Guidance on completion of Risk Assessment for Biological Activity (GM and BioCOSHH Assessment)

Contents

HEALTH AND SAFETY REGULATIONS AND GUIDANCE

Any number of the following list of Regulations and guidance documents may be applicable to the work undertaken and the BioCOSHH application procedure:

- The Control of Substances Hazardous to Health Regulations (as amended) 2002 (COSHH)
- HSE Approved Code of Practice (ACOP) 'Control of Substances Hazardous to Health (6th edition)', L5
- The Genetically Modified Organisms (Contained Use) Regulations 2014 (GMO(CU))
- The Specified Animal Pathogens Order 2008 (SAPO)
- 'Guidance for licence holders on the containment and control of specified animal pathogens', HSG280
- Anti-terrorism, Crime and Security Act 2001
- Human Tissue Act 2004
- The Importation of Animal Pathogens Order 1980
- The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009
- European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2017
- IATA Dangerous Goods Regulations (DGR)

1. DEFINITIONS

ACDP	Advisory Committee on Dangerous Pathogens
BA	Biological Agent
BSO	Biological Safety Officer
CL	Containment Level
COSHH	Control of Substances Hazardous to Health
CPW	Connected Programme of Work (see below)
DEFRA/Defra	Department for Environment, Food and Rural Affairs.
GM	Genetic Modification (Genetically Modified)
GMM	Genetically Modified Micro-Organism
GMO	Genetically Modified Organisms
GMSMC	Genetic Modification Safety Management Committee
MSC	Microbiological Safety Cabinet
PI	Principal Investigator
SACGM	Scientific Advisory Committee on Genetic Modification

Genetic Modification: Any alteration of the genetic material of an organism (e.g. DNA, RNA) which does not occur naturally (e.g. mating, recombination) and which involves introducing and incorporation of genetic material (whether derived from an existing organism or synthetically made) into the recipient in which they do not naturally occur. The following include some techniques considered to be genetic modification; recombinant techniques, techniques which involve the direct introduction of heritable genetic material (e.g. microinjection etc), cell fusion techniques, hybridization techniques, techniques which introduce foreign or synthetic genetic material (e.g. transfection, transduction, transformation, particle bombardment etc.)

Contained Use:	Any activity involving GMOs where barriers are used to limit contact with and protect humans and the environment. Barriers can be physical (e.g. building, container etc), chemical (e.g., use of chemicals to inactivate/destroy a GMO etc) or biological (e.g. GMO has characteristics like being attenuated, disabled or renders unable to survive outside a specialised environment. Biological barriers must be robust and well understood.
Connected Programme of work:	A series of activities involving contained use which form a coherent and integrated programme as part of a common scientific/research goal. (e.g. where an institution or company has several notified premises which all collaborate on connected work).
Biological Material:	Any biologically-derived material or materials which, either by accident or design, contain biological agents which might pose a risk to health and safety or the environment. This includes: 1) The intentional use of biological agents; 2) Use of materials which may incidentally contain such agents; 3) Biological materials which may contain toxic or harmful chemicals; 4) Live animals.
Biological Agent	A biological agent is defined in COSHH as: '*a micro-organism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health.'* This includes: (a) micro-organisms such as bacteria, viruses, fungi, and the agents that cause transmissible spongiform encephalopathies (TSEs): (b) Cell cultures: (c) parasites, e.g. malarial parasites, amoebae, and trypanosomes; and including the microscopic infectious forms of larger parasites, such as the ova and infectious larval forms of helminths.
Hazard Group (HG)	Biological agents are classified into four hazard groups according to: (a) their ability to cause infection; (b) the severity of the disease that may result; (c) the risk that infection will spread to the community; and (d) the availability of vaccines and effective treatment.
Hazard Group (HG) 1	A biological agent unlikely to cause human disease.
Hazard Group (HG) 2	A biological agent that can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or effective treatment available.
Hazard Group (HG) 3	A biological agent that can cause severe human disease and maybe a serious hazard to employees; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available.

Hazard Group (HG) 4 A biological agent that causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available. This category is highly specialised.

Biological agents in Hazard Groups 2 to 4 are listed in The Approved list of biological agents, which can be viewed via the HSE website at http://www.hse.gov.uk/pubns/misc208.pdf. The List is not exhaustive and a biological agent that does not appear on it does not automatically fall into Hazard Group 1.

2. RESPONSIBILITIES

Proposer

Responsible for ensuring:

- Assessment is completed and approved prior to the start of any work.
- Assessment is completed by persons with sufficient knowledge and expertise of the agents and process.
- Assessment is suitable and sufficient. Assessment is suitable and sufficient when this guidance is followed and all relevant questions are answered in full.
- Assessment considers up-to-date hazard data and complies with this procedure.
- Assessment is recorded and reviewed.
- Assessment is read and understood by all persons carrying out the work.

Genetic Modification Safety Management Committee (GMSMC)

The GMSMC is responsible for providing advice on proposer's biological risk assessment with a view to ensuring that it is complete, appropriately controlled, compliant and current. For full details see GMSMC ToR document **Appendix 3**. The following are the GM Centre Numbers for each entity.

Diamond Light Source DLS:	GM972
STFC (includes ISIS and CLF):	GM975
STFC Daresbury:	GM588
Research Complex at Harwell (RCaH):	GM3067
Rosalind Franklin Institute (RFI):	GM3564

Duties include:

- Providing guidance, advice and to assist persons carrying out suitable and sufficient biological risk assessments.
- Reviewing all Hazard Group 2 and GM Class 2 and above biological risk assessments sent to them. See **Appendix 1** for the workflow and approval timeline of GMSMC.
- Maintenance of records related to GMSMC activities.
- Ensuring appropriate controls, and where appropriate, an accurate GM classification for the activity has been indicated.

Employees, Users, Tenants and visitors

Employees, Users, Tenants and visitors are responsible for ensuring any work to be undertaken is sufficiently assessed prior to work commencing.

3. PROCEDURE

3.1 General Guidance

Biological risk assessments shall be prepared for an informed lay audience. They must contain enough background and detail to ensure that a reviewer with limited understanding of the precise nature of the work will not require further information to comprehend the nature of any hazards and the risks arising from them. All feasible potential hazards must be acknowledged and information must be based on established scientific knowledge where available. Any uncertainty must be acknowledged and dealt with appropriately and lack of evidence does not equate to a lack of hazard.

It is a legal requirement for biological risk assessments to be kept for 10 years after the work has ceased. Storage of materials is classed as active work.

The following areas of work **MUST BE** risk assessed and approved **BEFORE** starting any work.

- Work involving 'biological materials' or 'biological agents'. This will include the use of experimental materials which may *contain* a biological agent (adventitious agents).
- Work involving genetic modification or work with genetically modified organisms
- Work with cells, tissues or fluids of human, animal and/or plant origin.

Biological material/biological agents **MUST NOT** be brought onto the site without a current valid approved biological risk assessment in place.

Where work is covered by an overarching risk assessment (CL1/GM Class 1) or connected programme of work (GM Class 2), then a justification for the inclusion of the activity needs to be submitted to the local GMSMC rep using the proposal form (**Appendix 2**). In some cases, this will need approval by the GMSMC.

This document will guide proposers/investigators through an initial biological risk assessment for a proposed research project involving biological materials. Consideration must be given to the possible risk of harm or damage to humans, animals and the environment through the proposed work.
Of particular concern are biological materials which will require special containment facilities or licences including

- Cultures of cells/micro-organisms
- human body secretions or tissues
- materials likely to carry human pathogens, parasites or zoonoses
- pathogens which cause disease in plants
- genetically modified microorganisms, plants or animals.

These are generic guidelines, and as such not all sections or questions may be appropriate for all types of work or experiments. If in any doubt, please contact a member of the GMSMC as detailed in **Appendix 1**.

Based on the biological risk assessment, a provisional **C**ontainment **L**evel (CL) and/or GM activity class for the work must be assigned by proposer/assessor and agreed by the GMSMC.

All projects require approval and the completed biological risk assessment shall be forwarded to the GMSMC contacts (See **Appendix 1**) for this purpose. At present, our sites can facilitate work up to and including CL2. Copies of the final approved biological risk assessments should be retained by the investigator and the GM Centre(s).

Depending on the nature of the proposed research further risk assessments, approvals, licences and/or permissions may be required from other regulatory authorities (e.g. DEFRA, Home Office).

Samples obtained from commercial sources, such as purified proteins (e.g. serum albumin), enzymes (e.g. nucleases), nucleic acids (e.g. *E.coli* DNA), blood products (e.g. sera) or other specified extracts (e.g. tryptone) may not require risk assessments, if they are confirmed as non-hazardous. This information can usually be obtained by examining the safety data sheets (SDS) accompanying these products.

3.2 Guidance on the completion of the biological activity risk assessment form

Project Reference: This is assigned locally and the reference shall be inserted in the footer of the biological activity risk assessment.

3.2.1 Section A: Project overview

Applicant: The person completing the biological activity risk assessment.

Project Title: A short title for the project.

Name of Project Leader: The person responsible for this work.

Organisation: Detail the organisation which the applicant represents, this may be an internal organisation e.g. Diamond, RCaH, ISIS, STFC, RFI.

Contact details: The contact details of the applicant shall be recorded here. Include a phone number and email address.

Persons involved in the project: List all persons who will participate in this work.

Briefly describe the activity to be undertaken, including the aim of the work (Explain what you are proposing to complete e.g. summary of protocols): This section is to provide a short overview of the aims of the project, describing any biological materials methods and processes that will be used as part of the activity. Avoid technical language / jargon so that the description can be understood by a non-expert.

List all the locations of proposed work: This shall describe where the work will be completed and include locations where samples are handled and stored.

Is any of the material listed under the following regulations: If any of the materials used fall under the following legislation specify here:

- Specified Animal Pathogens Order (SAPO): Refer to guidance document http://www.hse.gov.uk/pUbns/priced/hsg280.pdf
- Schedule 5 of Anti-Terrorism, Crime and Security Act 2001: Refer to legislation https://www.legislation.gov.uk/ukpga/2001/24/contents
- Human Tissue Act (HTA 2004: Refer to legislation or contact a member of GMSMC if required Human Tissue Act 2004 (legislation.gov.uk)
- Importation of Animal Pathogens Order 1980 (IAPO): Refer to legislation and Guidance.

Does this work involve (Select one option only):

i) **Biological Non-GM activity only –** Choose this option if your work does not involve any genetic modification and uses only wild type biological agents.
ii) **Biological GM activity only –** Choose this option if your work involves genetic modification of the recipient organism. Genetic modification includes insertion of non-native genes or alteration of native genes.
iii) **Both Biological GM and Non-GM activities –** Choose this option if your work involves both the above options.

3.2.2 Section B: Project Risk Assessment involving Biological Non-GM activity

The nature of the biological material

i) Describe the biological materials to be used in the work

a) Provide as much information as you have available
b) Describe what biological materials will be used
c) Specify their origin
d) Will the work involve human tissue?

ii) Describe how and from where the materials will be obtained.

Provide as much information as you have available about where and how the materials will be obtained. E.g. commercial supplier, collaborators

iii) Explain any pre-treatment that will increase or reduce risk (e.g. fixation/inactivation etc.)

a) The way in which biological materials are treated and stored may increase or decrease the hazard. Specify any pre-treatment of the materials e.g. chemical extraction, culturing**,** disinfection, freezing, fixation, autoclaving, heat treatment or other processing which could affect agents present (e.g. inactivate or amplify).
b) Evidence for treatment of samples must be available where such processing is used as a means of removing pathogens/agents and evidence that this is a validated method (i.e. evidence that it kills the agent).

iv) Where will the biological materials be stored (short and long term)?

List all the possible places where samples will be stored for short-term and long-term.

v) How will the material be stored (e.g. frozen, refrigerated, liquid nitrogen?

a) In what state are they stored?
b) Are the refrigerated, frozen, kept on or in liquid nitrogen (vapour or liquid phase, or kept at room temperature?
c) What sort of containers are they in?

Risks from biological material and biological agents present in the material

i. Describe the risks associated with biological agent(s) or toxins likely to be present in the biological material?

List all known agents (or types of agents) or toxins which will be used or may be present in the biological materials. Include viruses, prions, bacteria, fungi or parasites (such as worms or protozoa). If the biological material also contains a toxin or other biologically active chemical which may pose a risk list it here.

ii. Provide information on the mode of transmission, disease caused and symptoms. If any toxin is present, please provide information on its likely concentration in the material and at what level it has an effect on human health.

- What is the route of infection by each agent?
- What disease and symptoms are produced?
- Is there an effective treatment for the disease?

iii. Provide information on the likely viability of the biological material and any biological agents present in it.

- Under what conditions will the agent survive, propagate or be killed?
- What disinfectants are effective against the agent?
- Consider the pre-treatment of the material and treatment prior to disposal.

iv. Provide information on any risks posed to the environment, e.g. ability to survive outside the laboratory, effects on the ecosystem

Describe the consequences of the escape of experimental organisms into the environment.

v. Does the biological material or biological agent(s) present appear on the ACDP Approved List of biological agents and, if so, what is its hazard group under COSHH?

Human pathogens are assigned to a **H**azard **G**roup (**HG 1-4**) depending on their human pathogenicity and effective measures of the treatment against the disease. The HG forms part of the assignment of work to a **C**ontainment **L**evel (**CL1 to 4**) along with other factors. There are no CL3 or CL4 wet laboratories on site. Consult The Approved List of biological agents. http://www.hse.gov.uk/pubns/misc208.pdf

If the biological material or biological agent(s) has not been assigned a hazard group, what is your provisional classification, based on existing knowledge of its ability to cause disease, spread in the community etc?

If an agent is not listed on the ACDP approved list, it does not mean that the agent can be assigned to HG1. Based on available information, what HG is appropriate for the agent handled/potentially present? In order for it to be considered HG1, it must be justified that the agent is *unlikely to cause human disease*

3.2.3 Section C: Project Risk Assessment involving biological GM activity only

Describe the individual elements of the GMOs to be constructed

List rather than detail the following.

i) Recipient organism(s)
ii) Genetic alterations made (e.g. sequences expressed)
iii) Vector sequences incorporated into the final GMM

i) Hazards associated with the recipient micro-organism (e.g. ACDP and SAPO classification, transmission, host range etc)

Detail the name of the organism(s) to be modified, or that have been modified (i.e. the wild-type organism or viral vector backbone from which it is derived and the hazards associated with it). Consider all GMM/GMOs to be constructed: (including intermediate cloning steps and viral vectors, not just the final intended construct. Factors to consider:

- ACDP Hazard Group
- Disabling mutations
- Mode of transmission
- Disease symptoms
- Host range and tissue tropism
- Available vaccines or chemotherapeutic agents

ii) Hazards arising directly from the inserted genetic material (e.g. does it code for a toxin, an oncogenic protein or anything which could cause harmful biological activity)

List of all modifications, including any altered genes. Genes must be identified in such a way that an outside reviewer will have a general idea of their function i.e. providing an acronym is not sufficient. Where the function is unknown, it may help to provide details of any known homologues or a prediction of function (if any). Consideration shall be given to whether the inserted DNA encodes

- A toxin
- An oncogenic protein
- An allergen
- A modulator of growth or differentiation (e.g. hormone or cytokine)
- A product that could result in potentially harmful biological activity

Note: Any human gene may be harmful if over expressed, especially if the over expression is in tissues that do not normally express the protein.

Detail the names of all the vectors to be used and any sequences that will be/have been incorporated into the GMM/GMO. This might include promoters, enhancers, regulatory elements and selection markers.

iii) Hazards arising from the alteration of existing pathogenic traits (e.g. alteration of host range or tissue tropism)

Factors to consider:

- Does the inserted gene encode a pathogenicity determinant, a penetration factor or a surface component providing resistance to host defence mechanisms?

- Does the inserted gene encode a surface component, envelope protein or capsid protein that might bind to a different receptor to that used by the recipient microorganism?
- Does the inserted DNA (or the plasmid sequence) encode resistance to a drug or antibiotic that might be used for the treatment of an infection?

iv) Potential risk of sequences within the GMM/GMO being transferred to related micro-organisms (e.g. via gene transfer or recombination, survivability in the environment)

Factors to consider:

- Could the GMM/GMO survive in the environment for long enough for gene transfer to take place? Consider in the event of a breach of containment
- If it could survive, might it persist?
- If it can persist, could become disseminated or infect animals/plants etc?
- Could it displace or out-compete other species in the environment/disrupt ecosystems?)

Briefly describe the GMOs to be used/constructed (if not known, predict it)
Provide an overview of the properties the final GMM will have. In some cases more than 1 GMM will be generated. In these cases, identify the most hazardous GMM constructed considering both human health and the environment. With some projects it may not be clear that any one GMM will be more hazardous than any of the others (e.g. if all class 1 work). If this is the case this shall be stated.

Consider the likelihood that, in the event of an exposure, the GMM/GMO could actually cause harm to human health or be a risk to the environment. For example, consider the overall fitness of the GMM/GMO and the probability that rare events like mutation or gene transfer may occur. Where the likelihood of harm is poorly understood, a precautionary approach shall be adopted until evidence to the contrary has been obtained.

Assignment of provisional Containment Level to protect human health
The requirements of the final containment level must be sufficient to control all the potential harmful properties of the GMM/GMO and offer sufficient protection for human health.

Assignment of provisional Containment Level to sufficiently protect against harm to the environment
The requirements of the final containment level must be sufficient to control all the potential harmful properties of the GMM/GMO and offer sufficient protection for the environment.

3.2.4 Section D: Control Measures

The risk assessment will have allowed users to determine what hazards are involved, and what risks there are. Based on this, it is now important to assign appropriate control measures to mitigate the risks arising from those hazards. Where relevant, users shall describe the control measures needed to reduce the risk of harm to human health and environment in the appropriate sections on the risk assessment.

a) **Risk of inhalation or escape via the air (aerosols).** Where a risk of harm to human health or the environment from air contaminated with the GMO is identified, describe any precautions or controls in place to reduce the production of aerosols e.g. use of microbiological safety cabinet. This usually arises when there is the potential for airborne transmission of an agent.

b) **Risk of sharps injury.** Where a risk of harm to human health or the environment from a sharp contaminated with the GMO (e.g. needle or blade) then describe any precautions or controls in place. This might include not using sharps, training in the use of sharps, or wearing cut resistance gloves etc. This usually arises where an agent is typically transmitted via blood-blood contact.

c) **Risk from direct contact and/or vectoring (contaminated surfaces, equipment, and objects).** Where a risk of harm to human health or the environment from GM material that could be removed on contaminated objects etc describe any precautions or controls in place to prevent this from happening or prevent escape. This might include lab coats, gloves etc that are retained within the laboratory. Typically, this arises with agents that are transmissible via the contact route, or materials that can survive in the environment (including microorganisms, pollen, seed etc)

d) **Any other required control measures (training, restricted access, procedures etc).** All control measures needed to mitigate risks to human health or the environment shall be described. Any other control measures, especially where safe working practices are needed to prevent harm or escape, shall be described here if not already described above.

e) **Describe how waste will be collected, treated and disposed of**

   a. **Solid waste.** This shall include information on how the waste is handled in the lab, how it is pretreated/treated and transported before being removed from the site, as well as indicating the final disposal route.

   b. **Liquid waste.** This shall include information on how liquid waste is handled in the lab, how it is pretreated/treated (e.g. what disinfectant, concentration and contact time is used), as well as indicating the final disposal route.

f) **Describe how spills will be dealt with in each location.** Describe the basic procedure for dealing with a spill, including all locations where it might be handled differently.

g) **Describe how materials will be transported.** Transportation of materials represents a foreseeable risk of exposure or escape. Briefly describe details of how material is transported:

   a. Nationally and internationally; CDG Regulations 2009, ADR 2017 and IATA Dangerous Goods Regulations (DGR). For off-site transport, a specialist courier is recommended;

b. Between buildings and identified locations;
c. Within the laboratory.

How is it packaged? What route will be taken? Where and how will the materials be unpacked?

h) Any other information (e.g. COSHH assessment for chemicals involved). If there are any non-biological risks etc, please provide evidence that these have been assessed elsewhere.

Assignment of the proposed GM activity class - This is done by comparing the containment and control measures (see section D). For further information please refer to table 1a from Schedule 8 of the GMO (Contained Use) Regulations found at http://www.legislation.gov.uk/uksi/2014/1663/schedule/8/made. The SACGM Compendium of guidance details these measures and can be found at http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm

3.2.5 Section E: Documentation, Licences & Approvals

a) Reference any supporting documentation, letters, references and/or procedures which support any of the information provided in this assessment. E.g. Codes of practice, journal articles, risk assessments from collaborating institutes, phytosanitary, UK REC approval, etc.
b) Does the proposed work, production and/or use of the biological material require any special licences, notification, approval or specific permission (e.g. IAPO for the import) from a legislative body or a council committee? If yes, is this in place and give details.

3.2.6 Section F: Signatures and Review

Signatures
The signatures will be completed after the GMSMC have reviewed the proposal. No work must start before all signatures have been gathered. Consult **Appendix 1**; Figure 1 for further details.

Review
All biological risk assessments are subject to review where there is a reason to suspect that the original assessment is no longer valid or where there has been a significant change in the activity to which the assessment relates or periodically depending on the risk. All current and ongoing work shall be reviewed periodically

- For GM Class 2 or ACDP HG2 at least every 2 years.
- For GM Class 1 or ACDP HG1 at least every 5 years.

Returning Users shall review their RA to ensure it reflects the current proposed work.

Document History

Issue	Date	Comment
1	28 June 2011	New document – Diamond only
2	06 December 2013	Full revision – Joint document. Site GMSMC established and implemented.
3	23 August 2016	Full revision – Joint Document
4	02 October 2018	Guidance updated to reflect the new merged GM and BioCOSHH assessment form
4.1	25 November 2019	Formatting amendments to reflect the biological activity form.
4.2	09 December 2021	Updating guidance to reflect addition of RFI
4.3	04 October 2024	Updated document to reflect amendments to biological activity risk assessment form and to provide further clarification.

APPENDIX 1: SUBMISSION OF BIOLOGICAL RISK ASSESSMENTS FOR APPROVAL

Before any biological work starts, a biological risk assessment must be completed. It shall be completed at the earliest opportunity to allow for necessary review process.

Once a biological risk assessment is submitted to any of the entities of the site (i.e. Diamond, RCaH, STFC (ISIS/BID) or RFI), the GMSM committee (GMSMC)/BSO/Local GMSMC rep will review this assessment. In some cases, GM class 2 or HG2 or above will need to be reviewed by GMSMC. In the majority of cases this can be done electronically but may require a GMSMC meeting to discuss the assessment.

The biological risk assessment should be circulated to all entities via the one of the following persons:

Diamond	Valerie Loughry	(diamondshe@diamond.ac.uk)
RCaH	Zuzanna Lalanne	(RCAHOPSBIOCOSHH@rc-harwell.ac.uk)
ISIS/STFC	Ludmila Mee	(ludmila.mee@stfc.ac.uk)
RFI	RFI Biosafety	(RFIBiosafety@rfi.ac.uk)
BID	Mark Roberts	(mark.roberts@stfc.ac.uk)

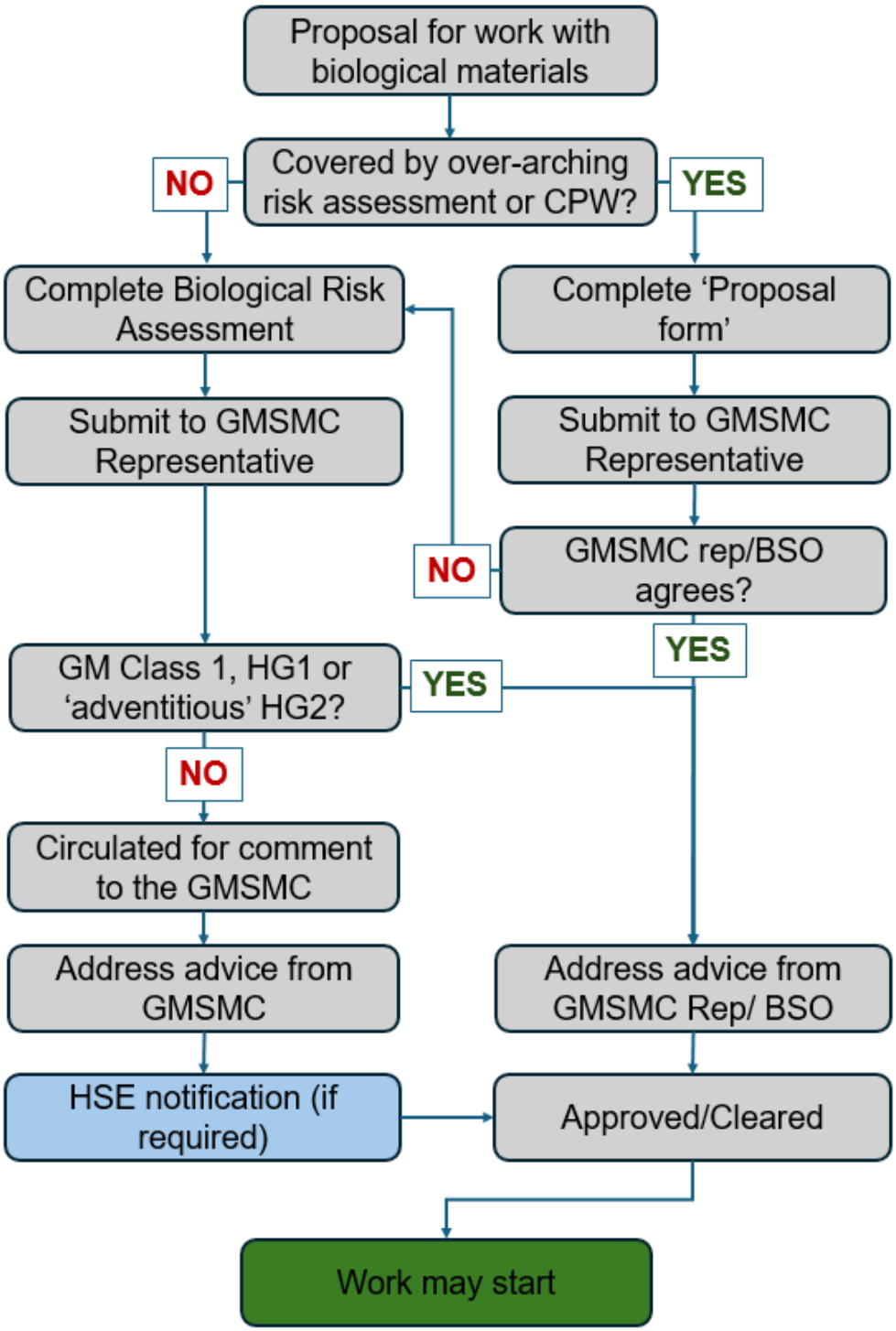
This biological risk assessment if necessary, will then be circulated to all GMSMC members as well as, if required, other relevant persons. This shall include requesting the biological risk assessment to be reviewed within a 2-week deadline and any comments to be sent back to one of the above points of contact.

Once the deadline has passed, all comments received will be collated by the entity where the biological risk assessment has been submitted. A GMSMC meeting can be arranged if required, however if minor comments are received these can be discussed electronically.

Once the biological risk assessment has been reviewed successfully, the assessment can be approved. Part of the approval process involves assigning a reference to the biological risk assessment. Once approved, the biological risk assessment can be circulated to all entities and the proposer for their records.

A flow diagram of this process can be found in Figure 1.

Figure 1: Process for approval of biological risk assessments



APPENDIX 2: PROPOSAL FOR GM WORK TO BE CONSIDERED UNDER AN OVERARCHING RISK ASSESSMENT

A – PROJECT OVERVIEW			
Applicant		**Date**	
Project Leader		**Applicant's organisation**	
Project Title			
Activity description (explain what you will be doing *e.g. summary of protocol*?)			
Locations			

B– JUSTIFICATION	
Title of overarching risk assessment that covers the work	
Justification for including this work under that RA	
Confirm control measures are appropriate and describe any changes required.	

C – CONFIRMATION THAT INFORMATION PROVIDED IS CORRECT			
Applicant		**Date**	

D – AUTHORISATION FOR WORK TO COMMENCE			
Comments			
Local GM representative		**Date**	
BSO		**Date**	

APPENDIX 3: GENETIC MODIFICATION SCIENTIFIC MANAGEMENT COMMITTEE (GMSMC) TERMS OF REFERENCE (TOR)

The Science & Technology Facilities Council (STFC which includes ISIS, CLF, DL), Diamond Light Source Ltd (DLS), the Research Complex at Harwell (RCaH) and Rosalind Franklin Institute (RFI) have agreed to combine the individual GMSMC committees to provide a single GMSMC committee that covers both biological agents and genetically modified organisms (GMO's). This will provide a consistent and co-ordinated approach to all notifications and risk assessments completed by both internal staff and external customers.

This joint committee will advise and support all organisations, but this does not remove any of the health and safety responsibilities of any individual organisation. Each will maintain their own GM (Genetic Modification) and Microbiology and Biotechnology Unit (previously known as BAU, Biological Agents Unit) HSE numbers and have ultimate responsibility for the work proposed and ongoing within their laboratories. The GM Centre Numbers are as follows:

Diamond Light Source (DLS): GM972; STFC (includes ISIS and CLF): GM975; STFC Daresbury: GM588;

Research Complex at Harwell (RCaH): GM3067; Rosalind Franklin Institute (RFI): GM3564

Role

- To ensure all work involving GMO's and Biological Agents are compliant with relevant legislation, specifically the Genetically Modified Organisms (Contained Use) Regulations and Control of Substances Hazardous to Health Regulations (COSHH) and all associated guidance.
- To ensure efficient communication and cooperation between all the organisations and external customers, so that work is appropriately reviewed and approved.

Functions

- To review and approve all GM and ACDP Hazard Group 2 (HG2) and above biological activity risk assessments before work commences. ACDP Hazard Group 1 (HG1) biological activity assessments will be reviewed locally by a competent person e.g. the BSO
- To ensure HSE receive notification of Class 2 GM activities and first use of ACDP (Advisory Committee on Dangerous Pathogens) HG2 and HG3 Biological agents, before work commences.
- To ensure all modifications and changes to legislation and guidance are adopted and communicated.
- To review incidents and ill health involving GM and biological agents and where appropriate, give advice to the relevant organisation.
- To be assured that the inspections of laboratories and facilities used for GM and biological agent activities have been completed.
- To review training and health monitoring requirements.

Membership and Meetings

The GMSMC will consist of staff from all organisations as described above and will include a nominated chairman, DLS BSO (Biological Safety Officer), STFC BSO, RCaH and RFI BSO and the appropriate individuals to be able to assess and advise on the GM and Biological agent activities proposed and assessed.

The GMSMC will meet a minimum of twice a year with all assessments, including class 1 GM and ACDP HG1 biological activity assessments circulated electronically as and when they are put forward. Class 2 (and above) GM and ACDP HG 2 biological activity assessments can be further reviewed if required at a meeting of the GMSMC. ACDP HG1 biological activity assessments will be reviewed locally by a competent person e.g. the BSO. A minimum of 5 members of the GMSMC must be present for the meeting to be quorum and there must be representation from all organisations.

Minutes will be taken and maintained.

End of document.