HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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

AUT-G0112-~~23~~
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CONTENTS

1. SCOPE

This guidance is intended to assist applicants in completing a Health Products Regulatory Authority (HPRA) 'Application for ~~an~~ Renewal/Amendment~~/Renewal~~ to a Breeder/Supplier/User Authorisation under Scientific Animal Protection Legislation' and establish conditions for renewal and amendment ~~and renewal~~ of breeder/supplier/user authorisations as required under Regulation 42(7) of S.I. No. 543 of 2012~~, as amended by S.I No. 434 of 2013 and S.I No. 174 of 2014~~ (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. ~~An amendment/renewal application form must therefore be submitted and granted in either of these circumstances.~~

~~Expiry of an existing authorisation or a significant change will require a renewal of this authorisation.~~ 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) ~~T~~the addition of a new building, premises, mobile facility or establishment site
b) ~~T~~the addition of a new species of animal that can be bred/supplied/used or kept at the establishment
c) ~~A~~a change in the main type of operations conducted at the establishment (e~~.~~g. adding breeding, supplying or using to the authorisation)

~~A breeder/supplier/user must operate in accordance with the terms and conditions~~Expiry of ~~its breeder/supplier/user~~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.

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

~~Select the purpose of the application as 'amendment' and/or 'renewal', provide~~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 will require an amendment. If the purpose of the application is for amendment(s), select all amendment types that apply in Section B and complete the relevant subsection(s) in Sections B1–B4.~~

~~3.3~~3.1 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 ~~C~~B and complete the relevant subsection(s) in Sections B1-B3.

3.2 Amendment

A change to any of the designated persons ~~C1–C4~~(see Appendix I for definitions) will require an amendment. If the purpose of the application is for amendment(s), complete Section C.

~~3.4~~3.3 Site master file

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

~~3.5~~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 ~~or renewal~~ 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.

4. MAKING AN APPLICATION

An application for a renewal or an amendment ~~or renewal~~ of a breeder/supplier/user authorisation must consist of a completed renewal/amendment~~/renewal~~ application form. It is possible to apply for both a renewal and an amendment within the same application. Signed copies of all application forms must be submitted to the HPRA through submission of ~~a hard copy~~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 ~~Section B of~~ the application form.

~~**5. ADMINISTRATIVE DETAILS**~~

4.1 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. ~~A separate guide for electronic submissions of applications using CESP will be available from the publications page of the HPRA website.~~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 further information.

Applications can also be submitted by standard e-mail to: sapsubmit@hpra.ie.

~~If the application cannot be submitted electronically, applications will be accepted in hard copy by post. Applications that arrive by post must be electronically scanned by the HPRA resulting in additional processing time for evaluation.~~

~~Send hard copy applications to:~~

~~Receipts and Validation Section~~

~~Health Products Regulatory Authority~~

~~Kevin O'Malley House~~

~~Earlsfort Centre~~

~~Earlsfort Terrace~~

~~Dublin 2~~

Applications that do not include the necessary information are not eligible for HPRA evaluation. If an application is incomplete, the applicant will be notified as quickly as possible ~~via the e-mail address on the application form~~.

Queries in respect of application requirements or communications relating to breeder/supplier/user applications submitted can be made by telephone or e-mail~~.~~:

Tel: +353 1 676 4971

~~Fax: +353 1 676 7836~~

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

4.2 Fees~~:~~

Currently there are no fees for this application.

APPENDIX I DEFINITIONS

~~**Animal care and welfare officer** – the person indicated in Regulation 45 of the S.I who is responsible for overseeing the welfare and care of the animals in the establishment and ensuring that the staff dealing with animals have access to information specific to the species housed in the establishment.~~

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.

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 – ~~a veterinarian or 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.

Training officer – the person indicated in Regulation 46 of the ~~S.I~~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 ~~of~~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.

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.