STATUTORY INSTRUMENTS

# 1992 No. 3217

# The Genetically Modified Organisms (Contained Use) Regulations 1992

## PART II

## NOTIFICATION OF AND CONSENT FOR ACTIVITIES INVOLVING GENETIC MODIFICATION

**Prohibition of certain work with genetically modified organisms outside containment**

**6.**—(1) Subject to paragraph (2), any operation in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of is prohibited unless it is undertaken in conditions of contained use in accordance with these Regulations.

(2) Paragraph (1) shall not apply to any operation in which—

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

(i) a consent granted by the Secretary of State under section 111(1) of the Environmental Protection Act 1990(**1**), or

(ii) a written consent given by another competent authority of a member State in accordance with Article 13(4) of Council Directive 90/220/EEC(**2**) on the deliberate release into the environment of genetically modified organisms, and

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

(b) genetically modified organisms are released or marketed in circumstances in which the consent of the Secretary of State is required under section 111(1) of the Environmental Protection Act 1990.

(3) In this regulation, "product" means a product consisting of or containing a genetically modified organism or a combination of genetically modified organisms.

**Risk assessment**

**7.**—(1) A person shall not—

(a) use any premises for activities involving genetic modification for the first time; or

(b) undertake any activity involving genetic modification,

(**1**) 1990 c. 43.
(**2**) OJNo. L117, 8.5.90, p.15.

unless he has ensured that, before commencing that use or activity, as the case may be, a suitable and sufficient assessment of the risks created thereby to human health and the environment has been made.

(2) Without prejudice to the generality of paragraph (1), the purposes of the assessment undertaken under that paragraph shall include—

(a) classifying any genetically modified organisms involved in the activity in accordance with the provisions of Schedule 2; and

(b) where appropriate, making decisions about the levels of containment required for the activity concerned.

(3) In making the assessment required by paragraph (1) the person undertaking that assessment shall—

(a) in particular, take due account of the parameters set out in Schedule 3 in as far as they are relevant; and

(b) in a case in which the Executive has approved a method in relation to the activity involving genetic modification concerned or in relation to a particular element of that assessment, undertake the assessment in accordance with that method.

(4) The assessment shall be reviewed forthwith if—

(a) there is reason to suspect that the assessment is no longer valid; or

(b) there has been a significant change in the activity to which the assessment relates.

(5) The person making the assessment shall make a record of it and of any subsequent review and shall keep that record for at least 10 years from the date on which use of the premises or the activity, as the case may be, to which the assessment related, ceased.

**Notification of the intention to use premises for activities involving genetic modification for the first time**

**8.**—(1) Subject to the following paragraphs of this regulation and regulation 10, no person shall undertake any activity involving genetic modification at any premises for the first time, unless he has notified the Executive of his intention to do so at least 90 days in advance or before such shorter time as the Executive may approve and with that notification has furnished the particulars specified in Schedule 4.

(2) In the case of activities involving the genetic modification of micro-organisms, separate notifications shall be made of an intention to use the premises for activities involving genetically modified micro-organisms of Group I or Group II.

(3) In the case of activities involving genetically modified micro-organisms of Group II, the premises shall only be used for those activities after the Executive has given its consent.

(4) In any other case, the use of the premises for the activity may be commenced at or after the end of the period of 90 days, or such shorter period as the Executive may have approved in pursuance of paragraph (1), unless the Executive objects in writing before the end of the relevant period.

(5) In any case in which a consent is required under paragraph (3), the Executive shall communicate its decision on the application in writing within 90 days after the application was received.

(6) Nothing in this regulation shall prevent a person from notifying under regulation 9 an individual activity which he intends to undertake in the premises at the same time as making a notification under this regulation; in such a case he shall not commence the activity except in accordance with the time periods specified in this regulation.

**Notification of individual activities involving genetic modification**

**9.**—(1) Subject to the following paragraphs of this regulation and regulation 10, no person shall undertake any activity involving genetic modification unless he has notified the Executive of his intention to do so at least 60 days in advance or before such shorter time as the Executive may approve and has furnished the particulars specified in the following paragraphs of this regulation and, except in the case of an activity to which paragraph (5) applies, the activity may be commenced after the expiry of the relevant period if by then the Executive has not objected in writing.

(2) In the case of an activity which is—

(a) a Type A operation involving only micro-organisms classified as Group I; or

(b) an activity involving genetically modified organisms other than micro-organisms and which satisfy the criteria set out in Part III of Schedule 2,

it shall be a sufficient compliance with paragraph (1) if the person undertaking the activity keeps a record of such activities and forthwith after the end of each calendar year notifies the Executive—

(i) of the total number of risk assessments under regulation 7 undertaken during that year;

(ii) where appropriate, that he is intending to continue to undertake such activities; and

(iii) that the information notified to the Executive in accordance with regulation 8 remains correct.

(3) In the case of an activity which is a Type B operation involving only microorganisms classified as Group I, the specified particulars for the purposes of paragraph (1) shall be those specified in Part I of Schedule 5.

(4) In the case of an activity which is—

(a) a Type A operation involving genetically modified micro-organisms classified as Group II; or

(b) an activity involving genetically modified organisms other than micro-organisms and which do not satisfy the criteria set out in Part III of Schedule 2,

the specified particulars for the purposes of paragraph (1) shall be those specified in Parts I and II of Schedule 5.

(5) In the case of an activity which is a Type B operation involving genetically modified micro-organisms classified as Group II, the specified particulars for the purposes of paragraph (1) shall be those specified in Parts I, II and III of Schedule 5 and the activity shall only be commenced with the consent of the Executive.

(6) In any case in which a consent is required under paragraph (5), the Executive shall communicate its decision on the application in writing within 90 days after the application was received.

(7) The Executive may accept as a single notification a connected programme of work covering more than one activity involving genetic modification at one site, or a single activity carried on by the same person at more than one site.

**Additional provisions relating to notifications and consents**

**10.**—(1) Where necessary for the purpose of evaluating a notification made under regulation 8 or 9, the Executive may require in writing the person making the notification to give such additional information relating to the proposal as it may specify and, in such a case, the person making the notification shall not proceed with the activity involving genetic modification, until the Executive gives its approval, and the period between the time when the Executive requires the information and the notifier responds to the satisfaction of the Executive shall not be taken into account in calculating the periods of days referred to in the provisions concerned.

(2) Any consent granted by the Executive under regulation 8 or 9 may be granted subject to conditions or to a limit of time and may be revoked or varied at any time and in such a case the person undertaking the activity shall comply with those conditions.

(3) In so far as they relate to the protection of the environment, the Executive shall not grant, vary or revoke a consent under regulation 8 or 9, or give its approval under paragraph (1), without the agreement of the Secretary of State.

(4) Where a person making a notification in pursuance of regulation 8 or 9 subsequently makes a significant change in any premises or activity to which the notification relates or becomes aware of any new information which would affect the particulars previously notified, he shall forthwith notify the Executive thereof.

(5) If information subsequently becomes available to the Executive which could have significant consequences for the risks to health or the environment created by an activity involving genetic modification which has been notified to it, it may require the notifier to modify the conditions under which the activity is carried out, or to suspend or terminate the activity.

(6) Notifications made in pursuance of regulations 8 and 9 shall be in a form approved by the Executive.

**Establishment of a genetic modification safety committee**

**11.** A person who undertakes an assessment made for the purposes of regulation 7(1) shall establish a genetic modification safety committee to advise him in relation to that assessment.