UCC Coláiste na hOllscoile Corcaigh, Éire University College Cork, Ireland

UCC Biosafety

Seventh Schedule

PART II

PRINCIPLES TO BE FOLLOWED FOR THE (RISK) ASSESSMENT REFERRED TO IN ARTICLE 36.

THIS PART OF THE SCHEDULE DESCRIBES IN GENERAL TERMS THE ELEMENTS TO BE CONSIDERED AND THE PROCEDURE TO BE FOLLOWED FOR THE PURPOSES OF PERFORMING THE ASSESSMENT REFERRED TO IN ARTICLE 36

A ELEMENTS OF ASSESSMENT

1 The following shall be considered as potentially harmful effects:

- disease to humans, including allergenic or toxic effects,
- acting as a human disease vector or reservoir,
- adverse effects to humans arising from change in behaviour or in physical nature,
- adverse effects arising from the inability to treat human disease or offer effective prophylaxis.

2 The assessment referred to in Article 36 shall be based on the following –

(a) Identification of any potentially harmful effects in particular those associated with:	
i) the recipient organism:	The recipient is a commonly used inbred strain of laboratory mouse. Potentially harmful effects: Low risk of allergenic effects to staff working with laboratory mice. The use of appropriate protective clothing and equipment can effectively eliminate this risk. Minimal risk of harmful effects due to aggressive behaviour in mice. Proper training of staff can effectively eliminate this risk. Minimal risk of mice acting as human disease vector or

	reservoir. No risk of harmful effects due to inability to treat human disease or offer effective prophylaxis
ii) the genetic material inserted (originating from the donor organism):	The genetic materials inserted are as follows: • The mouse nestin gene. • A neomycin resistance gene of bacterial origin. • A gene coding for the P1 bacteriophage enzyme cre-recombinase. • A promoter region from the human cytomegalovirus. • LoxP sequences from the P1 bacteriophage. Potentially harmful effects: No risk of harmful effects are associated with these materials. These materials have been widely used in biological research without any adverse consequences.
iii) the vector:	No vector is used to introduce the genetic material. Potentially harmful effects: None
iv) the donor organism (as long as the donor organism is used during the activity):	The donor organisms are as follows: • mouse • P1 bacteriophage • human cytomegalovirus • Bacterial Transposon Tn5 Only highly purified DNA fragments from these organisms are used. This is obtained from commercial sources or from collaborating laboratories. Thus the donor organism itself is not used. Potentially harmful effects: None
v) the resulting GMO:	The material introduced is stably maintained in the genome of genetically modified organism. The products of the genes that are introduced are non-toxic and non-infectious.
(b) Characteristics of the activity:	The genetically modified mice will be genotyped by taking tail biopsies. They will be treated with the drug tamoxifen (8mg per dose) by oral gavage. The mice will be killed under anaesthesia and tissues examined by histological methods.

(c) Severity of the potentially harmful effects:	Allergies associated with working with laboratory mice Severity Mild – moderate Harmful effects due to aggressive behaviour in mice. Severity Mild Risk of mice acting as human disease vector or reservoir. Severity Mild
(d) Likelihood of potentially harmful effects being realised:	Allergies associated with working with laboratory mice Low Likelihood of being realised Harmful effects due to aggressive behaviour in mice. Low Likelihood of being realised Risk of mice acting as human disease vector or reservoir. Minimal Likelihood of being realised

B PROCEDURE – STAGES OF ASSESSMENT

(1) First Stage -	
(a) Identification of the harmful properties of the recipient and, where appropriate, the donor organism	The level of risk associated with the genetically modified organism is identified as being low – level 1 This assessment is based on the following considerations: • The recipient and donor organisms are unlikely to cause disease or harmful effects.
(b) Identification of any harmful properties associated with the vector or inserted material, including any alteration in the existing properties of the recipient.	The level of risk associated with the vector, inserted material and alterations to the recipient genetically modified organism is identified as being low – level 1 This assessment is based on the following considerations: • The recipient and donor organisms are unlikely to cause disease or harmful effects. • The introduced genetic material do not endow the genetically modified organism with a phenotype likely to cause disease, or likely to cause adverse effects in the environment • The genetically modified organism is unlikely to cause disease to humans, animals or plants and is unlikely to have adverse effects on the environment. • The risks associated with the genetically modified organism are no greater than for the unmodified recipient organism. • These risks are of low to moderate severity and are

	unlikely to occur provided suitable precautions are taken

(2) Second Stage -	
(a) Identification of the level of risk associated with the genetically modified organism.	The level of risk associated with the vector genetically modified organism is identified as being low – level 1 This assessment is based on the following considerations: • The recipient and donor organisms are unlikely to cause disease or harmful effects. • The introduced genetic material do not endow the genetically modified organism with a phenotype likely to cause disease, or likely to cause adverse effects in the environment • The genetically modified organism is unlikely to cause disease to humans, animals or plants and is unlikely to have adverse effects on the environment. • The risks associated with the genetically modified organism are no greater than for the unmodified recipient organism. • These risks are of low to moderate severity and are unlikely to occur provided suitable precautions are taken

(3) Third Stage - Selection of containment and other protective measures on the basis of (a) (b) (c) below.	
(a) The level of risk associated with the genetically modified organism	Containment and protective measures Protective clothing: Shoe covers, disposable overalls, hair net, disposable gloves, face mask. Wash hands and disinfect footwear upon entering and leaving animal facility. Secure housing of animals to prevent their escape from animal facility Disposal of genetically modified animals and animal waste according to established protocols in use from animal facility. Maintenance of high standards of animal health and hygiene in animal facility. Carcasses are disposed of by incineration. The vendor who is contracted to dispose of carcasses is Healthcare Waste Management Services, an agent of Ecosafe Ltd who are authorised to dispose og GM waste.
(b) The characteristics of the environment likely to be exposed, and	same as (a) above
(c) The characteristics of the activity	same as (a) above

(4) Fourth Stage -	
Review and reconsideration of the overall assessment, having regard to the outcome of each of the first three stages	Stages 1 The risks associated with the genetically modified mice are no greater than for the unmodified mice. The risks are of low to moderate severity. Stages 2 The overall level of risk associated with the genetically modified organism is low. Stage 3 The risks are unlikely to occur provided the precautions outlined here are taken