
STATUTORY INSTRUMENTS

2000 No. 2831

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

PART I

INTERPRETATION AND GENERAL

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations 2000 and shall come into force on 15th November 2000.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

“the 1974 Act” means the Health and Safety at Work etc. Act 1974;

“accident” means an incident involving a significant and unintended release of genetically modified organisms in the course of an activity involving genetic modification which presents an immediate or delayed hazard to human health or to the environment;

“activity involving genetic modification” means a contained use;

“class”, in relation to an activity involving genetic modification of micro-organisms, means one of the four classes described in Schedule 1;

“competent authority” means—

(a) as regards England and Wales, the Secretary of State, the Minister of Agriculture, Fisheries and Food and the Executive, acting jointly; and

(b) as regards Scotland, the Scottish Ministers and the Executive, acting jointly,

and the expressions “competent authority as regards England and Wales” and “competent authority as regards Scotland” shall be construed accordingly;

“contained use” means an activity in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are used to limit their contact with, and to provide a high level of protection for, humans and the environment;

“EEA State” means a State, other than the United Kingdom, which is a Contracting Party to the Agreement on the European Economic Area signed at Oporto on 2nd May 1992, as adjusted by the Protocol signed at Brussels on 17th March 1993(1) and adopted as respects the United Kingdom by the European Economic Area Act 1993(2);

“emergency plan” means a plan required by virtue of regulation 20;

(1) Cm 2073 and 2183.

(2) 1993 c. 51.

“emergency services” means the police, fire and ambulance services;

“the Executive” means the Health and Safety Executive;

“genetic modification” in relation to an organism means the altering of the genetic material in that organism in a way that does not occur naturally by mating or natural recombination or both and within the terms of this definition—

- (a) genetic modification occurs at least through the use of the techniques listed in Part I of Schedule 2; and
- (b) the techniques listed in Part II of Schedule 2 are not considered to result in genetic modification,

and “genetically modified” shall be construed accordingly;

“joint competent authority” means the competent authority as regards England and Wales and the competent authority as regards Scotland, acting jointly;

“micro-organism” means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, and includes a virus, a viroid, and an animal or plant cell in culture;

“notifier” means a person who has submitted a notification to the competent authority pursuant to regulation 9(1), 10(1), 11(1) or 12(1);

“organism” means a biological entity capable of replication or of transferring genetic material and includes a micro-organism, but does not include a human or a human embryo; and

“working day” means any day other than a Saturday, a Sunday, Christmas Day or Good Friday, or a bank holiday within the meaning given by the Banking and Financial Dealings Act 1971(3).

(2) In these Regulations—

- (a) in relation to an activity involving genetic modification, any reference to an appropriate containment level is a reference to the containment level assigned to that activity in accordance with paragraphs 3(h) and 4 of Part II of Schedule 3;
- (b) any reference to an activity involving genetic modification in a numbered class is a reference to an activity involving genetic modification of micro-organisms which has been classified as belonging to the class of that number in accordance with paragraph 3(i) and (j) of Part II of Schedule 3; and
- (c) in relation to a notification submitted in accordance with regulation 13(1), any reference to the competent authority shall be construed as a reference to the joint competent authority.

(3) The provisions in—

- (a) Part II of Schedule 8 shall be applied in accordance with Part I of that Schedule; and
- (b) Tables 1a, 1b and 1c in Part II of Schedule 8 shall be applied in accordance with the notes set out at the end of the Table in question.

(4) In these Regulations, unless the context otherwise requires—

- (a) a reference to a numbered regulation or Schedule is a reference to the regulation or Schedule in these Regulations so numbered; and
- (b) a reference to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule in which that reference occurs.

Application

3.—(1) These Regulations shall have effect with a view to—

- (a) protecting persons against risks to their health, whether immediate or delayed, arising from activities involving genetic modification of organisms; and
- (b) protecting the environment against harm from activities involving genetic modification of micro-organisms.

(2) These Regulations (except regulation 17) shall not apply to the genetic modification of organisms solely by any of the techniques referred to in Part III of Schedule 2 nor to any organisms so modified.

(3) These Regulations shall not apply to any activity in which—

- (a) genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are or are contained in—

- (i) a product marketed in pursuance of either—

- (aa) a consent granted by the Secretary of State, or, as regards Scotland, by the Scottish Ministers, under section 111(1) of the Environmental Protection Act 1990(4), or

- (bb) a written consent given by the competent authority of an EEA State in accordance with Article 13(4) of Council Directive 90/220/EEC(5) on the deliberate release into the environment of genetically modified organisms,

and, in either case, that activity is conducted in accordance with any conditions or limitations attached to that consent,

- (ii) a medicinal product for human or veterinary use marketed in accordance with Council Regulation (EEC) No. 2309/93(6), or

- (iii) a novel food or novel food ingredient marketed in accordance with the provisions of Regulation (EC) No. 258/97 of the European Parliament and of the Council(7); or

- (b) genetically modified organisms are released or marketed in cases or circumstances in which the consent of the Secretary of State, or, as regards Scotland, the Scottish Ministers, is required under section 111(1) of the Environmental Protection Act 1990.

(4) Regulations 8 to 15, 17(2) and (3), 18 and 19 shall not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(5) Regulation 6 shall apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air, except that, in making the assessment required by regulation 6(1), the person undertaking that assessment shall not be required to include the steps set out in paragraph 3(h) to (j) of Part II of Schedule 3.

(6) These Regulations shall not extend to Northern Ireland.

(7) In this regulation, “product” means a product consisting of or containing a genetically modified organism or a combination of genetically modified organisms.

(4) 1990 c. 43.

(5) OJ No. L117, 8.5.90, p. 15, as amended by Commission Directive 94/15/EC (OJ No. L103, 22.4.94, p. 20) and Commission Directive 97/35/EC (OJ No. L 169, 27.6.97, p. 72).

(6) OJ No. L 124, 24.8.93, p. 1, as amended by Commission Regulation (EC) 649/98 (OJ No. L 88, 24.3.98, p. 7).

(7) OJ No. L 43, 14.2.97, p. 1 (to be read with Corrigenda published in OJ L 173, 1.7.97, p. 12 and OJ L 187, 20.7.99, p. 74).

Meaning of “work” and “at work”

4. For the purpose of these Regulations and Part I of the 1974 Act, the meaning of “work” shall be extended to include any activity involving genetic modification and the meaning of “at work” shall be extended accordingly.

Modification of the Health and Safety at Work etc. Act 1974

5.—(1) Sections 2(1), (2) and (3) and 7 of the 1974 Act shall be modified in relation to an activity involving genetic modification so as to have effect as if the reference to an employer therein includes a reference to an educational establishment providing a course of study, and the reference to an employee therein includes a reference to a student of that educational establishment and that student shall be treated as the employee of that educational establishment, to the extent that the activity involving genetic modification is under the control of that educational establishment.

(2) Section 3(2) of the 1974 Act shall be modified in relation to an activity involving genetic modification so as to have effect as if the reference in that section to a self-employed person is a reference to any person (except a student) who is not an employer or an employee and the reference in that section to his undertaking includes a reference to such an activity.

(3) In this regulation—

- (a) “educational establishment” means a university, polytechnic, college, school or similar educational or technical institute; and
- (b) “student” means any person studying at an educational establishment.