

UNIVERSITY OF LEICESTER

Risk assessment of activities involving genetically modified micro-organisms

- This form should be completed alongside an Application to carry out activities involving GM microorganisms.
- Please return your completed form to the Biological and Chemical Safety Officer, Safety Services Office, Block L, Freemans Common (sc128@le.ac.uk).
- Please complete the form in typescript. Please note that all text boxes can be expanded as required.
- Note that for the purposes of the Contained Use Regulations, “micro-organism” is defined as a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material including animal or plant cell cultures, viruses and viroids.
- The risk estimation table at the end of this form will help you to complete the risk assessment.
- *For guidance on how to complete this form, please see the University [Genetic Modification](#) guidance document, and the ACGM Compendium, which can be viewed at <http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/>*

Title of project:

iGEM 2015: Synthetic biology solution for therapeutic modulation of NAD+ levels

Part one: Human Health

1. Could the GMM be hazardous to human health?

No

If NO: Questions 2 and 3 do not apply.
If YES: explain the possible hazards to human health then continue to the next question.

Goto question 4

Comments:

None of the genes that are proposed to be cloned and expressed are known to be toxins to humans. Genes are either naturally occurring bacterial enzymes and involved in biosynthesis or bacteria specific toxin / anti-toxin proteins.

[GM Committee member commented “NAD genes are involved in biosynthesis of a common metabolite that will not have any known effect on pathogenic behavior”]

2. How likely is it that the GMM could actually harm human health in the event of exposure?

Likelihood: Negligible
Consequence: Negligible
Risk: Effectively Zero

Comments:

[GM Committee member commented “...and the strain being used will have poor survival in the environment.”]

3. Considering the nature of the work, are any additional controls necessary to protect human health? If so please outline them.

No

Part two: Environmental Protection	
4. Is the GMM able to survive, establish, disseminate and/or displace other organisms? Comments:	No
5. Is the GMM able to persist in the environment and cause harm, and is it possible for passive transfer of the gene to other organisms in which it might be expressed? Comments:	No If NO: no further containment is needed to protect the environment. Go to (10). If YES: describe how harm could be caused
6. Will the GMM be pathogenic to animals or plants? Are there any other identifiable negative effects on organisms? Comments:	No
7. How likely is it that there is potential for transfer of genetic material between GMM and other organisms (e.g. presence of conjugative plasmids; consider locality) Comments:	Likelihood: Negligible Consequence: Negligible Risk: Effectively Zero
The GMM will be handled entirely within a Biosafety Level 1 lab and the plasmids used are not conjugative.	
8. Will there be any products of gene expression that could be toxic to other organisms (e.g. bio-pesticide) Comments:	No
Genes are either enzymes involved in biosynthesis / degradation of organic chemical compounds or toxin / antitoxin proteins that are only known to be hazardous to bacteria.	
9. Assess the phenotypic and genetic stability of the GMM. (e.g. could genetic instability be hazardous?) Comments:	

As none of the gene products to be expressed are known to be intrinsically hazardous it would seem unlikely the genetic instability could confer hazardous properties.

Part Three: Assignment of Class/Containment

10. Assignment of a final class / containment level based on:

- the hazard classification of the host
- any identified hazards
- the severity of any harmful consequences should they occur
- estimated containment level to control the hazards


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Is the containment level designed to protect human health adequate to protect the environment?

Yes

Name of proposer	Email address	Telephone number
Dr Richard Badge	rmb19@le.ac.uk	2525042

Name of PI responsible for the work (if different to above)	Email address	Telephone number
NA	NA	

Signature of PI	Date
	03/08/15

The information provided in this form is to the best of my knowledge accurate and I undertake to notify the Biological Safety Officer of any future changes to procedures or materials described. I agree to take responsibility for, and act as Deputy Biological Safety Officer for this work.

PI for the work must sign this form if different from the proposer.

Risk estimation table:

	likelihood of hazard			
consequence of hazard	high	medium	low	negligible

<i>severe</i>	high	high	medium	effectively zero
<i>medium</i>	high	medium	medium/low	effectively zero
<i>low</i>	medium/low	low	low	effectively zero
<i>negligible</i>	effectively zero	effectively zero	effectively zero	effectively zero