MANCHESTER 1824

The University of Manchester

Safety Services

FAQs and notes about completing the GM Application Form and Risk Assessment

Q1. Who should complete the form? - the Principal Investigator

Q2. When should the form be completed? - whenever a new GM project is to be started, or when an existing approved project is changed in such a way that existing risk assessments do not cover it.

Q3. How do I complete the form? – refer to appropriate guidance from the Health & Safety Executive (HSE) and the **Compendium of Guidance** produced by the Scientific Advisory Committee on Genetic Modification (ACGM) - (see http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/) and the following notes.

Q4. What if my project consists of a series of experiments with different biological systems? - if parts of the project or host-vector systems differ in their possible risks, separate risk assessments for each part should be carried out using separate application forms. Each application form must provide a summary of the experimental objectives and an overview of the procedures. Submit them together as a single application, accompanied by a single introductory section in the Genetically Modified Organism Administration Form.

Q5. What if I need one-to-one advice? – ask your local Biological Safety Officer (BSO) who will either (a) answer your question, (b) refer you to someone carrying out similar work, or (c) (in some parts of the University) refer you to an academic advisor, or (d) consult the University's database of GM experts. If local advice cannot answer your question, then contact the University Biosafety Advisor (UBSA) who will either provide an answer or contact national or international experts on your behalf.

Q6. What happens to the completed form? – give it to your Local BSO who will (a) check it for obvious errors, and advise you how to modify the application if appropriate. After revision, your local BSO will convene a meeting of your Local GM/Biohazard Safety Committee for activities notifiable to HSE to consider your

application. Normally, the UBSA will attend. This meeting will agree the activity class with the applicant and may require further modifications or the provision of additional information.

Q7. When can work start on a Class 1 activity? – Work can start as soon as the local BSO has signed the application. However all Class 1 activities are subsequently considered by the Local GM/Biohazard Safety Committee for retrospective approval.

Q8. When can work start on Class 2 or 3 activities? - If the work is categorised as Class 2 or higher, then the HSE's form (CU 2 2000) must be completed by the PI in consultation with the UBSA if necessary. For Class 3, the UBSA will submit the application as approved by the Local GM Safety Committee to the University GM/Biohazard Safety Advisory Group. When the latter group has approved the application, perhaps requiring further amendments, the Group's comments will be minuted and the form signed by the Chair.

The UBSA will record the comments of the Local GM Safety Committee or University GM/Biohazard Safety Advisory Group on the CU2 2000 form and send it to the HSE with the final version of the University's application form and a cheque from the applicant for the HSE's fee (see http://www.hse.gov.uk/biosafety/gmo/acgm/acgmwarn.htm)

The flow diagrams show the process of risk assessment and notification submission.

Q9. What are the common mistakes when completing the CU2 GM notification form?

Please see the link below
http://www.hse.gov.uk/biosafety/gmo/acgm/acgm31/paper5.htm

Q10. How can I improve my risk assessment so that it goes through the GMSC with minimal delay?

Below are a number of bullet points that may help you.

- Where there are distinct phases to the project, for example cloning of your gene of interest in disabled E coli followed by expression in eukaryotic cells, ensure that the assessment clearly separates out these phases and separate assessments are prepared preferably using unique section number.
- Please provide brief justification to your statements. For example statements like, "The expressed protein is unlikely to have a deleterious effect" should be justified. For class 1 projects, the justification does not need to be extensive.

Further specific advice is given below,

1. **Ethical Approval** - see http://www.campus.manchester.ac.uk/researchoffice/researchethics/

2 **Summary of classification of GMO** The classification process is described in more detail in Paragraphs 43 -44 of "A Guide to the genetically Modified Organisms (Contained Use) Regulations 2000 (Fourth Edition)", ISBN 0 7176 1758 0. The full document is available on line. Log in to www.athens.ac.uk (Athens user name and password needed from the John Rylands Library). Scroll down to and click on IHS Technical Indexes Info4Education. Then click on the words "Occupational Health & Safety Information Service (OHSIS)" to the right of the box. This opens OHSIS. Type L29 in the simple search box (top left) and click "Go" Open the most recent version of document L29, which is currently the 4th Edition referred to above.

3 **Immunisation & health surveillance** – following discussions with Occupational Health, consider all staff/students who may be exposed to the GM material. The Occupational Health guidance is available.