

**UNIVERSITY OF BATH HEALTH AND SAFETY STANDARD**
**Working with Genetically Modified Organisms (GMOs) Safety Standard**

Version Number	Version 3	Date of Approval	June 2023	Review Date	Three years from acceptance by UHSC
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Aims	<p>The University is committed to ensuring the health, safety and welfare of all staff, students and visitors.</p> <p>The University will aim to achieve this by ensuring that the risks to human health and the environment arising from the contained use of genetically modified organisms are reduced to the lowest level that is reasonably practicable by carrying out suitable and sufficient assessments of the risk and obtaining expert advice on these assessments.</p>				
Scope	<p>The requirements of this standard apply to all employees of the University of Bath while undertaking work activities defined as “contained use” involving genetically modified organisms.</p> <p>Students are defined as employees under the Genetically Modified Organisms (Contained Use) Regulations 2014.</p>				
Relevant Legislation	<ul style="list-style-type: none"> <li>• Health &amp; Safety at Work etc. Act 1974 (HASWA)</li> <li>• The Management of Health &amp; Safety at Work Regulations 1999 (MHSWR)</li> <li>• Control of Substances Hazardous to Health Regulations 2002 (COSHH)</li> <li>• The Genetically Modified Organisms (Contained Use) Regulations 2014</li> </ul>				
Definitions	<p><b>Genetic Modification</b> The process of altering the genetic material of an organism by use of a method that does not occur in nature.</p>				
	<p><b>Genetically Modified Organism (GMO)</b> Organisms whose genes have been artificially altered to modify their characteristics in some way or another. GMOs may be plants, animals or (most commonly) micro-organisms (including bacteria, viruses, parasites and fungi).</p>				
	<p><b>Contained Use</b> Any activity involving GMOs where control measures, such as physical, chemical or biological barriers, are used to limit contact between GMOs and humans or the environment so as to provide a high level of safety.</p>				
	<p><b>Person Responsible for contained use</b> This means: (a) a person who has the authority to determine whether a particular contained use takes place, or (b) a person who has control of the planning or conduct (or both) of that contained use, and there may be more than one person responsible for the same contained use e.g. Head of Department, Supervisors, Managers, Principal Investigators, Users</p>				
	<p><b>Genetic Modification Safety Committee (GMSC)</b> A group of technical experts who provide competent advice on the adequacy of GMO risk assessments.</p>				
	<p><b>Scientific Advisory Committee on Genetic Modification (SACGM)</b> Advisory body appointed by the Health and Safety Commission (HSC). They produce guidance on GM that is considered to be good practice. Following this guidance is not compulsory, but if you do follow this guidance you will normally be doing enough to comply with the law. <a href="#">The SACGM Compendium of guidance</a></p>				

	<p>Employees</p> <p>Students (including visiting students) are considered as employees of the educational establishment in which they are studying and undertaking contained use. This means that responsibility for their safety as well as the safe conduct of contained use, rests with the educational establishment, but also that students are required to take reasonable care for their own health and safety as well as that of any other person who may be affected by their actions (or inactions). Educational establishment has a very broad interpretation and includes schools, universities, and training providers.</p>		
Responsibility for implementation	<p>Faculty Deans</p> <p>Heads of Departments</p> <p>Technical Managers</p> <p>Supervisors/Managers/Principal Investigators</p>		
Training availability:	<p>Induction Training by Supervisors/Area Safety Co-ordinators</p> <p>SHEW online course on Moodle</p> <p><a href="#">GM Wiki</a></p>		
Standard to meet:		Accountability	Reference documents and more information
1.	<p>Ensure GMO risk assessments are carried out for all work activities within department responsibility and identified control measures implemented before work involving GMOs can begin.</p>	<p>Heads of Department (HoD)</p>	<p><a href="#">HSE Guidance GMOs (contained use)</a></p>
2.	<p>Risk Assessment</p> <p>Produce a suitable and sufficient risk assessment. This must take full account of all aspects of the planned work, including handling, transport, work area decontamination, inactivation of GMOs, disposal and waste management. The key aspects to consider include:</p> <p>(a) identification of any potentially harmful effects;</p> <p>(b) characteristics of the proposed activity;</p> <p>(c) the severity of any potentially harmful effects;</p> <p>(d) the likelihood of them occurring; and</p> <p>(e) disposal of waste and effluent.</p> <p>Regulation 5(2) and Part 1 of Schedule 3 set out in more detail what to consider as part of the risk assessment.</p>	<p>Person responsible for contained use, e.g. HoD/ Supervisors/ Managers/ Principal Investigators/ Users</p>	<p><a href="#">University Templates for GMO risk assessments on GM Wiki</a></p> <p><a href="#">The Genetically Modified Organisms (Contained Use) Regulations 2014 HSE Guidance L29</a></p>
3.	<p>Hazard Identification</p> <p>Identify the hazardous properties of the micro-organism (including recipient and donor micro-organisms, vectors or inserted material) with reference to national categorisation lists.</p> <p>Consider how and where the contained use will be undertaken, and the impact on the hazardous properties of the micro-organism.</p> <p>Assign a provisional level of risk.</p>	<p>Person responsible for contained use</p>	<p><a href="#">HSE The Approved List of biological agents</a></p> <p><a href="#">Defra Animal pathogens: guidance on controls</a></p>
4.	<p>Containment Measures</p> <p>Select the appropriate containment measures (from the most applicable table in Schedule 8) based on the provisional level of risk to ensure risks are adequately controlled.</p> <p>Assign the contained use to the appropriate containment level.</p>	<p>Person responsible for contained use</p>	<p><a href="#">The Genetically Modified Organisms (Contained Use) Regulations 2014 HSE Guidance L29 Regulation 19 page 39 and Schedule 8 page 67</a></p>

5.	<p><b>Risk Classification</b></p> <p>Classify the activity into one of four classes according to the containment level selected. Based on level of classification required to control the risk. Review and confirm classification once risk assessment is completed to ensure it is adequate and appropriate.</p>	Person responsible for contained use	
6.	<p><b>Competent Advice</b></p> <p>Obtain expert advice (via the GMSC) on the GMO risk assessment prior to starting the work (contained use).</p>	Person responsible for contained use	<a href="mailto:gm@lists.bath.ac.uk">Contact and send assessment to GMSC via gm@lists.bath.ac.uk</a>
7.	<p><b>Notification</b></p> <p>When the contained use is classified as Class 2 or above, ensure this is notified to the competent authority (HSE). This entails a fee. Class 3 and 4 work requires written consent from the HSE before work can start. Class 2 requires only acknowledgement of receipt of the notification to begin work. Inform the GMSC and HSE if there are significant changes affecting the risks associated with a notified contained use.</p>	Person responsible for contained use	<p><a href="#">GMO Notifications</a></p> <p><a href="#">Notification to HSE should be arranged via the GMSC/SHEW Biological Safety Officer (BSO).</a></p> <p><a href="#">The GMSC will provide advice as to what constitutes a "significant" change</a></p>
8.	<p><b>Training</b></p> <p>Ensure employees receive appropriate instruction, information, supervision and training including signing onto the GMO risk assessment/s for their work. Maintain records of training.</p>	Supervisors/ Managers/ Principal Investigators	
9.	<p>Complete online course prior to starting work with GMOs</p>	Employees	<p><a href="https://moodle.bath.ac.uk/course/search.php?search=health+and+safety+training">https://moodle.bath.ac.uk/course/search.php?search=health+and+safety+training</a> <a href="#">Log in to Health and Safety Training: Genetic Modification course is first module</a></p>
10.	<p>Register as a GM worker with the GMSC using the University form and do not start work until approval is granted. Need to include details of relevant practical experience or attend UoB microbiological training course. Exceptions are: UG students in supervised practical classes or working on authorised Class 1 projects; and MRes/MSc students on short term (&lt;3 months) projects who are not closely supervised.</p>	Employees	<a href="#">Form and guidance on GM wiki</a>

**Table 1: Containment levels and the corresponding risk classification**

Containment necessary to control the risk	Risk Classification
Level 1	Class 1
Level 1 with the addition of measures from Level 2	Class 2
or Level 2 (without additional measures)	
Level 2 with the addition of measures from Level 3	Class 3
or Level 3 (without additional measures)	
Level 3 with the addition of measures from Level 4	Class 4
or Level 4 (with or without additional measures)	

Ref: Regulation 5 Table 1 of HSE Guidance L29; The Genetically Modified Organisms (contained use) Regulations 2014

**Table 2: Classes of contained use**

Class	Description
1	Contained use of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment.
2	Contained use of low risk, for which containment level 2 is appropriate to protect human health and the environment.
3	Contained use of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.
4	Contained use of high risk, for which containment level 4 is appropriate to protect human health and the environment.

Ref: Regulation 2(1) Schedule 1 of HSE Guidance L29; The Genetically Modified Organisms (contained use) Regulations 2014