LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de l'Agriculture, de la Viticulture
et du Développement rural

Administration luxembourgeoise vétérinaire
et alimentaire

Form_Am_Pr_Au_Edition Mai 2023

Application for an Amendment to a Project authorisation of animal experimentation under the grand-ducal regulation of the 11 January 2013 for the protection of animals used for scientific purposes

Legal basis:

Règlement grand-ducal du 11 janvier 2013 relatif à la protection des animaux utilisés à des fins scientifiques

Loi du 27 juin 2018 sur la protection des animaux

Internal number (to be fulfilled by the Ministry of Agriculture, Viticulture and Rural Development):

Please complete the form and send it back to Ministry of Agriculture, Viticulture and Rural Development together with the following documents:

- Certificates of the new personal (applicable for Section C1,C,2,C3)
- Approved project protocol with the proposed amendments highlighted in yellow or added as tracked changes (applicable for Section C4)
- Other: Click or tap here to enter text.

SECTION A: DETAILS OF THE PROJECT

PROJECT TITLE (≤ 500 characters)	
Acronym	
Number of submitted amendment	
NTS identifier	
Authorisation Number	
Date of authorisation	
Name of project leader	
E-mail	
Telephone	
Establishment name	
Address	

SECTION B: PROPOSED AMENDMENT

PROPOSED AMENDMENT

Tick all that apply and enter details in relevant section C (1-7) below:

☐ 1. Amendment to project leader (complete Section C1)
☐ 2. Amendment to or addition of deputy project leader(s) (complete Section C2)
☐ 3. Addition of new individual(s) who will be performing procedures (complete Section C3)
☐ 4. Amendments to existing experiment (complete Section C4)
☐ 5. Addition of new experiment(s) (complete Section C5)
☐ 6. Amendments to Species/Strains (complete Section C6)
☐ 7. Increase in the total animal numbers (complete Section C7)

Will the predicted severity change?
☐ Yes ☐ No
If yes, please indicate the new predicted severity :
☐ non-recovery,
☐ mild,
☐ moderate or
☐ severe

SECTION C: PROPOSED AMENDMENT DETAILS

C1: AMENDMENT TO PROJECT LEADER		
Title		
First name		
Surname		
Name of the Research Unit		
Address		
E-mail		
Telephone		
Education		
Education and training in laboratory animals		
Function B règlement gd. 11.01.2013 Art. 22§2b	☐ Yes	☐ No

C2: AMENDMENT TO OR ADDITION OF DEPUTY PROJECT LEADER(S) *For multiple deputy project leaders, select the entire table and copy and paste as required.*	
Title	
First name	
Surname	
Name of the Research Unit	
Address	
E-mail	
Telephone	
Education	
Education and training in laboratory animals	

Function B règlement gd. 11.01.2013 Art. 22§2b	☐ Yes	☐ No

C3. ADDITION OF NEW INDIVIDUALS WHO WILL BE PERFORMING PROCEDURES

Detailed list of the people involved in the project who perform any of the following functions:
A - Carrying out procedures on animals;
B - Designing procedures and projects;
C- Taking care of animals; or
D - Killing animals.

Title, FIRST NAME, SURNAME	Higher Education/ professional diploma	Education and training in laboratory animals, Function A,B,C,D	Details of the procedures to perform/ Treatments
		☐A, ☐B, ☐C, ☐D	
		☐A, ☐B, ☐C, ☐D	
		☐A, ☐B, ☐C, ☐D	
		☐A, ☐B, ☐C, ☐D	
		☐A, ☐B, ☐C, ☐D	

SECTION C4: AMENDMENTS TO EXISTING EXPERIMENT(S)

For amendments to more than one existing experiment, select this entire table and copy and paste it for each experiment as required. In addition, please append the currently approved project protocol with the proposed amendments highlighted in yellow or added as tracked changes. The specific details for each amended experiment must be provided in the updated project protocol.

Approved experiment number to be amended *(applicable for all projects submitted under the new form xxx):*	
Title of experiment :	
Description of amendment:	

Are animal numbers for this experiment changing (increasing or decreasing)?	
Number of animals currently approved:	
Amended number of animals requested:	
Provide detailed justification why it is necessary to amend this experiment. Explain how the experiment can answer the scientific question and whether this amendment has an impact on the scientific question.	
Provide details about any potential change(s) to the adverse effects and attrition rate. If new adverse effects are expected, detail the likely incidence and the % of animals these are expected to be seen in.	
Explain how animals will be monitored for the onset or development of adverse effects (when, frequency of controls, recorded parameters, and responsible persons). Describe any additional procedure-specific humane endpoints, or changes to the original humane endpoints, relating these directly to the adverse effects.	
Has the predicted severity of this experiment changed as a result of this amendment? If yes, provide details of the new predicted severity (non-recovery, mild, moderate or severe).	
Provide details of any additional refinements, including the introduction of anesthesia/analgesia, which will be put in place to minimize any harm to the animals.	
Note 1: If this amendment also involves a change to species/strains, please complete Section C6 of this form. **Note 2: If total animal numbers have increased as a result of this amendment please complete Section C7 of this form.** **Note 3: Please ensure to complete Section D of this form.**	

SECTION C5: ADDITION OF NEW EXPERIMENTS

To add multiple new experiments, select this entire table and copy and paste as many times as required. In addition, please append the currently approved project protocol with the proposed amendments highlighted in yellow or added as tracked changes. The specific details for each new experiment must be provided in the updated project protocol.

New experiment number:	**Name of new experiment:**	
Description/details of the experiment		
Justification/relevance of experiment. Justify why it is necessary to add this new experience and explain how this experiment will contribute to the benefits of the project.		
Species		
Life stage or age		
Number of animals to be used		
Will this new experiment increase total number of animals required for this project?		
Frequency of procedure (how many times will the procedure be performed?)		
Duration of experiment (how long will the experiment take/how long will the animal be affected for?)		
Proposed severity classification of the experiment	☐ Non-recovery ☐ Mild	☐ Moderate ☐ Severe
List all the potential expected adverse effects of the experiment. Include the estimated % of animals that may experience each effect listed.		
If there is an expected attrition rate, give the estimated % of animals and describe the potential reasons (e.g. reaching humane endpoints, anesthetic deaths, failure of animal model, other).		

Relating directly to the adverse effects, list all procedure-specific humane endpoints and give detail about the animal welfare monitoring arrangements.
Details of anesthesia (if not being used, provide justification)
Details of analgesia (if not being used, provide justification)
Other than analgesia and anesthesia, list all other refinements that will be applied to this experiment (refinement is a legal requirement).
What is the fate of the animals at the end of the experiment?
☐ Kept alive at the establishment ☐ Setting free to the wild or by rehoming ☐ Euthanasia

If the fate is euthanasia, what is the method?	
If this method is not an approved Annex IV euthanasia method (see Directive 2010/63/EU), provide justification:	

Note 1: If the new experiment require a new species/strain, please complete Section C6 of this form.
Note 2: Please complete Sections C7 and D of this form.

SECTION C6: AMENDMENT TO SPECIES/STRAINS

If the amendment includes the addition of a new animal species/genetic strain, please complete the table below. The table can be copied and pasted to add multiple species/genetic strains.

New species or strain	
Number of animals to be used	
Justification for this new species/strain	
Genetic status	☐ Not genetically altered ☐ Genetically altered without a harmful phenotype ☐ Genetically altered with a harmful phenotype ☐ Animals used for the creation of a new genetically altered line/strain
Details of genetic alteration (if relevant)	
Details of any refinements necessary to appropriately manage new strains with a harmful phenotype	
Name of supplier establishment (where animals originate from)	
Have any of these animals been previously used in a project (i.e. will this be a 'reuse' of these animals)?	☐ Yes ☐ No
- If yes, describe the cumulative effect of the procedures on the animal(s).	
- If yes, has the animal's general state of health and well-being been fully restored?	
- If yes, is the reuse in accordance with veterinary advice, taking into account the life-time experience of each animal?	
Note: If total animal numbers have increased as a result of this amendment(s), complete Sections C7 and D of this form.	

SECTION C7: INCREASE IN TOTAL ANIMAL NUMBERS *(if applicable)*

If the amendment involves an increase in animal numbers, please complete the fields below.

Total number of animals currently authorised for use (if multiple species, provide a breakdown of numbers per species)	
Amended total number of animals proposed (if multiple species, provide a breakdown per species)	

SECTION D: THE 3Rs

This Section must be completed in full in all instances where experiments have been amended or added and when additional animals are required.

D1: REPLACEMENT
If new experiments or animal models have been added, justify why live animals are required instead of using alternative (non-animal) methods.
D2: REDUCTION
If additional animals are required, or the experimental design has changed, provide justification for this, including statistical calculations (as an appendix) if appropriate.
Has any increase in animal numbers been approved by a biostatistician? If yes, provide details of their level of involvement.
D3: REFINEMENT
Provide details about any changes to: (i) monitoring/scoring arrangements (including in relation to scoresheets) and the application of humane endpoints to ensure the welfare of the animals
(ii) the care and accommodation provided, e.g. housing, environmental enrichment, diet

SECTION E: DECLARATION AND UNDERTAKING

The declarations and undertakings below are to be completed by:

- *the project leader for the project, and who is responsible for the overall implementation of the project and its compliance with the project authorisation; and*
- *the person responsible for ensuring compliance with the provision of the grand-ducal regulation of the 11 January 2013 for the protection of animals used for scientific purposes of the user establishment and where relevant any collaborating user establishment (pursuant to Article 19§2 of the grand-ducal regulation of the 11 January 2013 for the protection of animals used for scientific purposes) .*

Data protection notice

Personal data collected through this form is subject to a processing by the *Administration des services vétérinaires* to manage your request for accreditation, in accordance with the Article 19 of the *Règlement grand-ducal du 11 janvier 2013 relatif à la protection des animaux utilisés à des fins scientifiques*.

Personal data is retained by the *Administration luxembourgeoise vétérinaire et alimentaire* for the time necessary to achieve the purpose of the processing.

Under the conditions set by Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, you have the right to access, rectify, and erase your personal data. You also have the right to request for the restriction of the processing of your personal data, to object to this processing as well as, to withdraw consent in cases where the *Administration luxembourgeoise vétérinaire et alimentaire* has sought such consent for the processing. The legality of the processing based on the consent granted before withdrawal will not be affected.

If you wish to exercise these rights and / or obtain communication of your information, please contact the *Administration luxembourgeoise vétérinaire et alimentaire*, or the Data protection Officer (dpo@ma.etat.lu). For additional information, please consult the website: https://agriculture.public.lu/de/support/aspects-legaux.htm

If the response received has not been entirely satisfactory, you may also lodge a complaint with the *Commission Nationale pour la Protection des Données*, 1 Avenue du Rock'n'Roll, L-4361 Esch-sur-Alzette.

E1: PROJECT LEADER (USER)

The declaration and undertaking below should be signed by or on behalf of the user (i.e. the user or the project leader (designated pursuant to article 23§2 and article 39§2b) of the grand-ducal regulation of the 11 January 2013 for the protection of animals used for scientific purposes) on behalf of the user).

I hereby **declare** that I will be responsible for the overall implementation of the project and its compliance with the project authorisation and shall ensure that:

- Any unnecessary pain, suffering, distress or lasting harm that is being inflicted on an animal in the course of an experiment is stopped.
- The project is carried out in accordance with the relevant project authorisation.
- In the event of non-compliance, the appropriate measures to rectify it are taken and recorded.

I hereby **undertake** that in the event of the project authorisation being granted:

- To ensure fulfilment of the obligations arising by virtue of the terms and conditions of the project authorisation.

Signature of project leader (user): _____
(or person signing on behalf of the user)

Print/type name:

Date:

E2: THE PERSON RESPONSIBLE FOR ENSURING COMPLIANCE WITH THE PROVISION OF THE GRAND-DUCAL REGULATION OF THE 11 JANUARY 2013

The declaration below should be signed by the person responsible for ensuring compliance with the provisions of the grand-ducal regulation of the 11 January 2013 for the protection of animals used for scientific purposes at the relevant user establishment.

I hereby **declare** that:

- I am responsible for ensuring compliance with the provisions of the grand-ducal regulation of the 11 January 2013 for the protection of animals used for scientific purposes at the relevant user establishment referred to in Section A.
- I understand that if the applicant fails to uphold his/her responsibilities according to the grand-ducal regulation of the 11 January 2013, in the user establishment or additional locations for which I am compliance officer, this may have implications for the continued authorisation of the user establishment.

Signature of the person responsible:_____

(on behalf of breeder/supplier/user)

Print/type name:

Date: