(b) or has withheld information pursuant to paragraph (7); and

- (b) the person who provided the information has informed the competent authority of a change in circumstances pursuant to paragraph (8),

the competent authority shall, after consulting that person where appropriate, review whether the information in question should continue to be kept confidential, and shall inform that person of the result of that review.

(11) In this regulation, “general characteristics” in relation to a genetically modified micro-organism has the same meaning as it has in regulation 22.

Register of notifications

24.—(1) The competent authority shall maintain a register of every notification submitted under regulations 9 to 12.

(2) The register referred to in paragraph (1) shall contain—

- (a) in relation to every notification submitted under regulations 9 to 12—
- (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 receipt of the notification was acknowledged by the Executive, and
 - (iii) if the competent authority receives details of a matter referred to in sub-paragraphs (a) to (f) of regulation 15(2) or in regulation 15(3) or regulation 15(4), confirmation that such details have been received;
- (b) in relation to each notification submitted under regulation 10(1), 11(1) or 12(1), the date of any cessation of the activity involving genetic modification to which the notification relates.

(3) The register referred to in paragraph (1) shall also contain—

- (a) in relation to each notification submitted under regulation 9(1)—
- (i) the information specified in paragraphs (d) to (g), (h)(ii) and (h)(iii) of Schedule 5, and
 - (ii) if the competent authority has been informed of an accident under regulation 21 at the premises to which the notification relates, confirmation that the information has been received;
- (b) in relation to each notification submitted under regulation 10(1), the information specified in paragraph 1(e) to (l) of Part I of Schedule 6;
- (c) in relation to each notification submitted under regulation 11(1)—
- (i) the information specified in paragraph 2(e) to (m) of Part II of Schedule 6 and,
 - (ii) if appropriate, confirmation that a consent under regulation 11(3) or regulation 11(4), as the case may be, has been granted;
- (d) in relation to each notification submitted under regulation 12(1), the information specified in paragraph 3(e) to (k) of Part III of Schedule 6,

but the register shall not contain any information which the competent authority has decided shall be kept confidential under regulation 22(2)(b) or shall be withheld under regulation 22(8).

(4) Information shall be entered in the register within 14 days of its receipt by the competent authority, except that, where a notifier has requested that certain information—

- (a) be kept confidential in accordance with regulation 22(2); or
- (b) be withheld in accordance with regulation 22(8),

that information shall be entered in the register not less than 14 days and not more than 28 days following the day on which the competent authority informed the notifier of its decision not to keep that information confidential or not to withhold that information, as the case may be.

(5) Where a person withdraws a notification under regulation 15(7), information relating to that notification, which has been entered in the register, shall be removed from the register by the competent authority.

(6) The competent authority may remove from the register—

- (a) information relating to an activity involving genetic modification ten years after being notified in accordance with regulation 15(2)(d) or (e) that the activity has ceased; and
- (b) information relating to premises ten years after being notified in accordance with regulation 15(2)(c) of a decision no longer to use such premises for the purposes of undertaking any activity involving genetic modification.

(7) Copies of the register shall be maintained at the offices of the Executive at 83 Ladas Drive, Belfast BT6 9FR.

(8) The copies of the register shall be open to inspection by members of the public at any reasonable time.