HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

# Guide to
# Withdrawal of Breeder/Supplier/User Authorisations under Scientific Animal Protection Legislation

## 1 SCOPE

This guide applies to the withdrawal by the holder of a breeder/supplier/user authorisation of their authorisation for breeding, supplying and/or using animals for scientific purposes under Directive 2010/63/EU (the Directive) and S.I. No. 543 of 2012, as amended by S.I. No. 434 of 2013~~, and~~ S.I. No. 174 of 2014, and S.I. No. 553 of 2018 (hereafter known as the Regulations).

## 2 INTRODUCTION

The breeder/supplier/user authorisation holder must notify the HPRA of the intended withdrawal using the application form for withdrawal of a breeder/supplier/user authorisation.

Notification of the withdrawal of a breeder/supplier/user authorisation should be made using the 'Application for Withdrawal of a Breeder/Supplier/User Authorisation under Scientific Animal Protection Legislation' available at www.hpra.ie. The HPRA will acknowledge the withdrawal from the intended date of withdrawal indicated on the form.

The application form for withdrawal of a breeder/supplier/user authorisation must not be used to notify the HPRA of issues at the breeder/supplier/user establishment.

## 3 WITHDRAWAL NOTIFICATION

The application form requests information including:

### 3.1 Date of intended withdrawal of breeder/supplier/user authorisation

This is the date from which the withdrawal is intended to become effective. The HPRA requires that applications for withdrawal are submitted at least one month in advance of the intended withdrawal date of the authorisation in order to allow sufficient processing time.

### 3.2 ~~Date of~~Reason for intended withdrawal of breeder/supplier/user authorisation

The authorisation holder must provide information on the reasons for the withdrawal of the breeder/supplier/authorisation.

### 3.3 Details on the fate of the animals post withdrawal

In order for a breeder/supplier/user authorisation to be withdrawn, the animals kept at that ~~the~~ breeder/supplier/user establishment must be removed accordingly. For this reason, details on the planned fate of the animals at the breeder/supplier/user authorisation must be listed i.e. 'euthanised', rehomed', 'rehabilitated and set free', etc. A timeline outlining the planned action dates for each fate must be provided. As set out in Regulation 9, setting free or rehoming of animals must not commence without prior approval from the HPRA.

When a breeder/supplier/user authorisation is withdrawn, no further breeding, supplying or using of animals for scientific purposes may take place at the breeder/supplier/user establishment after the date of withdrawal. All approved projects within their HPRA authorisation period ~~or Department of Health licence~~ ~~are~~ should be withdrawn or transferred to a different authorised breeder/supplier/user establishment. Any projects not transferred ~~and all project work~~ must cease animal work immediately as of the withdrawal date of the breeder/supplier/user establishment authorisation.

All individual authorisations to manage projects, carry out procedures on animals and perform euthanasia at the breeder/supplier/user establishment must cease as of the withdrawal date of the breeder/supplier/user authorisation. Any individual commencing work in another breeder/supplier/user must first ensure they possess an individual authorisation for that breeder/supplier/user.

It is important to note that an application for withdrawal of a breeder/supplier/user authorisation may result in an inspection from the HPRA. The requirement for an inspection to be carried out is decided on a case-by-case basis, and depends on the particular circumstances in relation to the withdrawal of that breeder/supplier/user authorisation.

## 4 WITHDRAWAL NOTIFICATION

Due to the possible sensitive nature of information contained in a withdrawal application, 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.

Breeder/supplier/user withdrawal application forms can also be submitted by standard e-mail to sapsubmit@hpra.ie ~~or in hard copy to:~~

~~Scientific Animal Protection Section~~
~~Veterinary Sciences Department~~
~~Health Products Regulatory Authority~~
~~Kevin O'Malley House~~
~~Earlsfort Centre~~
~~Earlsfort Terrace~~
~~Dublin 2~~

Queries in respect of application requirements or communications relating to applications submitted can be made by telephone or~~,~~ ~~fax,~~ e-mail:
~~or by post to the address above:~~

Tel: +353 1 676 4971
~~Fax: +353 1 676 7836~~
E-mail: sap@hpra.ie

Fees:
Currently there are no fees for this application.