STATUTORY RULES OF NORTHERN IRELAND

2015 No. 339

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

PART 5

Miscellaneous and General

Enforcement and civil liability

- **30.**—(1) This regulation applies to the extent that any part of these Regulations are not health and safety regulations within the meaning of Article 17 of the 1978 Order.
- (2) The following provisions apply to the whole of these Regulations as if they were health and safety regulations for the purposes of that Order—
 - (a) Articles 18 to 28 (approved codes of practice and enforcement) and Articles 31 to 39 (provisions as to offences) and Article 43 (civil liability) of the 1978 Order(1); and
 - (b) the Health and Safety (Training for Employment) Regulations (Northern Ireland) 1994(2).
- (3) Every function of the Executive under any provision of the 1978 Order, or under health and safety regulations, is exercisable in relation to these Regulations as if the whole of these Regulations were health and safety regulations for the purposes of that Order.
- (4) Despite Article 31(1)(c) of the 1978 Order a failure to discharge a duty placed on the competent authority or the Executive by these Regulations shall not be an offence.
- (5) Despite regulation 4 of the Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999(3), the enforcing authority for these Regulations shall be the Executive.

Appeals

- **31.**—(1) A person responsible for contained use who is aggrieved by any of the following may appeal to the Department of Enterprise, Trade and Investment—
 - (a) a decision by the competent authority—
 - (i) to refuse to provide a written agreement requested under regulation 10(6);
 - (ii) to refuse consent for a class 3 or class 4 contained use notified under regulation 11(2);
 - (iii) to refuse to provide written agreement under regulation 19(2)(c) that a particular containment measure need not be applied for a specific activity;
 - (iv) to refuse to grant an exemption certificate under regulation 26(1) or to revoke such a certificate;

S.I.1978/1039 (N.I.9); Articles 18 to 20 and 31 were amended by, and Article 34A was inserted by, S.I. 1998/2795 (N.I.18), Article 6(1) and Schedule 1

⁽²⁾ S.R. 1994 No.1

⁽³⁾ S.R. 1999 No.90

- (v) to impose a condition or a time limit on an exemption certificate issued under regulation 26(1);
- (b) an instruction concerning the cessation of a contained use under regulation 16(3);
- (c) a request for additional information by the Executive under regulation 24(1);
- (d) a notice from the competent authority under regulation 25.
- (2) Chapter I of the Schedule to the Deregulation (Model Appeal Provisions) Order (Northern Ireland) 1997(4) shall apply to any appeal made under this regulation.
 - (3) Where an appeal is brought under this regulation—
 - (a) the following remain valid pending the final determination of the appeal—
 - (i) a decision of the competent authority referred to in paragraph (1)(a);
 - (ii) a request for additional information made under regulation 24(1);
 - (b) the following are not suspended pending the final determination of the appeal—
 - (i) the operation of regulation 16 and any instructions given under regulation 16(3);
 - (ii) a notice issued under regulation 25.
- (4) The period of time beginning with the date on which an appeal is lodged and ending with the date on which that appeal is determined 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).

Competent authority address

32. Anything required to be submitted or sent to the competent authority under these Regulations shall be sent to the Executive at the address published for this purpose on its website which may be, or include, an address for submission by electronic means.

Saving and transitional provisions

- **33.**—(1) Subject to paragraph (3) the following continue to have effect and will be deemed to have been made, granted or imposed under these Regulations—
 - (a) a notification made under any of regulations 9 to 13 of the 2001 Regulations, provided that the notification complied with the provisions of those Regulations, as if the notification had been made by a notifier under the corresponding regulation of these Regulations;
 - (b) a consent granted by the competent authority under regulation 11 of the 2001 Regulations as if it were granted under regulation 11 of these Regulations;
 - (c) an agreement by the competent authority under regulation 18(2) of the 2001 Regulations that a specific containment measure need not be applied to a contained use, as if it were made under regulation 19(2) of these Regulations;
 - (d) a request for additional information made under regulation 14(2) of the 2001 Regulations, as if it were made under regulation 24(1) of these Regulations;
 - (e) a condition, limit of time or other requirement imposed by the competent authority under regulation 15(1) of the 2001 Regulations, as if it were imposed under regulation 25 of these Regulations.
- (2) Every record required to be kept under regulation 8(2) of the 2001 Regulations shall be kept in the same manner and for the same period as specified in that regulation as if the requirement were imposed under regulation 7(2) of these Regulations.

- (3) A person responsible for contained use involving micro-organisms shall submit a notification to the competent authority in the following circumstances—
 - (a) the contained use was being undertaken in accordance with the 2001 Regulations before the date on which these Regulations come into operation;
 - (b) the appropriate containment level for the contained use is different under these Regulations to the appropriate containment level under the 2001 Regulations; and
 - (c) as a result the contained use is classified under these Regulations at a higher class than under the 2001 Regulations.
 - (4) The notification shall be submitted to the competent authority within the specified period.
- (5) Subject to paragraphs (6) to (8) the notification shall be treated as a notification required under regulation 10(2) or 11(2) of these Regulations.
- (6) The notification shall contain the information in Schedule 6 that is specified for the new class of contained use, unless the competent authority exempts the notifier from some or all of the requirements of Schedule 6.
- (7) Where a notification is submitted for a contained use that requires consent as class 3 or class 4 contained use, the competent authority shall inform the notifier of its decision whether or not to grant consent within 90 days of receipt of the notification.
 - (8) The contained use referred to in paragraph (3) may continue provided that—
 - (a) the notification is submitted within the specified period;
 - (b) the risk assessment shows no increase in the risks to human health or the environment created by the contained use;
 - (c) the competent authority does not require the notifier to suspend or terminate the contained use under regulation 25 of these Regulations; and
 - (d) the competent authority has not refused consent for the contained use.
 - (9) In this regulation
 - "specified period" means the 90 days beginning with the date on which these Regulations come into operation.

Consequential Amendments

- **34.**—(1) The Health and Safety (Fees) Regulations (Northern Ireland) 2012(5) shall be amended as follows.
 - (2) In regulation 8—
 - (a) in the heading, for "2001" substitute "2015";
 - (b) in paragraph (1), after "a notifier" add "or applicant" and for "2001" substitute "2015";
 - (c) for paragraph (2) substitute—
 - "(2) No fee shall be returned to a notifier where the notifier withdraws a notification under regulation 17 of the 2015 Regulations or the competent authority returns a notification under regulation 24(6) of the 2015 Regulations.";
 - (d) for paragraph (3) substitute–
 - "(3) In this regulation, "the 2015 Regulations" means the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015 and "notifier" and "competent authority" have the same meaning as in those Regulations.".
 - (3) In Schedule 6—

- (a) in the heading, for "2001" substitute "2015";
- (b) in column 1 of the table—
 - (i) for paragraph (a) substitute "Notification of premises to be used for contained use for the first time under regulation 9(2)";
 - (ii) for paragraph (b) substitute "Notification of class 2 contained use under regulation 10(2)";
 - (iii) for paragraph (c) substitute "Notification of premises to be used for contained use for the first time under regulation 9(2) at the same time as notification of class 2 contained use under regulation 10(2)";
 - (iv) for paragraph (d) substitute "Notification of class 3 contained use under regulation 11(2)";
 - (v) for paragraph (e) substitute "Notification of premises to be used for contained use for the first time under regulation 9(2) at the same time as notification of class 3 contained use under regulation 11(2)";
 - (vi) for paragraph (f) substitute "Notification of class 4 contained use under regulation 11(2)";
 - (vii) for paragraph (g) substitute "Notification of premises to be used for contained use for the first time under regulation 9(2) at the same time as notification of class 4 contained use under regulation 11(2)";
 - (viii) for paragraph (h) substitute "Notification of contained use under regulation 12(2)";
 - (ix) for paragraph (i) substitute "Notification of premises to be used for contained use for the first time under regulation 9(2) at the same time as notification of contained use under regulation 12(2)";
 - (x) for paragraph (j) substitute "Notification of a change or new information affecting risks under regulation 15(1)";
 - (xi) in paragraph (k) for "18(2)" substitute "19(2)" and for "9(1), 10(1), 11(1) or 12(1)" substitute "9(2), 10(2), 11(2) or 12(2)".
- **35.**—(1) The REACH Enforcement Regulations 2008(6) shall be amended as follows.
- (2) In Schedule 3, Part 3, paragraph 1(j) for the words "the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001" substitute "the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015".

Revocations

- **36.** The following shall be revoked—
 - (a) the 2001 Regulations,
 - (b) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 2006(7), and
 - (c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 2010(8).

⁽⁶⁾ S.I. 2008/2852

⁽⁷⁾ S.R. 2006 No.524

⁽⁸⁾ S.R. 2010 No.343