
STATUTORY INSTRUMENTS

2000 No. 2831

**The Genetically Modified
Organisms(Contained Use) Regulations 2000**

PART V

MISCELLANEOUS AND GENERAL

Exemption certificates

25.—(1) Subject to paragraph (2), 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 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 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 requirements imposed by or under any enactments which apply to the case,

it is satisfied about the matters referred to in paragraph (3).

(3) The matters about which the competent authority shall be satisfied for the purposes of paragraph (2) are—

- (a) that the health and safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it; and
- (b) that the environment will not be prejudiced in consequence of the exemption where the exemption is concerned with a requirement of, or a prohibition imposed by, these Regulations which relates to an activity involving genetic modification of a micro-organism.

Enforcement and civil liability

26.—(1) Subject to paragraph (2) and to the extent they would not otherwise do so, the provisions of—

- (a) sections 16 to 26 (approved codes of practice and enforcement), sections 33 to 42 (provisions as to offences) and section 47 (civil liability) of the 1974 Act; and
- (b) the Health and Safety (Training for Employment) Regulations 1990(1),

shall apply to these Regulations as if they were health and safety regulations for the purposes of that Act, and any function of the Health and Safety Commission under any other provision of the 1974 Act which is exercisable in relation to any function of the Executive under or in respect of health and safety regulations (including their enforcement) shall be exercisable as if these Regulations were, to the extent they would not otherwise be so, health and safety regulations for the purposes of that Act.

(2) A failure to discharge a duty—

- (a) placed on the competent authority or the Executive by these Regulations; or
- (b) placed on any other person by Schedule 11,

shall not be an offence, and section 33(1)(c) of the 1974 Act shall have effect accordingly.

(3) Notwithstanding regulation 3 of the Health and Safety (Enforcing Authority) Regulations 1998(2), the enforcing authority for these Regulations shall be the Executive.

Fees for notifications and applications

27.—(1) The fee specified in column 2 of the table in Schedule 9 shall be payable by a notifier to the competent authority in relation to any notification or application referred to in the corresponding entry in column 1 of that table.

(2) No fee shall be returned to a notifier where the competent authority returns a notification pursuant to regulation 14(7) or a notifier withdraws his notification pursuant to regulation 15(6).

Transitional provisions

28. Schedule 10 shall have effect.

Appeals

29.—(1) Any person who is aggrieved by a decision of the competent authority—

- (a) that he shall not undertake an activity involving genetic modification referred to in regulation 10(1), 11(1) or 12(1);
- (b) not to agree pursuant to regulation 18(2) that he need not apply a particular containment measure for the activity involving genetic modification in question;
- (c) to revoke an exemption certificate granted to him pursuant to regulation 25(1);
- (d) to grant to him an exemption certificate subject to a condition or a limit of time pursuant to regulation 25(1),

may appeal to the appropriate person.

(2) Any person who is aggrieved by—

- (a) a request to him made pursuant to regulation 14(2);
- (b) an instruction given to him pursuant to regulation 14(3);
- (c) a notice given to him pursuant to regulation 15(1),

may appeal to the appropriate person.

(3) Any person who is aggrieved by a decision of the competent authority—

- (a) made pursuant to regulation 22(2)(b) or regulation 23(2)(b), not to keep confidential information provided by that person to the competent authority in accordance with these Regulations;
- (b) made pursuant to regulation 22(8) or regulation 23(7), not to withhold information,

may appeal to the appropriate person.

(4) The provisions of Schedule 11 shall apply where an aggrieved person appeals to the appropriate person.

(5) Where an appeal is brought under this regulation, none of the following, that is to say—

- (a) a decision of the competent authority other than a decision referred to in paragraph (3);
- (b) an instruction given pursuant to regulation 14(3);
- (c) the operation of paragraphs (2) or (6) of regulation 14;
- (d) a notice given pursuant to regulation 15(1),

shall be suspended pending the final determination of the appeal.

(6) Where an appeal is brought under paragraph (3) in respect of any information provided pursuant to regulation 21, pending the final determination of the appeal, the information shall not be disclosed except to the extent necessary to enable the competent authority to comply with its obligations under paragraph (2)(a), (b) and (d) of that regulation.

(7) Where an appeal is brought under paragraph (3) in respect of information provided pursuant to regulations 9 to 15—

(a) pending the final determination of the appeal, the information shall not be disclosed except—

- (i) to the extent necessary to evaluate the notification, and
- (ii) to the European Commission;

(b) if—

- (i) the appeal is finally determined in favour of the competent authority, and
- (ii) the information is required to be entered in the register maintained in accordance with regulation 24,

the information shall be entered in that register within fourteen days following the day on which the appeal is finally determined.

(8) In this regulation, “the appropriate person” means—

(a) the Secretary of State, in the case of—

(i) an appeal under paragraph (1), (2)(c) or (3) against a decision of, or a notice given by, the competent authority as regards England and Wales, or

(ii) an appeal under paragraph (2)(a) or (b) against a request or instruction relating to—

(aa) the undertaking or proposed undertaking of an activity involving genetic modification, or

(bb) premises which are the subject of a notification under regulation 9(1) and which are situate,

in England or Wales;

(b) the Secretary of State and the Scottish Ministers, acting jointly, in the case of—

(i) an appeal under paragraph (1), (2)(c) or (3) against a decision of, or a notice given by, the competent authority as regards Scotland or the joint competent authority, or

(ii) an appeal under paragraph 2(a) or (b) against a request or instruction relating to—

(aa) the undertaking or proposed undertaking of an activity involving genetic modification, or

(bb) premises which are the subject of a notification under regulation 9(1) and which are situate,

in Scotland or in both England and Scotland, as the case may be.

Extension outside Great Britain

30. These Regulations shall apply in relation to premises and activities involving genetic modification outside Great Britain to which sections 1 to 59 and 80 to 82 of the 1974 Act apply by virtue of the Health and Safety at Work etc. Act 1974 (Application Outside Great Britain) Order 1995⁽³⁾ as they apply to premises and activities involving genetic modification within Great Britain.

Revocations, amendments and savings

31.—(1) The following are revoked—

- (a) the Genetically Modified Organisms (Contained Use) Regulations 1992⁽⁴⁾;
- (b) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996⁽⁵⁾;
- (c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1998⁽⁶⁾.

(2) In paragraph (3)(h) of regulation 8 of the Genetically Modified Organisms (Deliberate Release) Regulations 1992⁽⁷⁾, for the words “under regulation 11 of the Genetically Modified Organisms (Contained Use) Regulations 1992”, there shall be substituted the words “under regulation 16 of the Genetically Modified Organisms (Contained Use) Regulations 2000”.

(3) The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996⁽⁸⁾ shall be amended as follows—

- (a) in regulation 1(3), in the definition of “the Contained Use Regulations”, for the words “the Genetically Modified Organisms (Contained Use) Regulations 1992”, there shall be substituted the words “the Genetically Modified Organisms (Contained Use) Regulations 2000”;
- (b) in paragraph (2)(b)(i) of regulation 3, for the words “Schedule 1”, there shall be substituted the words “Schedule 2”; and
- (c) in paragraph (2)(b)(ii) of regulation 3, for the words “regulation 3(3) of, and Part III of Schedule 1” there shall be substituted the words “regulation 3(2) of, and Part III of Schedule 2”.

(4) In paragraph 12(5) of Schedule 3 to the Control of Substances Hazardous to Health Regulations 1999⁽⁹⁾, for the words “Genetically Modified Organisms (Contained Use) Regulations 1992”, there shall be substituted the words “Genetically Modified Organisms (Contained Use) Regulations 2000.”

(5) In the Health and Safety (Fees) Regulations 2000⁽¹⁰⁾, regulation 17 and Schedule 14 shall be omitted.

(6) Every record required to be kept under regulation 7(5) of the Genetically Modified Organisms (Contained Use) Regulations 1992 shall, notwithstanding paragraph (1), be kept in the same manner and for the same period as specified in that regulation as if these Regulations had not been made.

⁽³⁾ S.I. 1995/263.

⁽⁴⁾ S.I. 1992/3217.

⁽⁵⁾ S.I. 1996/967.

⁽⁶⁾ S.I. 1998/1548.

⁽⁷⁾ S.I. 1992/3280. Paragraph (3) of regulation 8 was amended by S.I. 1995/304; there are other amendments not relevant to these Regulations.

⁽⁸⁾ S.I. 1996/1106, to which there are amendments not relevant to these Regulations.

⁽⁹⁾ S.I. 1999/437.

⁽¹⁰⁾ S.I. 2000/2482.

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