Notification of premises to be used for contained use

- The public register sections MUST be understandable without reference to the risk assessment or other supporting documents.
- Please return your completed form to the Health and Safety Executive for Northern Ireland at the address given in Notes for Guidance.
- Please do not feel constrained by the box sizes - expand them or continue on separate sheets if necessary.
- Important - please refer to Notes for Guidance where identified.
- Fields marked with an asterisk (*) must be completed before the form is submitted to HSENI.

FOR HSENI USE ONLY

GM centre reference:			**Date notification acknowledged:**			**Date contained use ceased:**		
Dates on which additional information submitted								
Date on which accident notification submitted								

Public Register

1. Organisation Details

*** Name of organisation *(note 1)***

*** Address**

*** Telephone Number** **Fax Number**

E-mail Address

Public Register

2. Address(es) of the premises where the contained use will actually be conducted (if different from that at Section 1) *(note 2)*

Public Register

3. ☐ * Check to confirm that you have received advice from a person or a genetic modification safety committee with expertise in risk assessments relating to contained use

* Give brief details of the person or genetic modification safety committee - no actual names should be given *(note 3)*

4. Please indicate the nature of the premises, or sections of the premises, where the contained use is to be carried out (check all applicable) *(note 4)*

	Laboratory	Animal Unit	Growth Room	Glasshouse	Large scale (ie contained use to which Table 2 of Schedule 8 is appropriate)
Level 1 (GMMs)	☐	☐	☐	☐	☐
Level 2 (GMMs)	☐	☐	☐	☐	☐
Level 3 (GMMs)	☐	☐	☐	☐	☐
Level 4 (GMMs)	☐	☐	☐	☐	☐
Non-microbial, e.g. work with transgenic plants or animals	☐	☐	☐	☐	☐
Other (please specify)	☐	☐	☐	☐	☐

5. Nature of work to be undertaken at the premises (check all boxes which apply) *(note 5)*

☐ Bacteriology
☐ Virology
☐ Mycology
☐ Parasitology
☐ Transgenic Animals
☐ Transgenic Invertebrates
☐ Transgenic Birds
☐ Transgenic Fish
☐ Transgenic Plants
☐ Microbiology Research
☐ Gene Therapy
☐ Other (please specify):

6. For class 1 contained use involving GMMs, describe the waste management measures (include the inactivation method(s), the degree(s) of kill and proposed process testing / monitoring measures), which you will apply to the contained use *(note 6)*

For GMMs only - application for any derogation from full containment (Schedule 8) (Measures and justification) *(note 7)*

7. ☐ **Please check to confirm that you are attaching a summary of the risk assessment for class 1 contained use involving GMMs or non-notifiable contained use involving larger GMOs *(note 8)***

☐ Please check if you are claiming exemption from disclosure for sections of the risk assessment

8. * Please enter comments of the person or genetic modification safety committee with expertise on the risk assessment *(note 9)*

Personal Information

9. * Name of person responsible for supervision and safety of GM contained use at the premises

* Training and Qualifications

* Telephone Number

Fax Number

Email Address

10. Name of the Biological Safety Officer (if any) *(note 10)*

Training and Qualifications

Address (if different from that in section 1)

Telephone Number

Fax Number

E-mail Address

11. Contact name - if different from Biological Safety Officer (or other named person) *(note 11)*

Address (if different from that in section 1)

Telephone Number

Fax Number

E-mail Address

12. Please enter in this section any information required in sections 1-8 which you do not want disclosed, together with full justification for that claim *(note 12)*

13. Declaration

I am notifying an intention to use premises for contained use of genetically modified organisms with the authority and approval of the person (organisation or individual) named in section 1 of this form

Name

Position in organisation

Signed *(note 13)*

Date

THE GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS (NI) 2015
NOTIFICATION OF PREMISES TO BE USED FOR CONTAINED USE

NOTES FOR GUIDANCE

Data Protection Act 1998

This Act requires the Health and Safety Executive for Northern Ireland (HSENI) to inform you that this form may include information about you (this is called "personal data" in the Act) and that we are a "data controller" for the purposes of the Act. HSENI will process the data for health, safety and environmental purposes. HSENI may disclose this data to any person or organisation for the purposes for which it was collected or where the Act allows disclosure. As data subject, you have the right to ask for a copy of the data and to ask for any inaccurate data to be corrected.

All the information given in sections 1-8 of this form will be placed on HSENI's public register of notifications within 14 days of receipt. You may consider that there is information relevant to these sections whose disclosure would adversely affect your organisation's competitive position, intellectual property rights or which you do not wish to be disclosed on other grounds referred to in the Environmental Information Regulations (EIR) 2004, regulation 12. If so, you should enter such information in section 12 with a full justification for its exemption from disclosure. However, it should always be possible to provide some information in these sections for the public register. The Competent Authority will decide whether the information in section 12 will be exempt from disclosure and will notify you of its decision in writing.

Personal information will not be disclosed unless the individual concerned has given his or her explicit written permission.

Note 1

This will normally be the University, Institution, Company or Organisation. Only rarely will it be necessary to include an individual's name. Where there is more than one address for the premises being notified - for instance a geographically split site - the address given should be the main contact address. This might be the headquarters or administration office address.

Note 2

If you intend to carry out contained use involving GMMs, you must not leave this section blank unless you are claiming exemption from disclosure. If you are claiming that the precise address of the premises where contained use with larger GMOs (e.g. GM animals or plants) are to be carried out should not be disclosed, you must include this, together with the justification, in section 12.

Note 3

NB In relation to health and safety matters, you must also comply with the Safety Representatives and Safety Committees Regulations (NI) 1977 and, where any employees are not in groups covered by trade union safety representatives, you must consult such employees according to the Health and Safety (Consultation with Employees) Regulations (NI) 1996.

Brief details of the genetic modification safety committee might include its composition, operating procedures and frequency of meeting. Brief details of the person should relate to their relevant credentials to be considered as having appropriate expertise in risk assessment related to contained use. No names of individuals need to be given - refer to job titles, positions and representative functions instead. Any information you do not wish disclosed should be entered in section 12 together with justification.

Note 4

Please check all applicable boxes on the grid. Any information you do not wish disclosed should be entered in section 12 together with the justification.

Note 5

Please check all boxes applicable. Any information you do not wish disclosed should be entered in section 12 together with the justification.

Note 6

If you are notifying to use premises for genetic modification, and the first contained use which you intend to undertake is in class 1, OR is a non-notifiable activity involving larger GMOs, complete sections 6-8. Otherwise go straight to section 9. If the first contained use which you intend to undertake is in class 2, 3 or 4 contained use or a notifiable contained use involving larger GMOs, you should submit a separate contained use notification form with this premises notification. In such cases the fee payable will only be that relating to the contained use notification. Any information you do not wish disclosed should be entered in section 12 together with the justification.

Note 7

For contained use involving GMMs, you will normally need to apply all the measures specified as requirements for the relevant containment level. If, however, your risk assessment indicates that any of those measures are unnecessary, you may ask for permission to omit them by requesting a derogation. Indicate any such measures with a brief justification for the derogation that includes reference to the relevant parts of the risk assessment.

You cannot ask for non-disclosure for the actual containment measures (unless your intellectual property rights might be affected) BUT you may wish to request exemption from disclosure for the justification. If any request is made for non-disclosure, the exempt information must be included in section 12 together with the justification for non-disclosure.

Note 8

For contained use involving GMMs, the risk assessment must cover risks to humans and the environment. For contained use involving larger GMOs, assessment of risks to humans only is required to be sent in. However, note that you are required under Part VI of the Environmental Protection Act 1990 and the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996, as amended, to make an assessment in respect of environmental protection from larger GMOs. You must also keep a record of this assessment but **do not send it in**.

Check the lower box if you wish any of the sections of the risk assessment to be exempt from disclosure. The exempt information does not need to be entered in section 12, but justification for non-disclosure must be given with the risk assessment.

The risk assessment will not be placed on the public register, but will be open to disclosure subject to exemption provisions.

Note 9

Any information you do not wish disclosed should be entered in section 12 together with the justification.

Note 10

If the details of the Biological Safety Officer was given at section 9, simply refer.

Note 11

Please give details of the person to whom general correspondence should usually be sent if different from the Biological Safety Officer.

Note 12

Please enter in this section any information, required in sections 1-8, which you wish to be exempt from public disclosure on grounds that:

(a) disclosure would harm your organisation's competitive position; or
(b) disclosure would compromise your intellectual property rights; or
(c) the information falls into one of the other categories for exemption in regulation 12 of EIR 2004. Please state which.

For each piece of information entered you must:

(a) state clearly which the grounds applies. In particular, state which category of exemption allowed by the EIR 2004 applies, namely disclosure would adversely affect:

- international relations, defence, national security or public safety
- the course of justice
- confidentiality of proceedings
- commercial / industrial confidentiality
- intellectual property
- protection of the environment

(b) indicate the section of the form to which it is relevant; and

(c) provide a full justification, explaining why the stated ground for exemption applies

You do not need to enter any personal information as this is covered by the Data Protection Act and will automatically be treated as confidential.

Note 13

Send the completed form by email to:

mail@hseni.gov.uk

Or alternatively by post to the address below:

GM Notifications Officer
Health and Safety Executive for Northern Ireland
83 Ladas Drive
Belfast
BT6 9FR

Tel: 028 9024 3249
Fax: 028 9023 5383