HSE Health & Safety Executive

The Genetically Modified Organisms (Contained Use) Regulations 2000

Notification of intention to conduct individual contained use activities

- 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 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.

FOR HSE USE ONLY									
GM centre reference: GM			Date notification acknowledged: / /20			Date activity ceased: / /20			
Dates on which additional information submitted									
Date on which accident notification submitted									
Consent granted (Class 3 / 4) *please tick box*									

1. Name of organisation (Note 1) University of Sheffield

Address
40 Victoria Street
Sheffield
S3 7QB

Telephone number 0114 222 6198 Fax Number 0114 222 8741

e:mail d.m.edwards@sheffield.ac.uk d.v.hall@sheffield.ac.uk

Address(es) of the premises where the activities will actually be conducted (if different from that at Section1). (Note 1a)

2. Date of premises notification (Note 2) 25th November 1993; re-notified 14th January 2001

HSE centre number GM168

3. Please tick if notifying a connected programme of work (Note 3)

4. Class(es) of activity – tick all relevant boxes (Note 4)

Class 2 ☐ Class 3 ☐ Class 4 ☐ Activity involving notifiable non-micro-organisms ☐

For Class 3 or 4: Tick box if GMOs are likely to be imported from or exported outside the EC ☐

5. Please give a short descriptive title of the activity (or activities)

6. Purpose of the contained use (Note 5)

7. Characteristics of the GMO(s) including the evaluation of foreseeable effects (Note 6)

Recipient or parental organism

Host / vector system

Origins and intended functions of the genetic material involved

Evaluation of foreseeable effects

8. Containment and control measures for GMOs that are not micro-organisms (e.g. GM animals and plants) (Note 7)

9. Maximum culture volumes per experiment – <u>for GMMs only</u> (Note 8)

(i) Class 2 activities, state approximate culture volume

(ii) for Class 3 or Class 4 activities, specify the culture volume

10. For GMMs only, indicate the level of containment that will be applied (please tick the appropriate box(es)). (Note 9)

	Level 2	Level 3	Level 4
Laboratory activities			
Glasshouses			
Growthrooms			
Animal units			
Large scale activities (i.e. activities to which Table 2, Schedule 8 containment is appropriate)			
Human clinical applications			

11. For GMMs only – application for any derogation from full containment for the Class of activity. (Measures and justification) (Note 10)

12. Describe the waste management measures which you will apply to the activity (including the type and form, treatment, degree of kill, proposed process testing / monitoring measures, ultimate form and fate). (Note 11)

13. Is an emergency plan required according to regulation 20? **Yes** ☐ **No** ☐

If Yes, please tick to confirm that it is attached to this form ☐

14. Please tick to confirm that you have attached a risk assessment to this form (Note 12) ☐

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

15. Please enter comments of the genetic modification safety committee on the risk assessment. (Note 13)

PERSONAL INFORMATION

16. Name of person responsible for supervision and safety of GM activities at the premises.

Training and qualifications

NON DISCLOSURE OF INFORMATION

17. Enter in this section any information required in sections 1 – 15 which you do not wish disclosed , together with full justification. (Note 14)

18. Declaration

I am notifying an intention to carry out an activity involving 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 15)**

Date

THE GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 2000
NOTIFICATION OF INTENTION TO CONDUCT INDIVIDUAL CONTAINED USE ACTIVITIES

Notes for Guidance

Data Protection Act 1998

This Act requires the Health and Safety Executive (HSE) 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. HSE will process the data for health, safety and environmental purposes. HSE may disclose these 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 – 15 of this form will be placed on HSE'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 disclosed on other grounds referred to in the Environmental Information Regulations (EIR) 2004, regulation 12. If so, you should enter such information in section 17 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 17 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.

Compliance with other legislation

It is important to note that compliance with the provisions of the Contained Use Regulations does not constitute compliance with other relevant legislation. For example, you may also need to apply separately for licences or permits under legislation controlling plant health, animal health, animal scientific procedures, or the introduction of non-indigenous species. For clinical trials involving gene therapy, you will need approval from the Gene Therapy Advisory Committee.

Even if you have fulfilled the requirements of the Contained Use Regulations, and have any necessary consents or approvals under that legislation, you cannot begin the activity unless you also have the relevant licences / permits under any other applicable legislation.

Note 1

This will normally be the University, Institution, Company or Organisation. Only rarely will it be necessary to include an individual's name.

Note 1a

If you intend to carry out activities 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 activities with 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 2

If you have previously notified your premises, indicate the date of the notification and the HSE reference number assigned (e.g. GM111). If you have not notified your premises, you will not have a reference so please contact the notifications officer (see note 15) or e-mail Notificationofficer@hse.gsi.gov.uk for a GM centre reference number. Note that if not previously notified, you will also have to complete a premises notification – using the CU1form provided if you wish – and submit it at the same time as this activity notification. The fee payable in such cases will only be that related to the activity notification.

Note 3

It is permissible to notify a connected programme of work using this form. However you must include details of all of the component activities in sections 4-15. The fee payable in relation to connected programmes is the fee for the highest Class of activity involved. (Notifiable activities involving GM animals and plants are equivalent to Class 2 for this purpose).

Note 4

Please tick all applicable boxes. For class 3 and 4: The EC Regulation on transboundary movements of GMOs requires Member States to inform the Biological Clearing House and the European Commission of any decisions on class 3 and class 4 contained use activities

involving GMMs that are likely to be subject to transboundary movements. Transboundary movements are those entering or leaving the EC. In order for this information to be collected, please tick the box if your class 3 or 4 GMMs are likely to be subject to such transboundary movements. Any information you do not wish disclosed should be entered in section 17 together with the justification.

Note 5

Any information you do not wish disclosed should be entered in section 17 together with full justification.

Note 6

For activities involving GMMs, this section cannot be left blank unless you have a justified request for non-disclosure in respect of protection of intellectual property rights (IPR). If you are not making a request for non-disclosure in respect of IPR, you must at least include general characteristics of the GMMs involved in the intended activity. Where there are no justifiable requests for non-disclosure, you must include precise details. An evaluation of the foreseeable effects must also be included, in as precise detail as possible. The evaluation of foreseeable effects should include the identity and characteristics of the GMMs indicated by the risk assessment. Include information on hazards to human health and the environment with particular reference to those arising from the modification as opposed to being inherent properties of the host micro-organism. (A fuller account of these details will be included in the risk assessment).

For activities involving GMOs which are not micro-organisms (eg GM animals and plants), it is permissible to request non-disclosure for any of the required information, but the second section should still be completed in as precise detail as possible taking into account it may be disclosed. The evaluation of foreseeable effects is required to consider only human health and safety aspects. Any information you do not wish disclosed should be entered in section 17 together with the justification.

Note 7

For activities involving GMOs which are not micro-organisms (eg GM animals and plants), describe the containment and control measures which you will apply to the activity. These should be justified by reference to the risk assessment. Any information you do not wish disclosed should be entered in section 17 together with the justification.

Note 8

Any information you do not wish disclosed should be entered in section 17 together with the justification.

Note 9

You must not leave this section blank.

Note 10

For activities 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(s). Indicate any such measures with a brief justification for the derogation that includes reference to the relevant parts of the risk assessment. You cannot request non-disclosure for the actual containment measures (unless your intellectual property rights might be affected) BUT you may wish to request exemption for the justification. If a request is made for non-disclosure, the exempt information must be included in section 17 together with the justification.

Note 11

Waste management measures which will be applied to the activity must be described. You should take into consideration only the waste consisting of or containing viable GM material. You must specify the type and form of waste(s) generated, their treatment, ultimate form and fate and degree of kill. Include an indication of the numbers of viable GMOs remaining after treatment (if any), and proposals for testing / monitoring the inactivation process. For activities involving GMMs, this section cannot be left blank unless you are claiming protection for reasons of intellectual property rights. Even if this is not the case, it is permissible not to give precise details if claims for non-disclosure can be justified. For instance you could say that inactivation is by heat treatment to give100% kill, but the precise detail of how this is achieved may be commercially confidential information. If a request is made for non-disclosure, the information must be included in section 17 together with the justification.

Note 12

You must attach the risk assessment of the activity to this form. The risk assessment will not be placed on the public register, but will be open to disclosure to members of the public on request (subject to exemption provisions).

If you wish to claim exemption from disclosure for any sections of the risk assessment, please indicate those sections clearly on

the risk assessment and set out a full justification for exemption. If a request for information is received and your justification for non-disclosure is accepted, the risk assessment will be disclosed with the exempt sections removed. You are advised to submit a second version of the risk assessment from which those sections have already been removed. If it is decided, in the public's interest, to release the information, you will be informed of this decision in writing.

Note 13

NB: remember that, as well as consulting the genetic modification safety committee on the risk assessment, you must also comply with the Safety Representatives and Safety Committees Regulations 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 1996. If you do not wish some of the information to be disclosed, the exempt information must be included in section 17 together with the justification.

Note 14

Please enter in this section any information, required in sections 1-15, which you wish to be exempt from public disclosure on grounds that

a) disclosure would harm your organisation's competitive position;

b) disclosure would compromise your intellectual property rights; or

c) the information falls into one of the other categories for exemption in the EIR Regulations, regulation 12- state which.

For each piece of information entered you must:

d) state clearly which of the grounds applies. In particular, state which category of exemption allowed by the Environmental Information Regulations 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

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

f) provide a full justification, explaining why the stated ground for exemption applies.

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

Note 15

Send the completed form to:

Notifications Officer
Health and Safety Executive
Rm 443, Magdalen House
Stanley Precinct Bootle
Merseyside, L20 3QZ
Tel: 0151 951 4772 Fax: 0151 951 3474