HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

1 SCOPE

This guide describes the process for authorisation by the Health Products Regulatory Authority (HPRA) of persons, having activities and responsibilities under Directive 2010/63/EU (the Directive) and S.I. No. 543 of 2012 (hereafter referred to as the Regulations).

2 INTRODUCTION

All individuals performing the following activities involving animals used for scientific purposes:

- project management,
- carrying out procedures on animals, and
- performing euthanasia on animals;

must submit the following forms to the HPRA, where applicable:

- 'Application for an Individual Authorisation under Scientific Animal Protection Legislation',
- 'Application for an Amendment to an Individual Authorisation under Scientific Animal Protection Legislation',
- 'Application for a Renewal of an Individual Authorisation under Scientific Animal Protection Legislation',
- 'Application for Reactivation of an Individual Authorisation under Scientific Animal Protection Legislation'.

It is possible for one individual authorisation to encompass authorisation for each of the three activities listed above, i.e. one authorisation may cover any or all the activities 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. It is the project authorisation holder's responsibility to ensure that all individuals working on a project hold the relevant individual authorisations. The project authorisation holder is required to maintain a list which details all individuals who will be carrying out procedures under a project authorisation. Once granted an authorisation from the HPRA, individuals should immediately notify the project authorisation holder of any projects on which they intend to work. An individual authorisation for the purpose of performing euthanasia is not necessarily linked with a specific project and euthanasia can 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 limited circumstances for a maximum period of two months. These are principally intended for experts from outside the breeder/supplier/user establishment (e.g. 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, considering 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. If applying for a short-term individual authorisation, this should be indicated within the form and all necessary details and supporting documentation provided.

Individual authorisations are automatically invalidated if the breeder/supplier/user authorisation is allowed to lapse or is withdrawn. Individual authorisations may be suspended if any of the terms of authorisation are breached or 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 is not able to grant full-term individual authorisations for personnel who have not first completed an appropriate approved scientific animal training course including species-specific training. 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 and suitability to perform procedures/euthanasia on animals sits within the framework of the breeder/supplier/user training system, under the responsibility of the training officer (designated under Regulation 46 of the Regulations). More information on educational and training requirements and competency assessment is contained within the HPRA 'Guide to Training, Education and Competency Requirements under Scientific Animal Protection Legislation' available on the HPRA website at www.hpra.ie.

4 NEW INDIVIDUAL AUTHORISATIONS

4.1 Breeder/supplier/user establishment details

The activities described above under section 2 of the HPRA individual authorisation application form must only be undertaken in conjunction with an authorised breeder/supplier/user

establishment. Therefore, it is necessary for an applicant to be linked to an authorised breeder/supplier/user establishment (e.g. academic 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) and the expiry date(s) of any existing individual authorisation number(s) should be provided in the application form.

If an individual intends to perform euthanasia at an additional unauthorised location (e.g. commercial farm/river basin/coastal waters), 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 activities for which the authorisation is sought must be selected using the appropriate tick box (select all that apply). The applicant's Curriculum Vitae (CV) must be appended to the individual authorisation application. Further details on the education, training and competency requirements can be found under section 3 of this guide.

A CV is mandatory for all new individual authorisation applications, and either training records or a training plan are mandatory for applicants who are requesting approval to use neuromuscular blocking agents (NMBAs). CV and training record templates can be found on the HPRA website, under Guidance documents for Scientific Animal Protection. The HPRA will 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

All project managers 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.

Individuals applying for authorisation to manage projects should select 'Project management' for the relevant species. 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 also 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 to carry out procedures should select 'Carrying out procedures' for the relevant species.

The procedural category 'Use of neuromuscular blocking agents' is intended for the use of NMBAs in conjunction with anaesthesia during surgical procedures. If this is required, both 'Carrying out procedures' and 'Use of neuromuscular blocking agents' should be selected for the relevant species. As the use of these agents poses particular challenges, and can potentially have a significant negative impact on animal welfare, the HPRA applies careful control to their use. Therefore, if applying for the use of NMBAs, training records should be provided to outline the individual's previous training and expertise in the administration of these agents. Where the applicant is yet to be trained in the use of NMBAs, a detailed training plan including the name and specific qualifications/experience of the trainer should be provided. The trainer will require a HPRA individual authorisation approving them to use NMBAs.

To obtain authorisation to carry out procedures in the species selected, the HPRA will look for evidence that the individual has received relevant education, e.g. completion of a relevant approved animal training course. 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

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 undertaken until an individual authorisation has been granted.

Regulation 8 of the Regulations requires that the method of euthanasia used shall ensure minimal pain, suffering and distress, and that the animal is euthanised by a competent person.

Euthanasia must be performed using the methods set out in Annex IV of the Directive, unless justified in accordance with Regulation 8(4) of the Regulations. Individuals applying for authorisation to perform euthanasia should select 'Annex IV approved method' for the relevant

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

If it is intended to use another method of euthanasia not listed in Annex IV of the Directive, or if the method is not to be carried out strictly according to Annex IV specifications, then 'Non-Annex IV approved method' should be selected for the relevant species, and robust scientific justification must be provided in accordance with Regulation 8(4) of the Regulations 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

To make an amendment to an existing 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, available on the HPRA website, under 'Make a Submission'. Amendments refer to any change to the terms of the individual authorisation and include the following amendment types:

- addition of, or change to, an activity/activities which the individual is authorised to perform
- addition of, or change to, the species to which the activity/activities specified in the authorisation relates
- addition of a new unauthorised location where euthanasia is planned (outside the scope of a project authorisation)

Please select all amendment types that apply, as per section 4.2 of this guide.

Please note, 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 and may result in compliance action.

6 RENEWAL AND REACTIVATION OF, AND RE-APPLICATION FOR AN INDIVIDUAL AUTHORISATION

An individual authorisation holder must apply to the HPRA to obtain authorisation to continue, or recommence, the performance of activities involving animals used for scientific purposes. The appropriate form for completion is determined based on the following criteria:

- If an existing individual authorisation is due to expire in less than six months, but more than 28 days, the 'Application for a Renewal of an Individual Authorisation under Scientific

Animal Protection Legislation' form must be completed and submitted to the HPRA (**see section 6.1 of this guide**).

- If the status of individual authorisation has been changed by the HPRA to 'inactive' due to non-payment of the annual individual maintenance fee (e.g. following a period of absence) and the existing date of expiry of authorisation is more than 28 days away, the 'Application for Reactivation of an Individual Authorisation under Scientific Animal Protection Legislation' form must be completed and submitted to the HPRA (**see section 6.2 of this guide**).

- If an individual authorisation has expired, or is due to expire in less than 28 days (regardless of whether the individual was active or inactive prior to expiry), the 'Application for an Individual Authorisation under Scientific Animal Protection Legislation' form must be completed and submitted to the HPRA (**see section 6.3 of this guide**).

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 to renew an existing (full-term) individual authorisation which is due to expire. Individual authorisations will only be renewed for the activities for which the individual is currently authorised, for a period not exceeding 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, but not more than six months prior to the expiration date.

It should be noted that once renewal of individual authorisation has been granted, the HPRA will not be able to process any amendments to that individual authorisation until the existing authorisation has expired, and the renewed authorisation has come into effect. If amendment is required in advance of the renewed authorisation coming into effect, users should submit an application for amendment (at least 60 calendar days before the date of expiry of the existing authorisation, to allow for assessment) followed by the submission of an application for renewal (at least 28 calendar days before the date of expiry). Alternatively, users should apply for renewal and wait until the renewed authorisation has come into effect before applying for an amendment. 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 section 6.3 of this guide**). Short-term individual authorisations cannot be renewed.

Please note, where 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). Furthermore, failure to fulfil specific conditions may result in compliance action.

6.2 Reactivation of an individual authorisation

Non-payment of annual maintenance fees for individual authorisation will result in the individual authorisation being deemed 'inactive', meaning it cannot not be used for the purpose of project management, carrying out procedures, or performing euthanasia. However, individual authorisations can be reactivated upon payment of the appropriate fee. An individual authorisation holder must apply to the HPRA using the 'Application for Reactivation of an Individual Authorisation under Scientific Animal Protection Legislation' form in order to reactivate an existing (full-term) individual authorisation which has been previously assigned a status of 'inactive' (**see section 8 of this guide**). In this case, individuals will be issued with the same individual authorisation number. Individual authorisations will be reactivated only for the activities for which the individual was previously authorised, and until the original expiration date.

Application for reactivation of an individual authorisation should be submitted at any time **up to 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 section 6.3 of this guide**). It should be noted that if individuals reactivate their authorisation within six months of the expiration date of their existing authorisation, it is also possible to apply for renewal once the authorisation has been reactivated (**see section 6.1 of this guide**).

Please note, where an individual authorisation was previously issued with specific condition(s) attached, proof of fulfilment of specific condition(s) must be submitted with the reactivation application. Failure to have fulfilled a specific condition attached to an existing individual authorisation will preclude an individual from being authorised for the remainder of their five-year authorisation period, as a reactivated individual authorisation cannot be issued with specific condition(s). Furthermore, failure to fulfil specific conditions may result in compliance action.

6.3 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 authorisation application must be submitted, using the 'Application for an Individual Authorisation under Scientific Animal Protection Legislation' form, ensuring that all activities for which the individual wishes to be authorised are outlined. As this application type is assessed as a new application for an individual authorisation (as opposed to a re-issue of an existing authorisation), amendments can be made to the requested activities (i.e. removal or inclusion of new species or a new activity/activities) once supporting documentation is provided. 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, and authorisation may be issued with specific condition(s).

Please note, 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. Furthermore, failure to fulfil specific conditions may result in compliance action.

7 DOCUMENTS NEEDED TO SUPPORT AN APPLICATION

7.1 List of documents for each case type

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 Legislation' form, duly completed and signed by the applicant and the compliance officer
- CV of the applicant (setting out education, training and experience)
- Training records and a training plan should be submitted, if the applicant wishes to include the use of neuromuscular blocking agents. Training records are not required otherwise.
- 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. 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 that fees have been paid to the HPRA.

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 and a training plan should be submitted, if the purpose of the amendment is to add neuromuscular blocking agents. Training records are not required otherwise.
- Evidence of fulfilment of specific condition(s) (if relevant)

7.1.3 Reactivation of individual authorisation

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

- 'Application for Reactivation of an Individual Authorisation under Scientific Animal Protection Legislation' form, duly completed and signed by the applicant and the compliance officer
- 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. 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 that fees have been paid to the HPRA.

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 or training plan confirming competency or training intentions (where applicable)
- Cover letter (optional)
- Cert: to be used as evidence of completion of a HPRA-approved scientific animal training course
- Specific condition cert: to be used as evidence of the individual's fulfilment of a specific condition

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

DOCUMENT	FILE NAME
Cover letter	AE12345_IAN_Cover letter
HPRA-approved scientific animal training course certificate	AE12345_IAN_Cert
Evidence of fulfilling specific condition	AE12345_IAN_Specific Condition Cert
Fee application form	AE12345_IAN_Fee

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

8 INACTIVATION OF INDIVIDUAL AUTHORISATIONS

If an individual authorisation holder no longer requires their individual authorisation, either indefinitely or for a set period of time, the individual authorisation can be inactivated by the HPRA. Requests for inactivation can be made once annually (usually in June), with the submission of information pertaining to the collection of both individual maintenance and establishment fees. This is the only time at which the HPRA will accept requests for inactivation. For individuals who depart an establishment throughout the year, this information should be retained at the establishment, until requested by the HPRA. Notification of individuals who will no longer manage projects / carry out procedures / perform euthanasia after close of business on 30 June each year should then be submitted by email to sap@hpra.ie. The email should include the names and authorisation numbers of the relevant individual authorisations to be inactivated. There is no form or other associated documentation required currently; however, the request should be clearly outlined within the email to avoid potential queries and subsequent delays.

Once an individual authorisation is inactivated, it can be reactivated within the original period of authorisation upon payment of the appropriate fee and submission of an application for reactivation, and the applicant will be reissued their original individual authorisation number. However, 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 section 6.3 of this guide**).

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

9 ADMINISTRATIVE DETAILS

The HPRA provides a secure online system to enable submission of applications and data. This system is known as CESP, the Common European Submission Portal. 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 email to sapsubmit@hpra.ie.

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 assessment. If an application is incomplete, the applicant will be notified as quickly as possible via the email address on the application form.

Queries in respect of application requirements or communications relating to applications submitted can be made by telephone to +353 1 676 4971, or email to sap@hpra.ie.

Fees: Fees are detailed in the 'Guide to Fees for Scientific Animal Protection', which can be found on the HPRA website. Applications that are not accompanied by the appropriate fee will not be validated.