HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Applications for ~~Renewals and~~ Amendments and Renewals to Breeder/Supplier/User Authorisations under Scientific Animal Protection Legislation

~~AUT-G0112-3~~
~~30 JULY 2019~~
~~This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.~~

CONTENTS

1 SCOPE

This guidance is intended to assist applicants in completing a ~~Health Products Regulatory Authority (~~HPRA~~)~~ 'Application for ~~Renewal/Amendment~~amendment/renewal to a ~~Breeder/Supplier/User Authorisation~~breeder/supplier/user authorisation under ~~Scientific Animal Protection Legislation'~~scientific animal protection legislation' form and establish conditions for renewal and amendment of breeder/supplier/user authorisations as required under Regulation 42(7) of S.I. No. 543 of 2012, as amended (hereafter known as the Regulations).

2 INTRODUCTION

In accordance with Article 20 of Directive 2010/63/EU and Regulation 42 of the Regulations, a breeder, supplier or user shall notify the HPRA without undue delay of any change in the persons designated as compliance officer, animal care and welfare officer, information officer, training officer or designated veterinarian or expert. A change to any of the designated persons listed above will require an amendment of the existing breeder/supplier/user authorisation.

Regulation 42 also states that a breeder/supplier/user shall not make any significant change unless granted a renewal of the relevant authorisation by the HPRA. A significant change means any significant change to the structure or function of an establishment that has the potential to negatively affect animal welfare including (but not limited to):

a) the addition of a new building, premises, mobile facility or establishment site
b) the addition of a new species of animal that can be bred/supplied/used or kept at the establishment
c) a change in the main type of operations conducted at the establishment (e.g. adding breeding, supplying or using to the authorisation)

Expiry of an existing authorisation will also require a renewal of this authorisation.

Therefore, please note the terminology (as defined in the Regulations) that is used in this application process: '**amendment' refers only to a change to designated persons, with all other changes referred to as 'renewal'**. However, only renewal applications which are due to the expiry of an existing authorisation will result in the extension of the duration of the authorisation.

~~APPLYING~~

3 APPLICATIONS FOR ~~A RENEWAL OR~~AN AMENDMENT OR RENEWAL OF A BREEDER/SUPPLIER/ USER AUTHORISATION

Provide the breeder/supplier/user authorisation holder details~~,~~ and complete the relevant section(s) of the form.

3.1 Amendment

A change to any of the designated persons (see Appendix 1 for definitions) will require an amendment. If the purpose of the application is for amendment(s), complete section B of the form.

~~3.1~~3.2 Renewal

Expiry of an existing authorisation or a significant change will require renewal of a breeder/supplier/user authorisation. If the purpose of the application is for renewal, select the reason(s) for renewal from ~~Section B~~section C of the form and complete the relevant subsection(s) in ~~Sections B1-B3~~sections C1-C3.

~~3.23.1 Amendment~~

~~A change to any of the designated persons (see Appendix I for definitions) will require an amendment. If the purpose of the application is for amendment(s), complete Section C.~~

3.3 Site master file (SMF)

An updated ~~site master file~~SMF which reflects the proposed changes to the breeder/supplier/user authorisation must be submitted along with the application ~~for a renewal or amendment~~ form. Any changes made relative to the most recent version submitted must be highlighted or tracked.

3.4 Declaration and undertaking

The declaration and undertaking section must be signed by the compliance officer(s) on behalf of the breeder/supplier/user establishment. In the event of the breeder/supplier/user authorisation renewal or amendment being granted, by signing the declaration and undertaking the compliance officer(s) is assuming responsibility for ensuring the fulfilment of the obligations arising by virtue of the terms and conditions of the authorisation, and of the requirements of the Regulations.

Formatted: Space Before: 0 pt, After: 0 pt

4 MAKING AN APPLICATION

An application for ~~a~~amendment or renewal ~~or an amendment~~ of a breeder/supplier/user authorisation must consist of a completed ~~renewal/~~amendment/renewal application form. It is possible to apply for both an amendment and a renewal ~~and an amendment~~ within the same application. Signed copies of all application forms must be submitted to the HPRA through submission of an electronic or scanned original document. In addition, any relevant associated documentation must be included. The necessary documentation for each type of renewal/amendment is outlined in each of the relevant subsections within the application form.

4.1 Timeline

The HPRA endeavours to complete the assessment of breeder/supplier/user amendment/renewal applications within 90 calendar days, and amendment applications within 45 calendar days. If the application is a combined amendment and renewal, the timeline is 90 calendar days. It should be noted that this timeline does not include the time taken for the receipt and validation of the applications by the HPRA. Applications are not validated as eligible for HPRA scientific animal protection (SAP) assessment until all necessary documentation has been provided. Further, the time taken by applicants to respond to any queries raised is not part of the assessment timeline (the system 'stops the clock' on applications for the duration of the period when satisfactory responses to queries are awaited).

4.2 Naming convention

The HPRA requests that amendment/renewal applications and their accompanying documents are named appropriately. Each document must begin with the unique user establishment number, followed by an underscore and one of the following words/phrases:

Application form: to be used for the application form
SMF: to be used for the site master file
CVCO: to be used for the compliance officer's CV
CVDV: to be used for the DV's CV
CVACWO: to be used for the animal care and welfare officer's CV
CVIO: to be used for the information officer's CV
CVTO: to be used for the training officer's CV
CV2: to be used for the deputy project manager's CV (where applicable)

Note: where there are multiple people appointed to a role, the subsequent CVs must be numbered, e.g. CVACWO; CVACWO2, CVACWO3, etc.

Appendix (where applicable)
Cover letter (where applicable)

The following table shows an example of how the files should be named for a hypothetical amendment/renewal application from a hypothetical establishment with the establishment authorisation number AE12345:

DOCUMENT	FILE NAME
Breeder/supplier/user application form	AE12345_Application form
The SMF	AE12345_SMF
The compliance officer's CV	AE12345_CVCO
The DV's CV	AE12345_CVDV
The animal care and welfare officer's CV	AE12345_CVACWO
The information officer's CV	AE12345_CVIO
The training officer's CV	AE12345_TO
Cover letter	AE12345_Cover letter

4.3 Administrative details

Due to the possible sensitive nature of information contained in breeder/supplier/user establishment applications, the HPRA provides a secure online system to enable submission of applications and data. This system is known as CESP - the Common European Submission Platform. It is recommended that each establishment nominates one individual to register with CESP. Applicants should liaise with the nominated person within their establishment to organise the submission of applications. ~~Nominated persons can contact cesp@hma.eu for~~For further information~~.~~ nominated persons can email cesp@hma.eu.

Applications can also be submitted by standard ~~e-mail~~email to: the HPRA at sapsubmit@hpra.ie.

Applications that do not include the necessary information are not eligible for HPRA ~~evaluation~~assessment. If an application is incomplete, the applicant will be notified as quickly as possible.

Queries in respect of application requirements or communications relating to breeder/supplier/user applications submitted can be made by telephone ~~or e-mail:~~ to +353 1 676 4971 or email at sap@hpra.ie.

~~Tel: +353 1 676 4971~~

~~E-mail: sap@hpra.ie~~

4.2 Fees

Currently there are no fees for this application.

APPENDIX ~~I~~1 DEFINITIONS

~~**Compliance Officer** – the person(s) indicated in Regulation 44 of the Regulations who is responsible for ensuring compliance with the provisions of the Regulations.~~

Animal care and welfare officer – the person(s) indicated in Regulation 45 of the Regulations who is responsible for overseeing the welfare and care of the animals in the establishment.

Breeder – any natural or legal person breeding animals referred to in Annex I to Directive 2010/63/EU with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, or breeding other animals primarily for those purposes, whether for profit or not.

Compliance Officer – the person(s) indicated in Regulation 44 of the Regulations who is responsible for ensuring compliance with the provisions of the Regulations.

~~**Information officer** – the person(s) indicated in Regulation 45A of the Regulations who is responsible for ensuring that the staff dealing with animals have access to information specific to the species housed in the establishment.~~

Designated veterinarian or suitably qualified expert – the person indicated in Regulation 48 of the Regulations who is charged with advisory duties in relation to the well-being and treatment of animals at a breeder/supplier/user establishment.

Establishment locations – locations where breeder/supplier/user activities are conducted.

Information officer – the person(s) indicated in Regulation 45A of the Regulations who is responsible for ensuring that the staff dealing with animals have access to information specific to the species housed in the establishment.

Supplier – any natural or legal person, other than a breeder, supplying animals with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, whether for profit or not.

Training officer – the person indicated in Regulation 46 of the Regulations who is responsible for ensuring that staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence.

~~**Establishment locations** – locations where breeder/supplier/user activities are conducted.~~

~~**Breeder** – any natural or legal person breeding animals referred to in Annex I to Directive 2010/63/EU with a view to their use in procedures or for the use of their tissue or organs for~~

Formatted: HPRA_MainBodyText

Formatted: Space Before: 0 pt, After: 0 pt

~~scientific purposes, or breeding other animals primarily for those purposes, whether for profit or not.~~

~~**Supplier** – any natural or legal person, other than a breeder, supplying animals with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, whether for profit or not.~~

User – any natural or legal person using animals in procedures, whether for profit or not.