## EXPLANATORY NOTE

*(This note is not part of the Order)*

**1.** These Regulations consolidate, revoke and replace the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001 (S.R. 2001 No.295) and its amending instruments (S.R. 2006 No.524, S.R. 2010 No.343). The Regulations implement Directive EC No 2009/41 (O.J. L 125 21.5.2009 p. 75) which lays down measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment. Section 2(2) of the European Communities Act 1972 is used to implement the aspects of the Directive which relate to protection of the environment. The Regulations also apply to the contained use of genetically modified organisms that are not micro-organisms, known as larger GMOs, but only in relation to risks to human health. Larger GMOs are not covered by the Directive.

**2.** Contained use includes any activity or other action (for example storage) involving a genetically modified organism within a controlled environment where there are physical barriers and/or other controls in place to ensure that any genetically modified organism is not released into the environment. Certain techniques are or are not regarded as genetic modification and the Regulations do not apply to genetically modified organisms in a number of circumstances, for example, where there is a consent for use under other legislation. Some of the regulations are disapplied to genetically modified organisms when they are being transported (regulation 3 and Schedule 2).

**3.** The Regulations impose duties on people who are undertaking or proposing to undertake contained use (users) and persons responsible for contained use. These are people who either have the authority to determine whether contained use can take place, or people with control over the planning or conduct of the contained use. The competent authority is the Department of the Environment and the Health and Safety Executive for Northern Ireland acting jointly.

**4.** The meaning of some terms within the Health and Safety at Work (Northern Ireland) Order 1978 is modified so that the Regulations apply to educational institutions as if they were workplaces and students as if they were employees of the educational institution. They also apply to any person who is not an employee undertaking contained use (except a student) as if they were self-employed within the meaning of that Order (regulation 4).

**5.** Before contained use involving micro-organisms can commence, a person responsible for the contained use must ensure that an assessment of the risks to human health and the environment has been carried out. The person carrying out the risk assessment must classify the contained use (from class 1 to class 4) depending on the seriousness of the risks posed, with 4 being the highest risk (regulation 5, Schedule 1 and Schedule 3). Contained use involving larger GMOs cannot commence until the person responsible has ensured that an assessment is carried out in relation to risks to human health (regulation 6 and Schedule 4) although there is no requirement to assign a class of use. There are specific requirements relating to the review, recording and keeping of risk assessments (regulation 7). A person responsible for contained use must obtain advice on the risk assessment either from an individual or a genetic modification safety committee with relevant expertise (regulation 8).

**6.** Before premises are used for the first time, for contained use, a person responsible for the first contained use must notify the competent authority and provide information specified by regulation 9 and Schedule 5. One notification can include more than one premises.

**7.** Before class 2 contained use can commence, a person responsible for the contained use must notify the competent authority of the contained use and provide information specified in

Schedule 6 (regulation 10). A period of time must then elapse before contained use can begin. Class 3 or 4 contained use cannot commence unless the competent authority has given consent for the contained use. A person responsible must submit a notification for the contained use and provide the information specified in Schedule 6. Consent must be notified within a specified period that is dependent on whether the notifier already has consent for class 3 or class 4 contained use (regulation 11).

**8.** Before contained use can commence involving a larger GMO (and the contained use will result in a more hazardous organism than its parent organism) a person responsible for that contained use must notify the competent authority of that contained use and provide the information specified in Schedule 6 (regulation 12).

**9.** In certain circumstances the competent authority may accept single notifications for a connected programme of work or contained use at more than one premises (regulation 13). There are various duties to notify the competent authority of changes of circumstances and changes that affect risks (regulations 14 and 15).

**10.** If the competent authority asks for further information about a notification, the contained use must not commence or continue, except to store or destroy the genetically modified organisms, until the competent authority has agreed in writing that it may (regulation 16). A notifier may withdraw their application as long as the contained use has not commenced (regulation 17).

**11.** Users are required to ensure that occupational and environmental safety principles are observed (Schedule 7) and that risks are kept to the lowest level reasonably practicable (regulation 18).

**12.** A user carrying out contained use involving genetically modified micro-organisms is required to apply the containment measures which are appropriate to that contained use in accordance with the risk assessment. The containment measures are classified into different containment levels which largely correspond with the class assigned to the contained use, with level 4 being the highest level of containment. The measures are set out in Schedule 8 (regulation 19). A user carrying out contained use involving a larger GMO must apply the containment measures applicable in accordance with the risk assessment for that contained use (regulation 20).

**13.** Where a risk assessment shows it is warranted, an emergency plan must be prepared before contained use can commence. In the case of genetically modified micro-organisms the plan must address risks to human health and the protection of the environment, in the case of larger GMOs the plan need only address human health, (regulation 21). If an accident occurs the person responsible for the contained use must notify the competent authority immediately and provide specified information (regulation 22).

**14.** The competent authority is placed under a duty to examine a notification submitted to it under regulations 9(2), 10(2), 11(2) and 12(2) (regulation 23) and the Executive may ask the notifier for additional information on behalf of the competent authority (regulation 24). The competent authority has power to impose time limits or conditions on contained use, to suspend or terminate contained use or require that the contained use is not commenced. The competent authority may also vary or revoke any consent previously granted under regulation 11 (regulation 25). The competent authority may grant an exemption from the requirements of the Regulations but only if it is satisfied that the health and safety of persons and the environment are not prejudiced by the granting of an exemption (regulation 26).

**15.** The competent authority is to maintain a register of all notifications and copies of the register are to be made available by the Executive for public inspection by appropriate means (regulation 28). Certain information may not be published if it would be a breach of confidentiality (regulation 29).

**16.** Provision is made for the enforcement of the Regulations under the Health and Safety at Work (Northern Ireland) Order 1978 (regulation 30).

**17.** There is a right of appeal for any person who is aggrieved by certain decisions or actions of the competent authority or the Executive (regulation 31).

**18.** Anything that must be submitted to the competent authority under the regulations must be submitted to the Executive at the address it publishes on its website for the purpose (regulation 32).

**19.** There are various transitional, saving and consequential provisions and a number of instruments are revoked (see paragraph 1 above) (regulations 33 to 35).

**20.** In Great Britain the corresponding Regulations are the Genetically Modified Organisms (Contained Use) Regulations 2014 (S.I. 2014/1663). The Great Britain Health and Safety Executive has prepared a regulatory impact assessment in relation to those Regulations. A copy of that assessment together with a Northern Ireland supplement prepared by the Health and Safety Executive for Northern Ireland can be accessed at http://www.hseni.gov.uk/ or may be obtained, on request, from the Executive, at 83 Ladas Drive, Belfast, BT6 9FR. A copy of the transposition note in relation to implementation of the Directive can also be obtained from the Health and Safety Executive for Northern Ireland at the above address. Copies of both documents are annexed to the Explanatory Memorandum which is available alongside these Regulations at www.legislation.gov.uk.