→ Bob → Chris → Carolyn

Insert BA Categorisation (Hazard Group 1 or 2 or GMO Class 1):
HG1

Loughborough University

Health & Safety Unit Use Only	
Ref No:	N/A
Department Use Only	
Ref No:	BRA/CBE/023

RISK ASSESSMENT OF WORK WITH BIOLOGICAL AGENTS

Please note the following before completing this form:

1. University Health and Safety Policy requires that risk assessment of all work with biological agents (BAs) must be carried out in advance of work commencing. A key requirement of The Control of Substances Hazardous to Health Regulations (COSHH) is to assess the risks associated with any work activity involving the use of biological materials may contain biological agents.
2. YOU SHOULD COMPLETE ALL OF PART A, THE APPROPRIATE SECTION(S) OF PART B, AND ALL OF PART C. ALL RISK ASSESSMENTS MUST BE REVIEWED BY THE DEPT/SCHOOL BIOLOGICAL SAFETY ADVISOR AND, WHERE HAZARD GROUP 2 BIOLOGICAL MATERIAL IS INTENDED TO BE USED EXPLICIT APPROVAL IS ALSO REQUIRED FROM THE UNIVERSITY BIOLOGICAL SAFETY OFFICER. THIS FORM SHOULD BE SUBMITTED TO THE HEALTH, SAFETY & ENVIRONMENT UNIT FOR REVIEW VIA YOUR DEPARTMENTAL SAFETY OFFICER.
3. It is the responsibility of the Principal Investigator to ensure compliance to these requirements and that this risk assessment remains valid.
4. This risk assessment form **IS NOT** for assessing the risks associated with **Genetically Modified Organism activities.**

Date Submitted:	29/6/10	Date Approved:	7/7/10
Version Number:	1	Supersedes *(insert version number if applicable)*	N/A

PART A: Please provide the following general information:

School/Department			
Loughborough University/ Chemical Engineering			
Title of Project			
The Development of Encapsulated Probiotic Bacteria with Prebiotics Incorporated into Cereal Beverages.			
Project Reference Number:	N/A		
Person responsible for this work (*Principle Investigator*)			
Name:	Dr.A.G.F. Stapley	Position:	Senior lecturer
Department:	Chemical Engineering	University School:	Loughborough University
Person conducting this assessment			
Name:	MISS SUPAPORN PISPAN	Position:	Research Student
Department:	Chemical Engineering	Date Risk Assessment Undertaken:	1 July 20010
Proposed Project Start Date:	1 October 2007	Proposed Project End Date:	30 August 2010

Review History: *required at least once a year or immediately following any significant change to the project. Significant revisions must be detailed on a revision form. The person responsible must ensure that this RA remains valid.*

	Review 1	Review 2	Review 3	Review 4	Review 5
Due Date					
Date Conducted					

A1 PROJECT SUMMARY

A1.1 Scientific Goals of the Project.

This provides a useful background for the reviewer and reader. It need only be brief and should provide an overview of the scientific goals.

Probiotics are a very attractive product related to human gut health, for example, decreasing disease and inflammatory bowel disease as well as improving immune system. However, it is very important to deliver this product into human digestive system without losing their activity and maintain the sufficient number of viable and active cells. Therefore, the study of mixed materials and method to protect the probiotic bacteria from harsh conditions is very important and deserves great attention. This work aims to the develop an instant cereal beverage probiotic product in spray dried form which has objectives as followed:

- To develop the probiotic beverages by spray drying technique
- To investigate the viability of probiotic bacteria, *L. acidophilus*, after spray drying
- To investigate the viability of spray dried probiotic bacteria, *L. acidophilus*, after passing simulated gastric juice and bile solution
- To study the appropriate coating materials to protect probiotic bacteria, *L. acidophilus*, from heat, acid and bile stress

A1.2 Description of the Experimental Procedures

Describe laboratory procedures to be used and highlight any non-standard laboratory operations. This may need cross reference to supporting documentation i.e. protocols.

As part of a 3 year project – an experiment to study the population growth of *E. coli K12* and *L. acidophilus* and optimisation of encapsulated materials, as well as spray drying conditions, by comparison of cell viability after spray drying and after passing simulated gastric juice, will be carried out. Culture preparation and spray drying of liquid cultures will be finished in Chemical Engineering Department. Cell viability of spray dried cultures (*L. acidophilus*) measured by two techniques, plate count technique and flow cytometer technique, will be compared. For colony plate count, all work will be carried out in Chemical Engineering Department. For flow cytometer technique, spray dried samples will be transported to CBE Laboratory for use of the EPICS Altra cell flow cytometer, which will involve BA transportation and sample preparation according to the attached protocol and following Standard Operating Procedures.

All procedures will be conducted in accordance with the laboratory Quality Management System (QMS) requirements, Good Aseptic Technique, the local Code of Practice (COP) and the Loughborough University Biological Safety Policy.

PART B: Please provide information in one or more of the following sections, as appropriate. Only sections which you complete should be submitted:

Section 1: *micro-organisms (prions, viruses, bacteria, fungi, parasites in ACDP category 2 and pathogens controlled by the Department for the Environment, Food and Rural Affairs).* ***[Work with ACDP category 3 and 4 pathogens is not currently permitted in the University.]***

Section 2: *cell cultures, tissues, blood, body fluids or excreta*

Section 3: *plants and plant material*

Section 4: *animals and animal tissues*

SECTION 1: MICRO-ORGANISMS

B1.1 HAZARD AND RISK IDENTIFICATION: NATURE OF MICRO-ORGANISMS

*This information gives an indication of the **potential** harm that the biological material may cause*

B1.1.1 List all micro-organisms to be used

Name	Strain	ADCP cat*	Source
L. acidophilus	NCIMB 702470	1	NCIMB

see The Approved List of Biological Agents – available on the Health & Safety website

B1.1.2 Has any strain been genetically modified in any way?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If Yes, complete Genetically Modified Organisms (GMO) Risk Assessment Form	

B1.2 DESCRIPTION OF RISK TO HUMANS

B1.2.1 The disease(s) caused to humans

Describe the type and severity of effects or disease(s) on human health (including colonisation, infection, allergy, toxin-mediated disease) by each of the agents or strains to be used

Indicate in the adjacent box if Not Relevant (N/R)		N/R
Name	Type	Severity
L. acidophilus	Non pathogenic	N/R

B1.2.2 What is the likelihood of infection of this material? Indicate as None, Low Risk, Medium Risk, High Risk, Known Infected

Name of agent	Risk Category	Justification for Selection
L. acidophilus	None	General probiotic bacteria found in human which is generally recognised as safe (GRAS).(Non pathogenic)
		If none proceed to section B1.3

B1.2.3 Infectivity to humans

Describe ALL the route(s)of infection (relevant to the laboratory setting) and the minimum infectious dose(s) if known (e.g. percutaneous, mucocutaneous, inhalation, ingestion)

Name of agent(s)	**Route(s) of infection**	**Minimum infectious dose**
N/R	N/R	N/R

B1.2.4 Drug resistance

Is there any known or suspected drug resistance amongst the strains to be used? Identify & describe.

No

B1.2.5 Attenuation or increased virulence
Are the strains attenuated or do they have an increased virulence in any way?

Identify and describe: No

B1.2.6 Ability to survive
In what form is the agent present e.g. spores or vegetative bacteria, and are there any issues about the agents' robustness, including any resistance to chemical disinfectants?

Identify and describe: Non Motile, Non Sporulating GRAS bacteria. Sprayed dried (resuspended in PBS solution at CBE) and live bacteria (transportation was described in attached protocal). Either form of bacteria has no known issues with chemical disinfectants.

B1.2.7 Most hazardous procedure?
Identify and describe the most hazardous procedure(s) to be used.

Bacteria generally regarded as safe (GRAS), most hazardous procedure involves use of EPICS Altra Flow Cytometry which operates using a class 3b (operates as class 1) laser. Use of this equipment has been assessed on a separate CRAR risk assessment.

B1.3 HUMANS AT INCREASED RISK OF INFECTION

B1.3.1 Are there any pre-existing medical conditions that increase the risk associated with this agents listed in section 1.1 (including immunocompromised workers, pregnant workers, breast feeding mothers, diabetic workers)?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If yes, Occupational Health must be consulted:	

B1.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

B1.4.1 Give details of the volumes and concentrations of organisms to be used

Name & Strain	Volume	Concentration
L. acidophilus NCIMB 702470	~2 g. of powder form were diluted in PBS 10 ml	Ca.10^3-10^7 CFU/ml
L. acidophilus NCIMB 702470	~100 ml of broth culture	Ca.10^8-10^10 CFU/ml

B1.5 ENVIRONMENTAL CONSIDERATIONS:

B1.5.1 Are any of the agents capable of causing disease or other harm in animals, fish or plants?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No

If yes, describe briefly here (A separate risk assessment may be required if the agent to be used poses a significant risk to the environment):

B1.5.2 Will there be any other environmental risks?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If yes, describe briefly here (NOTE: A separate risk assessment may be required if the agent to be used poses a significant risk to the environment):	

B1.6 OTHER HAZARDS

B1.6.1 Are there any other hazards associated with this work? For example, hazardous chemicals, cryogenic gases ionising radiation.

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, identify these: Non cytotoxin chemicals used in the experiment are - bis-(1,3-dibutylbarbituric acid) trimethine oxonol ($DiBAC_4(3)$) (not hazardous) –COSHH (submitted for approval) - 3,3'-dihexyloxacarbocyanine iodide ($DiOC_6(3)$) (irritating to eyes, respiratory system and skin) –COSHH RA CBE/083 Propidium Iodide is a hazardous chemical (COSHH RA – CBE031) used in flow cytometry experiment.	
If yes, have these been risk assessed and any necessary approval obtained? Controlling of this chemical will provided in COP for work chemical carcinogens, mutagens and substances toxic to reproduction and cytotoxins. Procedure to manage waste from these chemical was provided in 'Storage, handling and disposal of waste chemicals and solvents (SOP039)'.	

PART C: CONTROL MEASURES

C1. CONTROL MEASURES

The risk of exposure must be prevented or adequately controlled to minimise the chance of harm arising. COSHH Regulations require minimum containment measures for laboratories handling organisms from the different ACDP hazard groups (http://www.hse.gov.uk/pubns/misc208.pdf)
The hazard group number typically indicates the level of containment (includes physical measures & working practices) that must be used for its handling).

C1.1 Preventing Exposure

C1.1.1 Substitution with a Safer Alternative

Is substitution with a safer alternative practical, by for example, replacement of a clinical strain or pathogen with one that is lab adapted? Provide reasons for your answer:

No.-Substitution is not necessary as *L. acidophilus* is generally recognised as safe (GRAS) (CLASS I organisms).

C1.1.2 Isolation/Segregation

(i) Is/Are the laboratory(s) to be used for this work to be shared with other workers not directly involved in this activity?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes

If yes, provide details:

The working room is shared with other different projects but all of them must be authorised before entering the CBE laboratory.

Access to the Containment Level 2 CBE Laboratory Unit is restricted to authorised laboratory workers with appropriate training in accordance with documented local Code of Practice (COP) and Quality Management System (QMS) requirements for Containment Level 2 work activities involving biological materials.

The laboratories are locked at all times outside of normal working hours to ensure safe storage of biological agents and unauthorised entry. Keys to the laboratories are only issued to authorised users. Access is also restricted to the building (swipe card) and CBE (key entrance) during normal working hours. Out of Hours/Lone working is logged and permitted subject to risk assessment.

No cleaning personnel are permitted in the CBE Laboratory Unit. Access by other Non-Laboratory or maintenance personnel is subject to risk assessment and Permit-to-Work system documented in the local COP.

(ii) Is access to the laboratory(s) to be used for this work restricted?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes

If yes, provide details:

Access is restricted to people with documented training (authorised access documented in each individual's training record) in accordance with the COP and QMS (see C1.1.2).

C1.2 Controlling Exposure

C1.2.1 Are sharps (needles, blades, scissors, forceps, glass or capillary tubes) to be used at any stage during this activity?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If yes, list the sharps: Glass bottle.	
If yes, justify there use – is there an alternative? Glass bottle is used for containing PBS solution that can resist high temperature when sterilising with autoclave.	
If yes, describe there use and disposal: Glass bottle used for containing of PBS solution. After used, all sample bottles will be sterilised using autoclave. Then sterilised bottles will be cleaned by washing machine in biological laboratory at Chemical Engineering Department.	
If yes, describe any additional precautions employed to reduce risk: Worker should pay more attention when carrying, holding or transporting of glass bottle during work. Place the bottle in rack or in carrying basket to prevent banging and drop down by accident when moving from place to place. In the event of a breakage the glass will be picked up using a forceps or other mechanical means and transferred to a sharps container. Once all glass has been dealt with the area will be cleaned using 1% virkon (max ten minute contact time) followed by 70% IMS. The sharps container will be sealed and immediately autoclaved before being disposed using the orange (autoclave) waste route (according to SOP038 & SOP044).	

C1.2.2 Containment and Ventilation

(i) Is the use of BSC required for the protection of the worker i.e. do the work procedures generate aerosols or splashes that pose a risk to workers?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, specify the type(s) and when they will be used: Biosaftey cabinet class II (located in Laboratory H23) will be used for preparation of liquid sample contained cultures that may produce aerosols or splashes of Hazard Group (HG) 1 and 2 Biological Agents (BAs). Procedures to be carried according to SOP009, "Use and Maintenance of HERASAFE KS Class II BSC". This engineering control measure is specifically to protect the worker (when handling HG2 BAs) and ensure protection of research materials as part of a quality assurance discipline (when handling both HG1 and 2 BAs). All manipulations of samples containing HG1 microbiological cultures will be carried out in the HERASAFE KS safety cabinet (CBE039) located in laboratory H23. Measuring of microbiological samples for viable count cell using Flow cytometry will be done following SOP081.	
(ii) Are there any requirements for room ventilation e.g. negative pressure, temperature control?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If yes, specify:	

C1.2.3 Transport and Storage within the laboratory

How and where are materials to be stored?

Bacteria culture will be prepared in Chemical Engineering Department and transferred to the CBE. Samples will not be stored in the CBE.

Dyes will be stored in the refrigerator at CBE. Label will be put on every bottle of dyes which specified date and responsible name. Controlling of dyes was described in SOP039. "Storage,handling and disposal of waste chemicals and solvents (SOP039)"

How will this material be transported within the laboratory e.g. between BSC and incubator? Detail the containment measures which will be used to prevent or contain accidental splashes or spills.

Bottles that contain a bacterial culture will be secured in racks or sealed bags which will be placed inside secondary containers with a lid to contain spills from leaking or broken vessels. These will be transported and handled according to the following SOPs:

1) SOP005, "Storage and transport of Biological Materials"
2) SOP038, "Biological spill response"

C1.2.4 Local transport out of the laboratory

How will this material be transported on-site (e.g. research material between labs on campus or movement of waste containing viable agents e.g. to a remote autoclave? Detail the containment measures which will be used to prevent or contain accidental splashes or spills

Transfer into and out of the CBE Laboratory Unit is constrained within the University site (see attached protocol). Material will be transferred from Chemical Engineering Dept to the CBE Autoclave Room (H31) where the containment package will be decontaminated before transporting to H23. All transport will be subject to controlled procedures according to the local COP and SOP005 (see below). For example, transfers will use double containment procedures as described in the attached protocol. Transport of research material between laboratories is done using sealed containers which are put into tube racks and trays and transported using trolleys according to the following SOPs. Waste potentially containing viable agents is not removed from the laboratories until it has been RENDERED SAFE

1) SOP003, "Disposal of Biological Waste"
2) SOP005, "Storage and Transport of Biological Material"
3) SOP038, "Biological Spill Response"

C1.2.5 Shipment of Biological Material

Will this material be shipped elsewhere in the UK or abroad?						
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)						No
If yes, give details to support compliance to the relevant regulation (e.g. category of material, correct packaging instruction):						
Description of material to be shipped (*indicate in available boxes*). Is this:						
Category A		UN2814		UN2900		*Packaging instruction 602 or 620 must be followed*
Or?						
Category B		UN3373				*Packaging instruction 650 must be followed*
Or?						
Non-hazardous						*Should be packaged to protect sample*

C1.2.6 Receipt of material

If material will be received from other sites or organisations, what precautions are being taken to ensure that the material is shipped correctly? *N/R*

C1.2.7 Centrifugation

(i) If material is to be centrifuged will sealed buckets and rotors be used?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
(ii) Where will these rotors/buckets be opened?	
(iii)Describe the procedures in place to deal with leaks and spillages in the centrifuge	

C1.2.8 Incubators

If incubators are to be used, what type of incubator (e.g. shaking, static) is used and describe procedures to prevent and contain spillages. The incubators will not be used in this experiment as all samples will be prepared in the Chemical engineering department and brought over to the CBE laboratory for measuring cell numbers by flow cytometry.

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used: The disinfectants were carefully chosen for effectiveness in use. The number of disinfectants in use is strictly limited to avoid errors and ambiguities in use and accidental mixing of compounds that may give rise to hazardous reactions or the formation of toxic products. Unless there are compelling reasons to do otherwise, Virkon (1% w/v) is the sole disinfectant used in the CBE Laboratory Unit other than 70% IMS which is used for general disinfection cleaning (SOP004) where Virkon cannot be used; for example stainless steel surfaces. Virkon has a wide range of bactericidal, virucidal, fungicidal and sporocidal activities. Representative viruses from all the major virus families are inactivated by Virkon. Working solutions of 1% w/v have low toxicity and no irritancy. Selection and procedures detailed in the following SOPs: 1) SOP004, "General Laboratory Housekeeping" 2) SOP006, "Selection and Use of Virkon Disinfectant" 3) SOP039, "Storage, Handling and Disposal of Chemicals" COSHH Risk Assessment reference for Virkon CBE/039.
Have these disinfectants been validated for use with the recipient biological material?
Indicate in the adjacent box as No, Yes or Not Relevant (N/R) — Yes
If yes, describe the procedure: For Hazard Group 1 and 2 Biological Agents it is normally sufficient to rely on the manufacturer's data, providing the recommended concentrations and contact times are used. Hence Virkon (1%) is used as per manufacturers instruction and according to standard procedures detailed in the following SOP: 1) SOP006, "Selection and Use of Virkon Disinfectant" Further supporting evidence is provided in the following reference: Walker, A.J. et al. Letters in applied microbiology 15 (2): pg 80 (1992)

C1.2.10 Personal Protective Equipment (PPE)

(i) What type of lab coats will be worn and where will they be stored? Side fastening Howie type lab coats are worn at all times within the CBE Laboratory Unit. They are stored outside the laboratory where the work will take place. Proper use of PPE is described in the following SOP: SOP037, "Use of Personal Protective Equipment (PPE)"
(ii) What type of gloves will be worn and where will they be stored? 1. Autoclave gloves - stored in close proximity to the autoclave equipment in the Autoclave Room (H31) 2. Latex powder free gloves for general use - stored in the change rooms and/or point of entry to each laboratory within the CBE Laboratory Unit. Correct use of PPE is described in SOP037, "Use of Personal Protective Equipment (PPE)"
(iii) Describe any other PPE to be used: Laboratory safety glasses (including those for spectacle wearers) Correct use of the above PPE is described in SOP037, "Use of Personal Protective Equipment (PPE)"

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located Designated hand washing facilities are located in each laboratory change room and in the Analytical Laboratory (H23). 2. Eye Wash stations are located next to each 'hand washing only' sink in each laboratory change room and in the Analytical Laboratory (H23).

C1.2.12 Vaccination

Are effective vaccines available against any of the agents listed in Section1, 2, 3, or 4 of Part B?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, describe:	

C1.2.13 Waste Treatment before Disposal

How must waste to be treated before disposal and how has it been validated as being effective?		
Type of Waste	Treatment before disposal	Validation of this treatment

Liquid waste	Virkon sterilise (SOP003 – Disposal of biological waste) or Autoclave sterilise. Liquid waste contaminated with cytotoxic agents will be collected in the safety labelled container and disposed as hazardous waste through the university waste system (SOP039) in accordance with the relevant COSHH and the COP for work chemical carcinogens, mutagens and substances toxic to reproduction and cytotoxins.	According to manufacturers instructions; see section C2.1.9 or Treatment Cycle validated according to SOP024 & 025, " Use and maintenance of the Systec VX95 Autoclave No CBE44 and CBE 45" N/A
Solid waste	Autoclave sterilise (SOP003 – disposal and disinfection of biological waste).	Treatment Cycle validated according to SOP024 & 025, " Use and maintenance of the Systec VX95 Autoclave No CBE44 and CBE 45"

C1.2.14 Autoclave sterilisation

If waste is treated by autoclave sterilisation then this section must be completed. If this section is not relevant then hatch the box

Type of Waste	Composition of waste	Autoclave cycle (temp, cycle time)	Treatment monitor
Liquid waste	-Cultured broth -Non toxic Dyes	121°C for 20 min sterilisation time 121°C for 20 min sterilisation time	Temperature probe inside the chamber. Designed autoclave tape monitors.
Solid waste	None	121°C for 15 min sterilisation time	Temperature probe inside the chamber. Designed autoclave tape monitors.

Location of autoclave	Servicing details	Location of back-up autoclave	Designated area for storage of unsterilised waste
Autoclave Room H31	Annual	H31 and H22	In secure cage within the Autoclave Room (H31)

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?
To the drain? Small amount of liquid waste will be disposed of to the drain, but will be autoclaved or chemically disinfected by validated means before disposal to drain according to SOP003.
As solid waste? None

Other? None

C1.2.16 Solid Waste Disposal

Describe the waste category and disposal route. *(For guidance refer* to http://www.environment-agency.gov.uk)

Colour Code	Categorisation	*Hatch relevant box(es)*	Disposal Method
Yellow	Sharps (not contaminated with cytotoxic/cytostatic material)	-	Yellow Sharps bin>autoclave sterilisation if known or potentially infected >clinical waste disposal (incineration)
Purple/Yellow Special case, contact DSO	Sharps (contaminated with cytotoxic/cytostatic material)	-	Purple/Yellow lidded Sharps bin>clinical waste disposal (incineration @ 1000C)
Yellow	Human body parts, organs, including blood bags and blood preserves and excreta (unless identified as medium or high risk or known infected in Section 2.2.1 of this RA in which case they must be pre-treated before disposal)	-	Yellow rigid one way sealed tissue bins>clinical waste disposal (incineration)
Yellow	Animal body carcasses or recognisable parts ((unless identified as medium or high risk or known infected in Section 2.2.1 of this RA in which case they must be pre-treated before disposal	-	Yellow rigid one way sealed tissue bins > clinical waste disposal (incineration)
Special Case – Contact DSO	Potentially or known infected lab wastes (including sharps) of HG2, GM Class 2, DEFRA Cat 2 or higher, that have not been pre-treated before leaving the site.	-	This is not a route of preference and is subject to special requirements
Orange	Infected or potentially infected lab wastes that have been pre treated before leaving the site	-	Disinfection or sterilisation (as identified in C1.2.14) in the laboratory suite > orange clinical waste bags > clinical waste disposal (incineration)
Yellow	Infected or potentially infected animal or human body parts, organs or excreta that have been pre treated before leaving site	-	Disinfection or sterilisation (as identified in C1.2.14) in the laboratory suite > yellow one way sealed tissue bins > clinical waste disposal (incineration)

C1.2.17 Work with Animals or Vectors (if none proceed to Section C1.2.18)

(i) Are animals or vectors to be infected with any of these biological agents?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If yes, describe the procedure and describe where this aspect of the work will be conducted:	
(ii) Is shedding of infectious materials by the infected animals possible or expected?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R

If yes, describe the routes of shedding, risk periods for such shedding and the additional precautions required to control exposure:
(iii) Who will perform the inoculations of animals/vectors? What training have they received?
Indicate in the adjacent box if Not Relevant (N/R) — N/R
Provide details of the training required:

C1.2.18 Bioreactor/Fermenters (if none proceed to Section C1.2.19)

Will a fermenter be used to culture a pathogen?
Indicate in the adjacent box as No, Yes or Not Relevant (N/R) — No
If yes, describe the size, and type of the fermenter.
(ii) Are any supplementary containment measures required, for example, the use of a BSC or spill tray.
Indicate in the adjacent box as No, Yes or Not Relevant (N/R) — N/R
If yes, describe:

C1.2.19 Other Control Measures Required?

None

C1.3 Emergency Procedures

C1.3.1 Describe the procedures in place for dealing with spillages *(specify disinfectants and any special containment for large volumes)*

Within the BSC: Procedures for dealing with small and large spillages are detailed in the following SOPs: 1) SOP006, "Selection and use of Virkon Disinfectant" 2) SOP009, "Use and Maintenance of HERASAFE KS Class II BSC" 3) SOP038, "Biological Spill Response" 4) SOP039, Storage, Handling and Disposal of Chemicals Labelled Biological Spill kits are located in each laboratory change room within the CBE Laboratory Unit. The nearest biological spill kit for use in **H23** is located in **H24 and chemical spill kit located in H30**. Signs are posted throughout the Laboratory Unit to enable workers to locate the nearest biological (and chemical) spill kits. Posters are also displayed in each laboratory within the Unit where a BSC is located to advise on spill response (inside the BSC) and reporting procedures.
Within the laboratory but outside the control measure e.g. BSC, spill tray Procedures for dealing with small and large spillages are detailed in the following SOPs: 1) SOP006, "Selection and use of Virkon Disinfectant" 2) SOP038, "Biological Spill Response" 3) SOP039, Storage, Handling and Disposal of Chemicals

Labelled Biological Spill kits are located in each laboratory change room within the CBE Laboratory Unit. The nearest biological spill kit for use in H23 is located in H24 and chemical spill kit located in H30. Signs are posted throughout the Laboratory Unit to enable workers to locate the nearest biological (and chemical) spill kits. Posters are also displayed in each laboratory within the Unit to advise on spill response (outside the BSC) and reporting procedures.

Outside the laboratory e.g. during transport

Procedures for dealing with small and large spillages are detailed in the COP and the following SOPs:

1) SOP005, "Storage and Transport of Biological Material"
2) SOP006, "Selection and use of Virkon Disinfectant"
3) SOP038, "Biological Spill Response

Describe the procedures in place for an accidental exposure (if necessary describe different procedures for different types of exposure e.g. eye splash or percutaneous inoculation)

1. Procedures to respond to accidental exposure are detailed in SOP038, "Biological Spill Response" and the local COP. These are detailed in spill response posters located in each laboratory within the Unit. Accident procedures in the case of glass or sharps injury are described in the local COP and displayed in posters located in each laboratory within the Unit
2. Designated hand washing facilities are located in each laboratory change room and in the Analytical Laboratory (H23). Signs are posted in H23 to enable workers to locate the nearest hand wash facility.
3. Eye Wash stations are located next to each 'hand washing only' sink in each laboratory change room and in the Analytical Laboratory (H23).
4. 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 each laboratory within the Unit

Essential and Emergency Contact details are posted in each laboratory within the unit.

C2 ASSIGNMENT OF CONTAINMENT LEVEL

The laboratory Containment Level is directly related to each of the 4 Hazard Groups; organisms categorised as HG1 (lowest hazard rating) should normally be handled in CL1 facilities (minimum level of containment), and likewise up to HG4 (highest hazard rating) in CL4 facilities (maximum level of containment). Where the identity or presence of a biological agent is not known the following rules apply: a) where uncertainty exists over the presence of pathogenic biological agent – minimum of CL2; b) where the presence of a pathogenic biological agent is known or suspected – minimum of Containment Level appropriate to the agent, where the assessment is inconclusive but where the activity might involve serious risk – minimum CL3

C2.1. What containment level is required for this work? (see COSHH Schedule 3, Part II for a list of criteria)

All procedures will be carried out under Containment level 2 (CL2) within the CL2 CBE Laboratory Unit. The work activities within this project involve biological agents (BAs) assessed as Hazard Group 1. Work, involving the use of Hazard Group 1 BAs that require Containment Level 1 are carried out at Containment Level 2 for reasons other than worker protection; this includes the need to ensure research material protection (e.g. the use of a class II safety cabinet) and to impose a quality assurance discipline.

C2.2. Describe extra controls or derogation from certain controls
:

None

C3 FACILITIES

C3.1 Where will this work take place?

Room(s)	Building	Campus	Person in Control of area
CBE Laboratory Unit; Rooms H23	Centre for Biological Engineering	Holywell Park campus	Professor Chris Hewitt Carolyn Kavanagh Bob Temple

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
PISPAN	S	A718317	Research student
Brosnan	KB	5013811	Cell Culture Technician

C4.2 Information, Instruction and Training

Describe the training that will be given to all those affected (directly or indirectly) by the work activity. Instruction should include the 'Local Rules' or 'Local Codes of Practice' which focus on the working instructions to be followed by all persons involved in the work activity to control or prevent exposure to hazardous biological agent(s). These should be written and readily available to all workers working at Containment Level 2. A formal record of training should be kept for all individuals working at Containment Level 2.

Formal records of training are kept for all workers authorised to work at Containment Level 2 (CL2) within the CBE CL2 Laboratory Unit. Instruction against local Code of Practice and QMS i.e. SOPs is provided to all authorised personnel.

Work in the CBE will be carried out under full supervision with authorised and competent person.

Practical waste management training will be provided to ensure operator is aware of approved waste disposal protocols for biological, chemical and cytotoxic waste.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Pispan	Documented in Personal Training File available for review in CBE Office (Training of disposal of waste, using safety cabinet (HERASAFE KS Class II BSC) and autoclave (Systec VX-95 Autoclave CBE044) have been completed on October, 2009) B.Sc and M.Eng projects related to microorganisms.
Brosnan	Documented in Personal Training File available for review in CBE Office

C4.4 Other people who may be at risk from the activity e.g. cleaners, maintenance workers or other workers in shared laboratory

Details:

Cleaners and Maintenance workers are not authorised to enter the laboratory. All laboratory cleaning is undertaken by authorised personnel (i.e. CBE staff). Access for non-laboratory workers is subject to local permit-to-work procedures. If access is needed for essential maintenance of equipment for example a clean down and decontamination of the laboratories will be performed. This will be documented with decontamination certificates and the maintenance worker fully supervised according to SOP004; "General Laboratory Housekeeping" and the local Code of Practice. Two laboratory shut downs occur every year for a week for maintenance work to be done in the CBE Laboratory Unit. Prior to these shut down weeks a full deep clean decontamination will be performed in the all laboratory areas.

C5 OCCUPATIONAL HEALTH

C5.1 Vaccination

Is an effective vaccination available for any of the pathogens associated with this work? Advice can be obtained from the Occupational Health Adviser (OHA) if required. All workers involved with handling unscreened blood, blood products and other tissues are recommended to have Hepatitis B immunization

No. It is not required for deliberate use of HG1 non-human microrganism.

C5.2 Health Surveillance

Is health surveillance required? (Health surveillance is typically applied if working with a hazardous substance that: a) produces an identifiable disease or adverse health effect that can be related to exposure; b) there is a reasonable likelihood that the disease or effect may occur under the conditions of work, and c) there are valid techniques for detecting indications of the disease or effect).

No.

C6. NOTIFICATIONS: Human Tissue Act

C6.1.1 Relevant material covered by the Human Tissue Act

Are any of the cells, tissues or fluids to be used covered by the Human Tissue Act? Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R

C6.1.2 Does This Work Have Ethical Approval? If Yes, Provide Details

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)			N/R
Approval number:			
Date obtained:		Ethics committee name:	

C6.1.3 Are other registrations/notifications required for this work? For example HSE notification under COSHH, Home Office notification under anti-terrorism, crime and security act etc

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If Yes, give details:	

7. LICENSING REQUIREMENTS FOR ANIMAL PRODUCTS

C7.1.1 Are there any licensing requirements for this work?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R

The regulations covering the import of animal products (including tissue cultures, tissues, body fluids or fractions thereof) are in a state of flux. Current procedures to be followed:

- If you wish to import any animal products that you know are not infected with an animal pathogen, or have good reason to expect that they are not infected with an animal pathogen, from within or outside of the EC you must apply for a Research Sample Licence using the Defra form IAPPO1. Follow this link to download the form http://www.defra.gov.uk/corporate/docs/forms/ahealth/iapppo1.htm

- If you wish to import such an animal product but it is known or suspected of being infected with an animal pathogen then you must use DEFRA form IM137. Follow this link to download the form http://www.defra.gov.uk/corporate/docs/forms/ahealth/inttrade/im137.htm

- If you wish to import an animal pathogen listed under the Specified Animal Pathogens Order then you must use DEFRA form PATH1. Follow this link to download the form http://www.defra.gov.uk/corporate/docs/forms/ahealth/path1.htm

In all cases the instructions for their submission is stated on the forms themselves.

ALL APPLICATIONS SHOULD BE REVIEWED BY THE DEPARTMENTAL SAFETY OFFICER AND THE UNIVERSITY BIOLOGICAL SAFETY OFFICER BEFORE SUBMISSION.

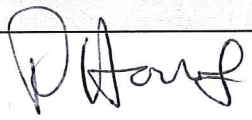
8. DECLARATION

*The declaration must be signed **before** submitting this assessment to the Departmental Safety Officer and University Biological Safety Officer*

I, the undersigned:

- confirm that all information contained in this assessment is correct and up to date
- will ensure that **suitable and sufficient instruction, information and supervision** is provided for all individuals working on the activity
- will ensure that no work will be carried out until this **assessment has been completed and approved** and that all necessary control measures are in place
- that all information contained in this assessment must remain correct and up to date (the assessment should be **reviewed once a year** and whenever any **significant changes** to the work activity occur)
- will re-submit the assessment for approval if any significant changes occur

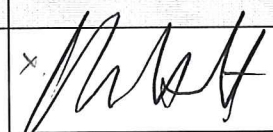
Name: Person conducting assessment	**Signature:**	**Date:**
Supaporn Pispan	S. Pispan	29/6/10
Name(s): All named persons involved in the project *(add additional rows below, as required)*	**Signatures(s):**	**Date:**
Name: Principal Investigator/Supervisor	**Signature:**	**Date:**
Dr. A.G.F. Stapley		29/6/10

Name: Other signature (s) (if required – please state position e.g. *Quality Manager*)	**Signature:**	**Date:**
P.Hourd (CBE QM)		01/07/10.

9.APPROVAL

For work involving **Hazard Group 1** biological agents approval will usually be required by the Departmental Safety Officer before the work begins

For work with **Hazard Group 2** biological agents, explicit approval is required from the Departmental Safety Officer and the University Biological Safety Officer. Approval may be provided by email

Name: Departmental Biological Safety Advisor	**Signature**	**Date**
Professor C.J. Hewitt		7/7/10
Name: University Biological Safety Officer	**Signature**	**Date**
N/A		

Bacterial Treatment Protocol

1. Spray dried *L. acidophilus* will be used in this experiment which is classed as hazard group 1 (non-pathogenic).
2. Broth culture of *L. acidophilus*, approximately 10^8-10^10 CFU/ml, were stored in sterilised plastic bottles. Bottles will be placed in racks to keep them upright and stop it banging together to prevent broken. Similarly, plastic bottles containing approximately 2 g of spray dried micro organisms will be placed in racks to keep them upright and stop the bottles banging together. These racks of bottle will be placed inside leak proof cooler box.
3. PBS solution stored in the sterilised bottle prepared from biological laboratory at Chemical Engineering will be placed in leak proof plastic box.
4. These sample boxes, PBS and culture, will be transported over to the CBE lab inside a secondary leak proof cooler box.
5. When the samples reach the CBE lab, PBS and the universal bottles containing broth culture and dried culture will be taken out from the cooler box in the autoclave room (H31) and sprayed down with 70% IMS. These bottles will be placed in a suitable sealable container and then transferred to room H23.
6. Dried culture will be re-suspended with PBS and all samples will be prepared in Biosafety cabinet class II for cell analysis using Flow cytometry refer to SOP009 for using the safety cabinet correctly. Since the micro organisms used for this work are hazard group 1, this work could ideally be conducted on an open bench top. The use of the safety cabinet is to add better protection to the samples being treated so not to contaminate them.
7. All samples will be removed from the class II safety cabinet after use and sprayed down with 70% IMS and the cabinet is cleaned down in accordance with SOP009.
8. Universal bottles containing the resuspended bacteria are then placed in racks which are then placed inside a suitable container which has been cleaned with 70% IMS for transporting the bottles back to the change room.
9. The container with the bottle contained PBS and universal bottles in the rack is placed into the cooler box for transportation back to the Chemical Engineering building for determination of moisture content.

10. All biological wastes e.g. eppendorf tube, blue tube, membrane filter and liquid culture (after use with Flow cytometry), will be put in autoclave basket and transport to the autoclave room to sterilise.