HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
New, ~~and~~ Amendment and Renewal Applications for Individuals under Scientific Animal Protection Legislation

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CONTENTS

1 SCOPE

This guide describes the process for authorisation by the Health Products Regulatory Authority (HPRA) of persons, ~~by the Health Products Regulatory Authority (HPRA)~~, having activities and responsibilities 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. 552 of 2016 (hereafter referred to as the Regulations).

2 INTRODUCTION

The 'Application for an Individual Authorisation under Scientific Animal Protection Legislation' ~~or~~ 'Application for an Amendment to an Individual Authorisation under Scientific Animal Protection' ~~L~~legislation' or 'Application for a Renewal of an Individual Authorisation under Scientific Animal Protection Legislation' forms must be submitted to the HPRA by all individuals performing the following roles involving animals used for scientific purposes:

- Project management
- ~~Persons c~~Carrying out procedures on animals
- ~~Persons p~~Performing euthanasia on animals

It is possible for one individual authorisation to encompass authorisation for each of the three purposes listed above i.e. one authorisation may cover any or all of the purposes selected.

An individual authorisation will detail the activities which the applicant is authorised to perform, and will identify the breeder/supplier/user establishment at which they are authorised to carry out those activities. Procedures can only be conducted within the scope of an authorised project. Project authorisations issued by the HPRA will list those individuals who will be conducting the envisaged procedures; all of whom must possess an individual authorisation, granted by the HPRA. However, an individual authorisation for the purpose~~s~~ of performing euthanasia is not necessarily linked with a specific project and euthanasia can therefore be conducted outside of the scope of an authorised project.

Full-term individual authorisations are granted for a period not exceeding five years and are subject to renewal thereafter. However, short-term individual authorisations may be granted in certain circumstances for a maximum period of two months. ~~individual authorisations may be for a much shorter period, depending on the circumstances involved (for example, in the case of~~ These are principally intended for experts from overseas being recruited for a short period of time to perform specific procedures or train personnel in a new procedure~~).~~, or for trainee human surgeons who need to gain competence in specialist surgical procedures, e.g. microvascular surgery. The HPRA will consider the suitability of an individual seeking a short-term individual authorisation on a case-by-case basis, taking into account the applicant's proposed role in the project, their experience, species-specific knowledge, and qualifications. It is important to note that short-term individual authorisations are only intended for persons

with prior experience or relevant expertise.~~In such cases the HPRA may, following application, recognise the qualifications and experience of individuals in making its decision to grant or refuse authorisation.~~ If applying for a short-term individual authorisation, this should be indicated within the form and all necessary details and supportive documentation provided. If such applications are approved, the HPRA may grant short-term authorisations for these individuals, rather than the standard full-term five year individual authorisation. ~~A short-term individual authorisation is granted for a maximum period of two months.~~ Individual authorisations are automatically suspended if the breeder/supplier/user authorisation is allowed to lapse or is withdrawn. Individual authorisations may also be suspended if any of the conditions of the authorisation are not fulfilled.

The HPRA endeavours to complete the assessment of individual applications within 28 days. Timeframes may be extended if applications are incomplete or incorrect. Queries raised during the assessment or a delay in applicants submitting responses to queries may also result in timeframes being extended.

3 TRAINING, EDUCATION AND COMPETENCY REQUIREMENTS FOR INDIVIDUAL AUTHORISATIONS

In accordance with Article 23 of Directive 2010/63/EU and Regulation 43 of the Regulations, all personnel performing activities requiring an individual authorisation must be adequately educated and trained. The compliance officer, as defined in Article 20(2) and Regulation 44, must endorse the suitability of the applicant by signing a declaration and undertaking.
The HPRA are not in a position to grant individual authorisations for personnel who have not first completed an appropriate approved scientific animal training course. However a short-term individual authorisation may, on a case-by-case basis, be granted to individuals who have not completed an approved scientific animal training course, but who have previous experience in the use of scientific animals, or other expertise.

The assessment of competence is a matter for the breeder/supplier/user and is described further in the 'Guide to ~~all~~ Training, Education and Competency ~~Assessment~~ Requirements under Scientific Animal Protection Legislation'.

4 NEW INDIVIDUAL AUTHORISATIONS

4.1 Breeder/supplier/user establishment details

The activities described above under ~~S~~section 2 must only be undertaken in connection with an authorised breeder/supplier/user establishment. Therefore it is necessary for an applicant to be ~~sponsored or hosted by~~linked to an authorised breeder/supplier/user establishment (e.g. academic institution, ~~university institution,~~ government body, contract research organisation etc.) before being considered eligible to hold an individual authorisation.

Individuals wishing to collaborate between, or perform activities involving the use of scientific animals in more than one breeder/supplier/user establishment may do so; however that individual must first hold a separate individual authorisation for each breeder/supplier/user establishment in which they intend to carry out activities involving the use of scientific animals. A separate individual authorisation application must therefore be submitted and signed by the appropriate compliance officer for each relevant breeder/supplier/user establishment. If a person is applying for a second or subsequent individual authorisation, their existing individual authorisation number(s) should be provided in the application form.

If an individual plans to perform euthanasia at an additional unauthorised location (e.g. commercial farm/~~ or~~ river basin/coastal waters), without being associated with an authorised project, the additional location should be listed and a scientific justification as to why the additional location is necessary should be provided for consideration by the HPRA.

4.2 Purpose of individual authorisation

The proposed function/purpose for which the authorisation is sought must be selected using the appropriate tick box (select all that apply). The applicant's CV must be appended to the individual authorisation application. Further details on the education, training and competency for each of the purposes for individual authorisation can be found under section 3 above.

CV and training record templates (mandatory only for procedures involving the use of neuromuscular blocking agents) can be found on the HPRA website. The HPRA will also accept CVs and training records in other formats provided the information captured is comparable to the templates on the HPRA website.

4.2.1 Project management

The person(s) responsible for a project must hold an individual authorisation for the purpose of project management. Individuals intending to act as a deputy project manager for a project authorisation must also hold an individual authorisation for the purpose of project management.

The HPRA will look for evidence that the individual has received relevant education, e.g. completion of a relevant approved animal training course.

The project manager or deputy project manager(s) may or may not be the same person(s) who will carry out procedures as part of a project.

4.2.2 Person(s) carrying out scientific procedures on animals

A procedure is defined as any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or for educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice. Procedures can only be conducted within the scope of an authorised project.

Individuals applying for authorisation should select the category or categories of procedures for which authorisation is sought in the application form.

The procedural category 'use of neuromuscular blocking agents' is intended for the use of neuromuscular blocking agents in conjunction with anaesthesia during surgical procedures. As the use of these agents is particularly challenging and can potentially significantly negatively impact animal welfare, the HPRA applies careful control to their use. Therefore if applying for the use of neuromuscular blocking agents, training records must be provided to outline the individual's training and expertise in administration of these agents. Specific qualifications and experience in this area must be listed in the applicant's CV before authorisation to perform this category of procedure will be granted.

If a procedure is required that does not fall within the scope of the categories of procedures in the application form, a brief description of the relevant procedure should be provided under the option 'other'. The species of animal on which this 'other' procedure is requested to be carried out must also be entered.

For the procedures selected, the HPRA will look for evidence that the individual has received relevant education, e.g. completion of a relevant approved animal training course.

Individuals may apply for a greater range of procedures than might be initially required for a project to avoid the need for future amendments. However, persons authorised to carry out procedures on animals must be supervised in the performance of a procedure until the requisite competence has been demonstrated.

4.2.3 Person(s) performing euthanasia

Regulation 8 of S.I. No. 543 of 2012 requires that the method of euthanasia used shall ensure that ~~the minimum~~ minimual pain, suffering and distress is used and that the animal is euthanised by a competent person.

For the methods of euthanasia selected, the HPRA will look for evidence that the individual has received relevant education, e.g. completion of a relevant approved animal training course.

Euthanasia of live animals can only be performed by person(s) possessing a valid individual authorisation for this purpose. Training of euthanasia using live animals cannot be performed until an individual authorisation has been granted.

Euthanasia must be performed using the methods set out in Annex IV of the Directive, unless justified in accordance with Regulation 8(4) of S.I. No. 543 of 2012. If another method of euthanasia is to be used or if the method is not to be carried out according to the strict limitations (e.g. weight specifications) set in the Directive, scientific justification must be provided in accordance with Regulation 8(4) of the S.I. and Article 6 (4) of the Directive. An individual authorisation for the exclusive purposes of euthanasia does not have to be linked to a specific project authorisation, but must be linked to an authorised breeder/supplier/user.

5 AMENDMENTS TO AN INDIVIDUAL AUTHORISATION

An individual authorisation holder must apply to the HPRA using the 'Application for an Amendment to an Individual Authorisation under Scientific Animal Protection Legislation' form in order to make an amendment to an existing individual authorisation. Amendments refer to any change to the terms of the individual authorisation and include the following amendment types:

- addition of a new purpose to the authorisation
- addition of a new species for the purpose of project management
- addition of a new category of procedure and/or a new species
- addition of a new method of euthanasia and/or a new species
- addition of a new unauthorised location where euthanasia is planned (outside the scope of a project authorisation)

Please select all amendment types that apply and complete the relevant subsequent section(s) of the form.

For example, applicants wishing to add project management as a new purpose to their existing individual authorisation or adding a new species to their existing individual authorisation for project management can do so by selecting amendment type 'Part 1'- Project management: Addition of this new purpose or addition of a new species for this purpose'.

~~N.B~~Please note, ~~W~~where an individual authorisation was previously issued with specific condition(s) attached, proof of fulfilment of specific condition(s) must be submitted with the amendment application. Failure to have fulfilled a specific condition attached to a previously issued individual authorisation will preclude an individual from making an amendment to their authorisation.

~~6 TRANSITIONAL ARRANGEMENTS~~

~~Individuals named under existing Department of Health project licences do not need a HPRA individual authorisation, provided that they operate in conformity with the terms and conditions of the project licence. If such individuals wish to work on a new project authorisation, an individual authorisation would be required before or at the time of applying for a new project authorisation. An individual authorisation would also be required to join an existing project licence issued by the Department. If an applicant requests to carry out procedures under an existing Department of Health project licence, a cover letter outlining this request and a copy of the project licence should be provided at the time of submission of the individual authorisation application.~~

~~If personnel, after issue of an individual authorisation, wish to join an existing project licence issued by the Department of Health, the existing project licence should be submitted along with a cover letter signed by the compliance officer of their breeder/supplier/user establishment, explaining that they wish to work on that Department of Health project licence. The HPRA individual authorisation number of the person requesting addition to the Department of Health project licence should also be included in the cover letter.~~

~~An individual who wishes to perform euthanasia outside of a Department of Health project licence must hold a HPRA individual authorisation for this purpose.~~

6 RENEWAL AND RE-APPLICATION OF AN INDIVIDUAL AUTHORISATION

6.1 Renewal of an individual authorisation

An individual authorisation holder must apply to the HPRA using the 'Application for a Renewal of an Individual Authorisation under Scientific Animal Protection Legislation' form in order to renew an existing (full-term) individual authorisation, which is due to expire. Individual authorisations will only be renewed for the purposes for which the individual is currently authorised, for a period not exceeding ~~5~~ five years. Application for a renewal of an individual authorisation should be submitted at least 28 calendar days before the date of expiry of the existing authorisation. If the expiry date has already passed, or is less than 28 calendar days away, the authorisation holder must re-apply for a new individual authorisation (see 6.2). Short-term individual authorisations cannot be renewed.

~~N.B.~~Please note, w~~W~~here an individual authorisation was previously issued with specific condition(s) attached, proof of fulfilment of specific condition(s) must be submitted with the renewal application. Failure to have fulfilled a specific condition attached to a previously issued individual authorisation will preclude an individual from being authorised for a further five year period, as a renewed individual authorisation cannot be issued with specific condition(s).

6.2 Re-application for an individual authorisation

If an individual authorisation is due to expire within 28 calendar days, or has already expired, a new individual application must be submitted, using the 'Application for an Individual Authorisation under Scientific Animal Protection Legislation' form, ensuring that all purposes for which the individual wishes to be authorised are outlined. In this case, individuals will be issued with the same individual authorisation number, but these applications will be subject to the standard fee that applies for new individual authorisation applications.

~~N.B.~~Please note, ~~w~~Where an individual authorisation was previously issued with specific condition(s) attached, proof of fulfilment of specific condition(s) must be submitted with the re-application for individual authorisation. Failure to have fulfilled a specific condition attached to a previously issued individual authorisation will preclude an individual from being authorised for a further five year period.

7 DOCUMENTS NEEDED TO SUPPORT AN APPLICATION

7.1 List of documents for each case type

~~6.1.1~~7.1.1 New/Re-application for individual authorisation

An application for an individual authorisation must consist of the following:

- Application for an Individual Authorisation under Scientific Animal Protection ~~form~~ Legislation~~Individual application form~~, form duly completed and signed by the applicant and the compliance officer
- CV of the applicant (setting out education, training and experience)
- Training records of the applicant (mandatory only for the use of neuromuscular blocking agents)
- Certificate confirming successful completion of a relevant animal training course
- Evidence of fulfilment of specific condition(s) (if relevant)
- Fee application form and the accompanying fee***
- Proof of payment ****

***The appropriate fee must be paid before the application can be validated for assessment. Information in relation to fees can be found on ~~the HPRA website here~~www.hpra.ie. Queries in relation to the payment of fees should be submitted to accounts@hpra.ie.

****Proof of payment should be a remittance advice or bank statement showing th~~e~~at fees have been paid to the HPRA ~~(where possible)~~

~~A covering letter may also be provided, but this is not a requirement. However, if the applicant is applying for individual authorisation in order to move to an existing Department of Health project licence, a covering letter outlining this intent should be provided, as well as a copy of the existing Department of Health project licence.~~

If the applicant currently holds a valid individual authorisation for another breeder/supplier/user establishment, and the purpose of the application is to apply for an individual authorisation for a second or subsequent breeder/supplier/user establishment, the only document required in relation to the application for an additional individual authorisation at the time of submission is the individual application form.

7.1.2 Amendment/Renewal of individual authorisation

An application for an amendment to/renewal of an individual authorisation must consist of the following:

- Application for an Amendment to an Individual Authorisation under Scientific Animal Protection Legislation form or Application for a Renewal of an Individual Authorisation under Scientific Animal Protection Legislation form, duly completed and signed by the applicant and the compliance officer
- Training records of the applicant (mandatory only if the purpose of the amendment is to add neuromuscular blocking agents)
- Evidence of fulfilment of specific condition(s) (if relevant)

7.2 Name of accompanying documents

The HPRA requests that individual applications and their accompanying documents are named appropriately. Each document should begin with the unique breeder/supplier/user establishment number. This should be followed by an underscore and the letters 'IAN' (this stands for individual application number, as a number will not yet have been assigned to new individual applications). This should be followed by an underscore and one of the following words/phrases:

- Application: to be used for the signed individual application form that has been signed and electronically scanned.
- CV: to be used for the individual's curriculum vitae.
- Fee: to be used for the fee application form
- Train: to be used for submission of training records confirming competency (where applicable).
- Cover letter (optional~~where applicable~~).
- Cert: to be used as evidence of completion of a HPRA approved scientific animal training course~~for the animal training certificate or equivalent~~.
- Specific condition ~~C~~cert: to be used as evidence of the individual's fulfilment of a specific condition.
- ~~DoH: to be used for a Department of Health project licence for situations where the applicant requests to be added to the existing licence (where applicable).~~

The following is an example of how the files should be named for a hypothetical individual application from a hypothetical breeder/supplier/user establishment number AE12345. If multiple training records were provided (e.g. historical and recent) the training records should

be numbered sequentially after the letters, e.g. 'AE12345_IAN_Train1'; 'AE12345_IAN_Train2'. If multiple individual applications are submitted simulataneously, number each application after 'IAN', e.g. 'AE12345_IAN1_Application' and 'AE12345_IAN2_Application'.

DOCUMENT	FILE NAME
Application form signed	AE12345_IAN_Application
CV	AE12345_IAN_CV
Training records	AE12345_IAN_Train
Cover letter	AE12345_IAN_Cover letter
HPRA approved scientific animal training course certificate~~Animal handling certificate~~	AE12345_IAN_Cert~~ERT~~
Evidence of fulfilling specific condition	AE12345_IAN_Specific Condition Cert
Fee application form	AE12345_IAN_Fee

Applications for an amendment or renewal and any associated documentation can be submitted using the naming convention described above. However, please substitute the word 'application' with 'amendment' or 'renewal' and instead of the letters 'IAN' include the existing individual authorisation number.

~~7~~8 WITHDRAWAL OF INDIVIDUAL AUTHORISATIONS

If an individual authorisation holder no longer requires their individual authorisation, the individual authorisation can be withdrawn by the HPRA upon request. Withdrawal requests should be submitted by e-mail to sapsubmit@hpra.ie. The e-mail should include the names and authorisation numbers of the relevant individual authorisations to be withdrawn. There is no form or other associated documentation required currently, however the request should be clearly outlined within the e-mail to avoid potential queries and subsequent delays.

Once an individual authorisation is withdrawn, this process is irreversible. It is not possible to reactivate a withdrawn individual authorisation. If the individuals affected wish to be authorised again in the future, a new individual authorisation application will be required.

For project managers requesting withdrawal of their individual authorisation, an amendment (and transfer application if they are also the authorisation holder) to any currently active project authorisations on which they are listed as the project manager will be required as soon as possible.

~~8~~9 ADMINISTRATIVE DETAILS

T~~Due to the possible sensitive nature of information contained in individual applications, t~~he HPRA provides a secure online system to enable submission of applications and data. This system is known as CESP; the Common European Submission Portal~~latform~~.
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 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. Send hard copy applications to:~~

~~Receipts and Validation Unit~~
~~Health Products Regulatory Authority~~
~~Kevin O'Malley House~~
~~Earlsfort Centre~~
~~Earlsfort Terrace~~
~~Dublin 2~~

~~Applications that arrive by post must be electronically scanned by the HPRA resulting in additional processing time for validation.~~

All information requested must be provided in the application form and any appended documents. 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 applications submitted can be made by telephone, fax, e-mail or by post to the address below:

Scientific Animal Protection Section
Veterinary Sciences Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
D02 XP77
Tel: +353 1 676 4971
Fax: +353 1 676 7836
E-mail: sap@hpra.ie

Fees:

Fees are detailed in the 'Guide to Fees for Science Animal Protection', which can be found at www.hpra.ie. Applications that are not accompanied by the appropriate fee will not be validated.