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STATUTORY INSTRUMENTS

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**2014 No. 1663**

**The Genetically Modified Organisms  
(Contained Use) Regulations 2014**

**PART 2**

**Risk Assessment and Notification of Contained Use**

**Risk assessment of contained use involving micro-organisms**

5.—(1) Before any contained use involving micro-organisms is commenced, a person responsible for the contained use must ensure that a suitable and sufficient assessment of the risks to human health and the environment created by the contained use is carried out.

(2) The assessment required by paragraph (1) must take into account the matters set out in Part 1, and include the steps set out in Part 2, of Schedule 3.

**Risk assessment of contained use involving larger GMOs**

6.—(1) Before any contained use involving larger GMOs is commenced, a person responsible for the contained use must ensure that a suitable and sufficient assessment of the risks to human health created by the contained use is carried out.

(2) The assessment required by paragraph (1) must take into account the matters set out in Part 1, and include the steps set out in Part 2, of Schedule 4.

**Review and recording of risk assessments**

7.—(1) A person responsible for contained use must ensure that the risk assessment is reviewed immediately where—

- (a) there is reason to suspect that the risk assessment is no longer valid; or
- (b) there has been a significant change in the contained use to which the risk assessment relates.

(2) A person responsible for contained use must—

- (a) keep a record of the risk assessment and any review of the risk assessment, for at least 10 years from the date the contained use stops; and
- (b) make the record available to the competent authority when requested to do so.

**Advice from a genetic modification safety committee**

8.—(1) Subject to paragraph (2), a person responsible for contained use must obtain advice on a risk assessment from either—

- (a) a person; or
- (b) a genetic modification safety committee,

with expertise in risk assessment relating to contained use.

(2) Where the risk assessment indicates that the contained use is classified as class 2 or above the advice must be obtained from a genetic modification safety committee.

#### **Notification of premises to be used for contained use**

**9.**—(1) A user must not use premises for contained use unless the premises have been notified to the competent authority in accordance with this regulation.

(2) Before premises are used for contained use for the first time, a person responsible for the contained use must—

- (a) submit a notification to the competent authority containing the information specified in Schedule 5; and
- (b) have received an acknowledgement of receipt of the notification from the Executive.

(3) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) A single notification may include more than one premises.

(5) Where a notification includes more than one premises and at least one of those premises is situated in England or Wales and at least one of those premises is situated in Scotland the notification must be submitted to the joint competent authority.

(6) The notifier must nominate one address which is to be the principal address for the purposes of a notification under paragraph (4) or (5).

#### **Notification of class 2 contained use**

**10.**—(1) A user must not undertake a contained use involving micro-organisms classified as class 2 unless the provisions of this regulation have been complied with.

(2) A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) Where the premises in the notification have not previously been notified for class 2 or a higher class of contained use, a user may undertake the class 2 contained use if—

- (a) 45 days have elapsed since the acknowledgement of receipt was received, provided that the competent authority has not informed the notifier that the class 2 contained use may not be undertaken; or
- (b) the competent authority has agreed in writing that the class 2 contained use may commence sooner.

(5) Where the premises in the notification have—

- (a) previously been notified for class 2 contained use; or
- (b) already been granted consent for class 3 or class 4 contained use,

a user may undertake the class 2 contained use if the notifier has received the acknowledgement of receipt.

(6) Where a notifier submits a notification for a class 2 contained use which is to be undertaken for the second or subsequent time at the premises in the notification, the notifier may request that the competent authority provide a written agreement that the contained use may be undertaken.

(7) The competent authority must make a decision and, if they agree, provide the written agreement requested under paragraph (6), within 45 days of the date on which the acknowledgement of receipt was sent to the notifier.

#### **Notification of class 3 or class 4 contained use**

**11.**—(1) A user must not undertake a contained use involving micro-organisms classified as class 3 or class 4 unless written consent for that contained use has been granted by the competent authority.

(2) A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) Where the premises in the notification have not previously been notified for class 3 or class 4 contained use, the competent authority must inform the notifier, in writing, of its decision to grant or refuse consent for the class 3 or class 4 contained use, within 90 days of the date on which the acknowledgement of receipt was sent to the notifier.

(5) Where the premises in the notification have previously been notified for class 3 or class 4 contained use and all relevant conditions of existing consents have been complied with, the competent authority must inform the notifier, in writing, of its decision to grant or refuse consent for the class 3 or class 4 contained use, within 45 days of the date on which the acknowledgement of receipt was sent to the notifier.

(6) Before granting consent, the competent authority must ensure that an emergency plan has been prepared where the risk assessment shows an emergency plan is required.

(7) Before deciding whether to grant or refuse consent, the competent authority must take into account any representations made to it by any person within 30 days of the date on which the acknowledgement of receipt was sent to the notifier.

(8) A consent granted under this regulation may be granted subject to conditions.

#### **Notification of contained use involving larger GMOs**

**12.**—(1) A user must not undertake a contained use involving larger GMOs unless the provisions of this regulation have been complied with.

(2) A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) A user may undertake the contained use if—

(a) 45 days have elapsed since the acknowledgement of receipt was received, provided that the competent authority has not informed the notifier that the contained use may not be undertaken; or

(b) the competent authority has agreed in writing that the contained use may commence sooner.

(5) This regulation does not apply to a contained use which results in a larger GMO that poses no greater risk to humans than its unmodified parental organism.

**Single notifications to the joint competent authority and for connected programmes of work**

13.—(1) Where a notification is required under regulation 10(2), 11(2) or 12(2) in respect of a contained use which is to take place in premises that fall within regulation 9(5) the notifier must submit the notification for that contained use to the joint competent authority.

(2) A competent authority, or where paragraph (1) applies the joint competent authority, may accept a single notification submitted under regulation 10(2), 11(2) or 12(2) in respect of a connected programme of work undertaken at—

- (a) one premises; or
- (b) more than one premises.

(3) A competent authority, or where paragraph (1) applies the joint competent authority, may accept a single notification submitted under regulation 10(2), 11(2) or 12(2) in respect of a single contained use undertaken at more than one premises.

(4) In this regulation—

“connected programme of work” means a series of activities involving contained use which form a coherent and integrated programme.

**Changes of circumstances relating to notifications**

14.—(1) Full details in writing must be sent immediately to the competent authority of—

- (a) any change in the information specified in paragraph (a), (d) or (e) of Schedule 5 in relation to premises previously notified in accordance with regulation 9(2);
- (b) any new building—
  - (i) added to premises previously notified in accordance with regulation 9(2); and
  - (ii) under the notifier’s control;
- (c) premises notified under regulation 9(2) that will no longer be used for contained use;
- (d) any cessation, for the time being, of all contained use at premises notified under regulation 9(2);
- (e) any cessation of a contained use notified in accordance with regulation 10(2), 11(2) or 12(2);
- (f) any recommencement of contained use at premises in respect of which the notifier had previously given details of a cessation under sub-paragraph (d);
- (g) any use of additional premises in connection with a single contained use where a single notification for that contained use was accepted by the competent authority under regulation 13(3);
- (h) any change in the information specified in paragraph (b) or (c) of Schedule 5 as provided by the original notifier in accordance with regulation 9(2);
- (i) any change in the information specified in paragraph (c) or (d) of Schedule 6 as provided by the original notifier in accordance with regulation 10(2), 11(2) or 12(2).

(2) Where—

- (a) a notifier has informed the competent authority of additional premises under paragraph (1) (g); and
- (b) that information, taken together with the notification for that single contained use accepted under regulation 13(3), provides all the information required for notification of those premises under regulation 9(2),

the provision of that information will be treated as notification of those premises for the purposes of regulation 9(2).

- (3) The details required by paragraph (1) must be provided by—
  - (a) the original notifier;
  - (b) a person responsible for the premises notified under regulation 9(2); or
  - (c) a person responsible for the contained use notified under regulation 10(2), 11(2) or 12(2).
- (4) In this regulation—

“notifier” means the person who sends the details required by paragraph (1) to the competent authority; and

“original notifier” means the person who submitted the notification of the premises under regulation 9(2) or the contained use under regulation 10(2), 11(2) or 12(2).

#### **Duty to notify significant changes affecting risks**

- 15.—(1) Where, after submitting a notification, a notifier—
  - (a) makes a change in the premises or the contained use to which the notification relates which may have significant consequences for the risks arising from the contained use; or
  - (b) becomes aware of any new information which may have significant consequences for the risks arising from the contained use,

the notifier must immediately send to the competent authority full details in writing of the change or the new information.

(2) As long as the change or new information does not affect the class of the contained use, the notifier need not submit a further notification under regulation 10(2), 11(2) or 12(2), and the change or new information will be treated as a modification of the original notification.

#### **Action of notifier and user on receipt of request for additional information**

16.—(1) If additional information relating to a notification is requested by the Executive under regulation 24(1), a user must not commence the contained use that is the subject of the notification until the competent authority has given its approval in writing.

(2) Subject to paragraphs (3) and (4), if the contained use has commenced before the Executive requests additional information, a user may not continue the contained use until the competent authority has given its approval in writing.

(3) The Executive may give the notifier instructions concerning the cessation of the contained use and the notifier and any user undertaking the contained use must comply with the instructions.

(4) Subject to any instructions, the notifier or user may continue the contained use only to the extent necessary to store or destroy all genetically modified organisms resulting from the contained use.

#### **Withdrawal of notification**

17. A notifier may withdraw a notification by giving written notice to the competent authority, provided that the contained use to which the notification related has not commenced.