Loughborough University	Safety Department use only		Material(s) Classification	
	Reference Number:		Hazard Group 1	☐
			Hazard Group 2	☑
Biological Risk Assessment	CBE Use only		GMO	☐
	Reference Number:	CBE BRA 187	HTA Licensable	☐

FORM CBE-RA-Form/002 Version 1.0

RISK ASSESSMENT AND PROJECT REGISTRATION FOR WORK INVOLVING BIOLOGICAL MATERIAL

PLEASE READ CAREFULLY

This form acts to register projects involving the Use of Biological Agents and / or Genetically Modified Micro-Organisms, or of materials that may be contaminated with these agents. It assesses the hazards and risks associated with the project as well as identifying those at risk and the measures necessary for preventing, or controlling these risks. Please ensure that sufficient detail is provided when completing this form and that the relevant written SOPs are referenced where required. Once completed and approved, all risk assessments must be supplied to all those working within this project. The work described within this form must not commence until this risk assessment has been completed and approved and that all necessary control measures are in place.

Any changes to the work, or the persons involved, must be notified to the authorised person. All changes requested must be recorded within the risk assessment change control form and may also need to be incorporated within an amended version of this form.

A separate risk assessment will be required for assessing risks associated with GMO activities.

The following declaration must be completed and undersigned by the Principal Investigator or Person Responsible for the project

- All information contained in this form is accurate and comprehensive.
- All workers involved will be instructed that their work must remain within the boundaries of this project registration & assessment.
- All workers have been given, or will be given before they become involved, adequate training and where necessary their competency assessed.
- All workers have, or will be before their involvement begins, enrolled with Occupational Health for health clearance where necessary.
- It is understood that this risk assessment shall not be transferred to a third party without the PI/Supervisor/Line Manager named in this form either taking responsibility for the new activities, or ensuring that a new proposal is submitted.
- All changes to the work covered by this form will be reassessed & the changes submitted to the authorised person before those changes are made to the work.

Principal Investigator	
Name	Dr. Elliot Woolley
Position	Senior Lecturer
Department	
School	Wolfson of MEME

Person conducting this risk assessment	
Name	Rania Harastani
Position	PhD student
Department	
School	Wolfson of MEME

The Project Activity	
Title	Tackling obesity by creating a knowledge-base on food reformulation for industrial application.
Reference Number	
Start Date	8 Nov 2019
End Date	1 Apr 2020

Others Involved in the work	
Names	Lewis James
	Senior lecturer

Name	Dr. Elliot Woolley	Signature		Date	3 Oct 2019

1. INTRODUCTION

1.1 Background & aim of project	This research investigates reformulating ultra-processed foods in an aim to tackle obesity. A knowledge-base on food reformulation was developed with built-in tools to evaluate and assess sugar/fat reduction techniques from nutritional and technical perspectives. In order to validate the knowledge-base, a case study on muffin reformulation will be conducted. In this part of the study, muffins will be prepared by substituting sugar and fat partially with dietary fibres. The shelf-life of reformulated muffins might be affected, and hence microbial analysis will be conducted to investigate the total counts of bacteria as well as yeasts and molds in both control and reformulated muffins during storing them at 25 degree Celsius for 15 days. Objectives: - Investigate total counts of bacteria in muffins using Nutrient Agar. - Investigate total counts of yeasts and molds in muffins using Potato Dextrose Agar.
1.2 Description of experimental procedures	1- Muffin samples will be stored at 25 degrees Celsius in sealed transparent bags and analyzed in three folds for total counts of bacteria as well as yeasts and molds using Nutrient and Potato Dextrose Agar. Samples will be analyzed at the 1st, 4th, 7th, 10th and 15 days of storage. 2- Nutrient agar plates will be incubated at 37 degrees Celsius for 24 hours (mesophilic bacteria), while potato dextrose agar plates will be stored at 25 degrees Celsius for 72 hours for yeasts and molds counts. 3- This analysis will be conducted using the traditional method in food microbiology, i.e. homogenising 10 gr of muffins in 90 ml of peptone water (buffer) then making serial dilutions (using a buffer) then adding 1 ml of each dilution into the plates containing the growth medium. 4- Materials and plates containing the growth mediums will be sterilized and prepared a couple of days before analysis.
1.3 Where will this work be carried out?	Rooms/areas: Wolfson T208-b
	Building(s): Wolfson School

☐ 2.1 Human or animal tissues, cells, body fluids or excreta will be used in this project

☐ 2.11 Biological agents will be used in this project

3. CLASSIFICATION OF HAZARD GROUP

3.1. Are you confident that any non-GM organism, tissue, cell, body fluid, excreta or any component thereof covered by this assessment cannot potentially pose a threat to humans or cause human diseases?	○ Yes - Classify as HG1
3.1.1. Can any non-GM organism, tissue, cell, body fluid, excreta or any component thereof cause human disease and potentially be a hazard to humans but is unlikely to spread to the community and for which there is usually effective prophylaxis or treatment available?	☑ Yes - Classify as HG2
3.1.2. Can any non-GM organism, tissue, cell, body fluid, excreta or any component thereof cause severe human disease and potentially be a serious hazard to humans and that may spread to the community, where effective prophylaxis or treatment may or may not be available?	○ Yes
3.2. Do any of the materials contain pathogens or toxins covered by the Anti-Terrorism Crime and Security Act?	○ Yes — ATCSA Schedule 5
ASSIGNMENT OF CONTAINMENT LEVEL	

4. TISSUES, CELLS, BODY FLUIDS OR EXCRETA

4.2. Will any culturing of the material described in section 2 take place? *If Yes, describe which cell(s) will be cultured and under what conditions.*	○ Yes ☑ No	
4.3. Could HIV permissive cells be present? *If Yes, describe the cells and for how long these cultures will be allowed to grow.* *If unsure seek advice. Refer to CBE Code of Practice for details on additional precautions.*	○ Yes ☑ No	
4.4. What is the maximum volume of culture grown?	Per Vessel	
	Number of vessels	
4.5. Will the tissues, cells, body fluids or excreta be manipulated in any way that could result in the concentration of adventitious biological agent present? *If Yes, explain.*	○ Yes ☑ No	

4. TISSUES, CELLS, BODY FLUIDS OR EXCRETA

4.6. Will any of the tissues, cells or fluids be donated by you or your colleagues working in or with access to the labs?	○ Yes Ⓥ No	

5. RISKS AND CONTROL MEASURES

Risk		How will this be controlled?	Reference to SOP's / Other documentation
5.1. Might infectious droplets, aerosols or splashes be created, either deliberately or by accident?	Ⓥ Yes ○ No	Microbial plating and counting will be done using a class II bio-safety cabinet which insures that all work will be carried out using an aseptic technique.	Biological spill response SOP038 and SOP009 use and maintenance of Class II BSC
5.2. Will this material be transported within the laboratory e.g. between BSC & Incubator?	○ Yes Ⓥ No		
5.3. Will this material (including waste) be transported locally between sites on campus but outside the laboratory?	○ Yes Ⓥ No		
5.4. Will material(s) listed in section 2.2 or section 2.3 be shipped to organisations elsewhere in the UK or abroad?	○ Yes Ⓥ No		
5.5. Will this material be received from organisations elsewhere in the UK or abroad?	○ Yes Ⓥ No		
5.6. Will this material be stored?	○ Yes Ⓥ No		
5.7. Will infectious material be centrifuged?	○ Yes Ⓥ No		
5.8. Are biological samples to be cultured in an incubator?	Ⓥ Yes ○ No	Total viable counts and yeasts and molds will be grown on agar plates, then counted. Counting will be done while plates are closed inside the biosafety cabinet, then plates will be autoclaved and discarded.	Autoclave: Dx-90 SOP024, SOP025, SOP054
5.9. Are sharps to be used at any stage during this activity?	○ Yes Ⓥ No		
5.10. Are animals to be used in this project?	○ Yes Ⓥ No		
5.11. Will a fermenter / bioreactor be used to culture a biological agent or material?	○ Yes Ⓥ No		
5.12. Is there any stage within the experimental procedures when an infectious material is inactivated (other than for disposal)?	○ Yes Ⓥ No		
5.13 Are any of the following to be used in conjunction with the project?	☐ Carcinogens or Mutagens ☐ Toxins ☐ Liquid Nitrogen ☐ Ionising radiation		

Risk		How will this be controlled?	Reference to SOP's / Other documentation
	☐ Lone working		
5.14. Are there any conditions associated with the hazards described in section 5.13 that require additional control measures?	○ Yes ⊘ No		

6. PPE AND HYGIENE

Control Measure	Details		Reference to SOPs / other documentation
6.1 When will gloves be worn?	Autoclave gloves stored near the autoclave will be worn at all times when operating the autoclave as directed by SOP034"Use and Maintenance of Systec DX-90 autoclave". Disposable Nitrile gloves for general use will always be worn when in the T208b, as directed by SOP037 "Use of Personal Protective Equipment".		Use of personal protective equipment: SOP037
6.2 What type and where will they be stored?	Nitrile	In Lab and In Changing Area	Use of personal protective equipment: SOP037
6.3 When will laboratory coats be worn and what type are these?	At all times	Coloured Howie	Use of personal protective equipment: SOP037
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	They are stored outside the laboratory in a dedicated change area. Guidance on the proper use of PPE will be taken from SOP037 "Use of Personal Protective Equipment". The lab coats will be autoclaved and sent for cleaning every month.		Use of personal protective equipment: SOP037
6.5 Provide details of any other types of PPE to be used?	Safety spectacles		
6.6 Describe the lab hygiene facilities available and where they are located	Sink, hand disinfectant, eyewash, spill kits		Use of personal protective equipment: SOP037
6.7 Where are the first aid boxes and emergency spill kits located?	Designated eye wash station		

7. WASTE

7.1 How will waste be treated prior to disposal

(Note that all differently treated wastes must be included e.g. If some liquid is autoclaved, but others not, then describe both)	Treatment prior to disposal	Is the treatment validated?	Reference to SOPs / other documentation
☑ Liquid waste	Liquids will be treated by autoclave (121°C for 45 minutes)	⊘ Yes ○ No	Treatment cycle is validated according to SOP024
☑ Solid waste	Used Petri-dishes will be treated by autoclave (121°C for 45 minutes).	⊘ Yes ○ No	Treatment cycle is validated according to SOP024 Autoclave used DX-90 will be serviced annually by the contractor.
☐ Other (Specify)			

7. WASTE

7.2 Is any waste being autoclaved?	☑ Yes ○ No	
All cycles have been validated for the actual load types used? *(If Yes, documentary evidence of the validation must be available)*	○ Yes ☑ No	
The successful completion of every load is checked prior to disposal?	☑ Yes ○ No	

7.3 How will liquid waste be disposed of?

☑ To drain?	after 1% Virkon decontamination for 24 hours, waste is poi	○ Yes ☑ No	
☐ As solid waste?			
☐ Other (Specify)			

7.4 How will solid waste be disposed of?

Categorisation	Waste stream colour code	Disposal method (Edit as required)
☐ Sharps		
☐ Sharps contaminated with cytotoxic or cytostatic material		
☐ Human body parts, organs, including blood bags and blood preserves and excreta that have been pretreated before leaving the site		
☐ Animal body carcasses or recognisable parts that have been pretreated before leaving the site		
☐ Potentially or known infected lab wastes contaminated or potentially contaminated with cytotoxic or cytostatic material that have NOT been pretreated before leaving the site		
☐ Potentially or known infected lab wastes that have NOT been pretreated before leaving the site		
☑ Infected or potentially infected lab wastes that HAVE been pretreated before leaving site	Orange	Disinfection or sterilisation in the lab site > orange clinical waste bags > clinical waste disposal (incineration)

8. MAINTENANCE

8.1 Are preventative maintenance and monitoring regimes in place for the following laboratory equipment?

	Inspection / Servicing Frequency	Cleaning / Disinfection Frequency	Monitoring / Alarms Frequency	Reference to SOPs
☐ Centrifuges				
☑ BSCs	Inspected before every use and during weekly clean. Regularly serviced	BSCs are cleaned before and after every use with 1:50 chemgene and 70% IMS and undergo deep clean once a week. After each use, BSC also undergo a round of UV disinfection.	Record is kept of downflow velocity (m/s) and performance factor after each use.	SOP009- use and maintenance of Class II BSC SOP004- General laboratory housekeeping.

8. MAINTENANCE

☐ Fume Hoods				
☑ Autoclaves	Inspected before every use and serviced when needed.	Room and autoclave cleaned weekly. Inside not cleaned as its routinely sterilised during use.	Monitor before use-results from previous run printed off once its complete.	Use and maintenance of Systec VX Autoclave | H&S document reference: CBE SOP 24 Use and maintenance of Systec VX Autoclave (2) | H&S document reference: CBE SOP 25 Use and maintenance of Classic 2100 autoclave | H&S document reference: CBE SOP 11
☑ Incubators	Inspected once a week and regularly by operator prior to use.	Incubators are cleaned and decontaminated unless a contamination occurs	Constant monitoring for the shaker speed and temperature	Use and maintenance of Sartorius Certomat BS 1 Incubator: SOP 124 at Wolfson school T208b
☐ Liquid N_2 Stores				
☐ Freezers				
☑ Fridges	Weekly Inspection, PAT tested yearly	Cleaned every month	Constant monitoring with temperature probe.	Use and maintenance of fridges and freezers; SOP016 Temperature Monitoring of Refrigerators and Freezers: SOP028
Failure contingency plan				
☐ Others				

9. TRAINING

9.1. Have all project research workers undertaken safety training for working with hazardous or potentially hazardous biological materials and agents at CL2?

Name of researcher	Had Training	Date training completed (or will be completed)	If no, state why
Rania Harastani	◉ Yes ○ No	7 Oct 2019	

☐ 9.2. This work involves HTA 'Relevant Material', confirm that all project research workers have undertaken HTA training

10. EMERGENCY PROCEDURES

10.1 Are procedures in place for dealing with spillage of infectious or potentially infectious material

Equipment	Reference to SOPs
☑ Within the BSC	Local Procedures described in CBE SOPs which specifically detail spillage pr
☐ Within the centrifuge	
☑ Within the laboratory, but outside any primary control measures (e.g. BSC)	Local Procedures described in CBE SOPs which specifically detail spillage pr
☐ Outside the laboratory	

Are procedures in place for the security of these HTA Relevant samples?

☐ Loss or theft of samples (including whilst in transit)	

10. EMERGENCY PROCEDURES

☐ Loss of traceability of samples	
☐ Incorrect disposal of samples	

10.2 Describe the procedures in place for an accidental exposure

Immediate action	Wipe area using paper towel containing 1% Virkon , dispose of as clinical waste. Eye wash stations are readily available in each laboratory change area and within laboratories that do not have a change area. A first aid kit is located outside the laboratory unit. Signs are posted throughout the laboratory unit to enable workers to locate the nearest medical kit. Contact details for first aiders are posted in laboratories. Any sharps injury is to be reported and treated by local first aider immediately.	Ref to SOP's	Biological Spill response: SOP038
When and whom to report the incident	Essential and emergency contact details are posted in the lab T208-b	Ref to SOPs	

11. ACCESS

		Explanation	References
11. Is/are the lab(s) adequately separated from other areas (e.g. offices)?	(✓) Yes ( ) No		
11.2. Is/are the lab(s) or other work areas shared with other users not involved in the project?	(✓) Yes ( ) No	There is minimal risk to other lab users as the experiment will be conducted in BSC-2. Further, all microbial work will be performed only in Wolfson T208b to reduce any potential exposure or contamination.	SOP009- use and maintenance of Class II BSC. SOP003- Disposal of biological waste. SOP004-General lab housekeeping.
11.3. Describe the measures in place to ensure that hazardous biological agents or HTA relevant material is secure	( ) Yes. (✓) No		

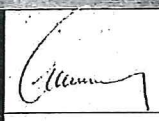
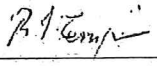
12. OCCUPATIONAL

12.1. All workers involved with handling unscreened blood, blood products and other tissues are recommended to have Hepatitis B immunisation. Have all workers involved in this project been immunized?	(✓) Yes ( ) No
12.2. Is health surveillance required?	( ) Yes (✓) No

13. NOTIFICATIONS

☐ 13.1. Are any of the cells, tissues or fluids covered by the Human Tissue Act (HTA) under the University HTA Licence?	
☐ 13.2. Are any of the cells, tissues or fluids obtained from a HTA licensed biobank with REC approval for generic research use?	
☐ 13.3. Does this work have ethical approval from a recognised NHS Research Ethics Committee?	
☐ 13.4. Does any of the work require approval from the University Ethical Committee?	

13. NOTIFICATIONS	
☐ 13.5. Do any of the materials require approval for use from the UK Stem Cell Bank Steering Committee (MRC)?	
☐ 13.6. Do any of the materials or biological agents listed require any other licenses?	

14. APPROVALS	
Authorised Person	
Departmental Biological Safety Advisor	
University Biological Safety Officer (or Deputy)