

Guide to Applications for Breeder/Supplier/User Authorisations 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.



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1 SCOPE

This guidance is intended to assist applicants in completing the HPRA 'Application for authorisation of breeder/supplier/~~user establishment authorisation users~~ under scientific animal protection legislation' form, which must be submitted as part of the breeder/supplier/user establishment authorisation process. The legislation governing this process is Directive 2010/63/EU (the Directive) and S.I. No. 543 of 2012, as amended by S.I. No. 434 of 2013, [S.I. No. 174 of 2014](#), [S.I. No. 552 of 2016](#) and S.I. No. ~~474~~[553 of 2014](#)~~2018~~ (hereafter referred to as the Regulations). This legislation aims to improve the welfare of animals used in research, and promote the application of the principles of the 3Rs - replacement, reduction and refinement.

In accordance with Article 20(1) of the Directive and Regulation 35 of the Regulations, an establishment associated with the breeding, supply or use of animals for scientific purposes must be registered with, and authorised by, the competent authority.

In accordance with Article 20 of the Directive and Regulation 42 of the Regulations, a renewal of a breeder/supplier/user authorisation is required for any significant change to the structure or the function of a breeder/supplier/user if that significant change could negatively impact on animal welfare. ~~..~~ [A renewal can also be applied for upon expiry of an existing authorisation.](#) An amendment of a breeder/supplier/user authorisation is required if there is any change in the persons designated as compliance officer, animal care and welfare officer, [information officer](#), training officer or designated veterinarian or expert.

2 INTRODUCTION

Breeder/supplier/users must be authorised by the HPRA and this authorisation is the central control point without which it will not be possible to apply for a project authorisation or an individual authorisation. In particular, the compliance officer is a key figure who bears ultimate responsibility for compliance with scientific animal protection legislation.

Authorised ~~breeders/suppliers~~breeder/supplier/user establishments are subject to regular [HPRA](#) inspections to ensure that they are operating to the required animal welfare standards, are complying with the conditions of their authorisation(s) and the requirements of the scientific animal protection legislation. The frequency of inspections will be based on a risk assessment strategy with a number of inspections of establishments being conducted on an unannounced basis.

To gain a breeder/supplier/user authorisation, the breeder/supplier/user application form must be submitted together with an up-to-date site master file (SMF) outlining the relevant information pertaining to the breeder/supplier/user. ~~Guidance~~[Separate advice](#) on the ~~preparation content and construct of an~~ [site master file is outlined in the HPRA 'Guide to Preparation of a Site Master File \(SMF-is\) for Breeder/Supplier/Users under Scientific Animal Protection Legislation'](#), available at www.hpra.ie/publications.

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3 DEFINITIONS

Refer to Appendix I for relevant definitions relating to the application form.

4 APPLICATIONS FOR A BREEDER/SUPPLIER/USER AUTHORISATION

This form should be completed by the compliance officer(s) as defined in Article 20(2) of the Directive and Regulation 44 of the Regulations. This person(s) is legally responsible for ensuring compliance with the conditions of the breeder/supplier/user authorisation and for governing procedures, personnel, premises and equipment at the establishment of the breeder/supplier/user.

5 SECTION A - BREEDER/SUPPLIER/USER AND PERSONNEL ESTABLISHMENT DETAILS

Additional details on some of the terms used are given below.

5.1 Establishment locations

Note that in the context of establishment locations, the word 'establishment' is defined as 'any installation, building, group of buildings or other premises and may include a place that is not wholly enclosed or covered and mobile facilities'.

Establishment locations are the locations at which the breeder/supplier/user wishes to be authorised to conduct activities. The names and addresses of all establishment locations (various sites) where breeder/supplier/user activities are conducted must be listed here. This specific section should be copied and pasted as many times as is necessary to include all establishment locations. For each separate establishment location, the nature of the activities conducted (i.e. breeding/supplying/using), along with the relevant species should be stated. ~~Please ensure to number each establishment location when completing the form.~~

If approved, the breeder/supplier/user authorisation document will specify all establishment locations where ~~breeder breeding~~breeding/supplying/using is authorised to take place. Therefore, please ensure that all establishment locations are listed as any establishment locations omitted from the application will not be authorised.

Detailed information on all establishment locations where breeding/supplying/using takes place must also be included in the SMF. Separate advice on the content and construct of the site master file is available in the HPRA 'Guide to Preparation of a Site Master File (SMF) for Breeder/Supplier/Users under Scientific Animal Protection Legislation'.

5.2 Establishments with no locations

Where a breeder/supplier/user establishment does not have an animal facility itself but acts as a coordinator for projects, for example projects undertaken at commercial farm level, or at additional locations that do not have their own breeder/supplier/user authorisation, it will be necessary to be authorised as a 'user'. This is to ensure, following inspection of the records kept at the user establishment, that:

- responsibilities for project conduct, compliance and follow-up are exercised,
- quality management systems are maintained,
- training and competence assessment of personnel involved is assured, and
- the ~~overall safety and~~ welfare of animals involved in ~~the~~ procedures and projects undertaken is ~~assured~~protected.

In these cases ~~only 'user', 'User only'~~ should be selected ~~in relation to and~~ the ~~activities conducted~~relevant species included.

5.2 Personnel details

6 SECTION B - PERSONNEL DETAILS

The Directive and the S.I. refer to specific requirements for personnel at the breeder/supplier/user establishment who are named in the various roles described in Articles 20(2), 24 and 25 of the Directive and Regulations 44, 45, 45A, 46 and 48 of the Regulations. Details on each of the responsible personnel must therefore be provided. Note that an amendment to the breeder/supplier/user authorisation must be obtained from the HPRA for any change in the persons designated as compliance officer, animal care and welfare officer, information officer, training officer or designated veterinarian or expert under this section.

5.36.1 Compliance officer

Information on the person responsible for ensuring compliance of the breeder/supplier/user establishment with the provisions of the Directive as defined in Article 20(2) and the Regulations as defined in Regulation 44 should be provided. This person will be legally responsible for ensuring compliance to the conditions of the breeder/supplier/user authorisation and for governing procedures, personnel, premises and equipment.

This person should ensure that those conducting procedures, managing projects and/or performing euthanasia of animals kept at or used by the breeder/supplier/user have the necessary individual and project authorisations from the HPRA and the necessary resources, knowledge, training and supervision to exercise their responsibilities appropriately.

In some cases, breeder/supplier/users may have more than one designated compliance officer (the application form allows for up to three to be named). This information should be captured in the application form, and the appropriate contact details for each of the compliance officers should be included in the application. It should be clear in the SMF whether there is a hierarchy in relation to compliance officers, or where compliance officers have varying responsibilities.

5.46.2 Designated veterinarian or suitably qualified expert

In accordance with Article 25 of the Directive and Regulation 48 of the Regulations, each breeder/supplier/user must have available a designated veterinarian or suitably qualified expert, with relevant expertise in laboratory animal medicine and/or appropriate qualifications in this field. This person is required to provide advice and information in relation to animal welfare, care and ~~care~~veterinary matters.

The curriculum vitae as it relates to the professional education and training of the designated veterinarian or suitably qualified expert must be provided with the application. The Directive requires that veterinarians dealing with laboratory animals have specialist expertise in that area. This is interpreted as having a higher degree of skill or knowledge than that of a general veterinary practitioner in the same discipline. Such individuals are expected to have successfully completed advanced supervised training in the discipline and have passed examinations from an approved institution. Veterinarians dealing with non-laboratory species used for scientific purposes are also expected to have additional expertise appropriate to their role. It is expected that persons currently in that post that do not have specific additional expertise will proactively address the position. Where a breeder/supplier/user depends on a local veterinary practice to attend to the animals involved, it will be necessary to nominate a lead veterinary practitioner from the practice concerned to be the designated veterinarian.

The breeder/supplier/user will be expected to have a contract in place with the practitioner that specifies how the responsibilities for animal wellbeing/welfare required by the legislation are to be/being undertaken and how that veterinarian will provide input to the animal welfare body. The naming of a designated veterinarian in the application form does not preclude that a breeder/supplier/user has made provision for the services of locum or assistant veterinarians to meet the 24/7 care and animal treatment requirements. However, the designated veterinarian or suitably qualified expert is expected to have oversight and awareness of all issues which affect research animals and he or she bears/they bear ultimate responsibility under the legislation for the veterinary care of research animals at that breeder/supplier/user establishment. The DV may delegate any of his or her responsibilities, but information on any delegation of responsibility must be clearly outlined in the SMF.

Where an application for a breeder/supplier/user authorisation is in respect of wild animals, birds or fish or for farms not owned or managed on behalf of the breeder/supplier/user, it will still be necessary to identify a designated veterinarian or suitably qualified expert in the application form. This person is the individual charged with advisory duties in relation to the

~~wellbeingwelfare~~ and treatment of the animals concerned. Again, local arrangements with veterinary practices for animal treatment do not obviate the requirement that the authorisation holder must designate a veterinarian or suitably qualified expert who has overall responsibility for advising on the ~~wellbeingwelfare~~ and treatment of the animals and inputting his or her advice and recommendations to the animal welfare body.

5.56.3 Animal care and welfare officer

Article 24(1a) of the Directive and Regulation 45 of the Regulations require each breeder/supplier/user to designate at least one person to have overall responsibility for overseeing the welfare and care of animals kept or used. ~~—~~This person is also required to form part of the animal welfare body membership (Article 26(2) and Regulation 50(1)(a)).

If they so wish, breeder/supplier/users may designate more than one animal care and welfare officer ~~(the application form allows for up to three to be named but additional persons can be included in an appendix).~~ In each case the appropriate contact details for each of the animal care and welfare officers should be included in the application. The SMF should provide details about what facility each ACWO is responsible for if the establishment includes multiple animal facilities.

In respect of users that do not have their own animal facility, they should ensure that someone working with the animals is designated in this capacity, whether directly employed by the user establishment or not. ~~This~~If not directly employed, this individual would be expected to have a contractual relationship with the user and to be a member of the animal welfare body ~~of the user.~~

The curriculum vitae as it relates to the professional education and training of the person ~~responsibility~~responsible for the welfare and care of animals must be provided with the application.

~~The staff number of the individual named is required in order to avoid confusion in the case that there are two persons with the same name at the breeder/supplier/user establishment.~~

6.4 Information officer

Article 24(1b) of the Directive and Regulation 45A of the Regulations require each breeder/supplier/user to have a person responsible for ensuring that the staff dealing with animals have access to information specific to the species housed in the establishment. This includes information on animal care and husbandry, animal welfare and the 3Rs, EU and national legislation and guidance, external information and publications on best practice, and information on new initiatives and practical advancements in relation to the species. This role should not work in isolation but in cooperation with other roles and should be complementary to the work of the AWB.

If they so wish, breeder/supplier/users may designate more than one information officer. In each case the appropriate contact details for each of the information officers should be included in the application.

The curriculum vitae as it relates to the professional education and training of the person(s) responsible for the ensuring access to species-specific information in the establishment must be provided with the application.

5.66.5 Training officer

Article 24(1c) of the Directive and Regulation 46 of the Regulations require each breeder/supplier/user to have a person responsible for ensuring adequate education, competency and continuous training of staff. For new staff members, a supervisory period is necessary until requisite competency has been demonstrated.

In the case of large breeder/supplier/users, this individual is expected to be a manager who may delegate specific training and supervisory tasks for particular procedures to technicians, health-care professionals or other experts. However, even when the tasks are delegated, it is up to the named individual to ensure that the system for ensuring the competence of all personnel engaged in the procedures is adequate and adequately monitored, and that staff knowledge and training is maintained up-to-date.

If they so wish, breeder/supplier/users may designate more than one training officer ~~(the application form allows for up to three to be named but additional persons can be included in an appendix).~~ In each case the appropriate contact details for each of the training officers should be included in the application.

In the case of breeders/suppliers/users that do not have their own animal facility, the training officer has the responsibility to ensure that those carrying out procedures, managing projects and euthanising animals have the necessary capacity and competency to do so expertly and professionally. The curriculum vitae as it relates to the professional education and training of the training officer(s) should be provided with the application.

~~The staff number of the individual named is required to avoid confusion in the case that there are two persons with the same name at the breeder/supplier/user.~~

67 SECTION BC - ANIMAL WELFARE BODY

This section relates exclusively to the animal welfare body. The scientific animal protection legislation requires an animal welfare body to operate in each breeder/supplier/user establishment, in accordance with Article 26 and Regulation 50. The animal welfare body shall consist of at least the animal care and welfare officer(s) and in the case of a user, at least one scientist. In practice therefore, there must be at least two members of the animal welfare body in each breeder/supplier/user establishment. The designated veterinarian or suitably qualified

expert may or may not be a member (preferably ~~he or she~~they will be), but at the very least, ~~he or she~~they must provide input to the animal welfare body and this input must be documented and available on request during inspection. The HPRA recommends that the animal welfare body should contain sufficient members to allow for expert input, proper understanding and a fruitful discussion of the issues. The duties of the animal welfare body are set out in Article 27 of the Directive and Regulation 50(2) of the Regulations.

Information on each member appointed to the animal welfare body should be provided along with a clear outline of their role in the animal welfare body.

~~There is sufficient space in the application form to include the details of up to ten members of the animal welfare body.~~

~~For some breeder/supplier/users, the animal welfare body may be linked to the ethics committee. If this is the case, the relationship between the two bodies should be described in the site master file.~~

78 SECTION CD - SITE MASTER FILE

This section refers to the site master file that must accompany each breeder/supplier/user application as required by Regulation 36(2)(h) of the Regulations. The function of a site master file is to provide the HPRA inspector with:

- an introduction to the breeder/supplier/user and its activities,
- an indication that appropriate animal care and welfare monitoring systems are in place,
- an indication that the principles of the 3Rs (replacement, reduction and refinement) are being applied,
- an indication that an appropriate quality management system is present, and
- information about the site's previous audit history and record of compliance.

The site master file will contain specific and factual information about the main activities carried out at all the establishment locations of the breeder/supplier/user, the quality management system in operation, and the lines of control and responsibilities exercised by the personnel of the breeder/supplier/user. The site master file is the means by which the HPRA is provided with details relating to the premises, equipment and procedures and must be kept up-to-date.

Separate guidance on the format and content of the site master file for breeder/supplier/users authorised under scientific animal protection can be found at www.hpra.ie/publications.

89 SECTION DE - DECLARATION AND UNDERTAKING

The declaration and undertaking must be signed by the person(s) indicated in section 5.26.1 above, i.e. the compliance officer(s) under scientific animal protection legislation. By signing the document, this person(s) is assuming legal responsibility for undertaking all the conditions set out in the declaration and in the authorisation. If multiple compliance officers are listed, signatures are required from each compliance officer.

910 MAKING AN APPLICATION

A valid application for a breeder/supplier/user authorisation consists of the following:

- Breeder/supplier/user establishment application form, duly completed and signed
- Site master file
- CVs which demonstrate the relevant qualifications and training of the:
 - o compliance officer(s)
 - o designated veterinarian or suitably qualified expert
 - o animal care and welfare officer(s)
 - o information officer(s)
 - o training officer(s)
- ~~— Cover letter (where relevant)~~
- ~~— Appendix (where relevant)~~

~~Signed copies of all application forms must be submitted to the HPRA through submission of a hard copy or scanned original document.~~

1011 DURATION OF AUTHORISATION

Once a breeder/supplier/user authorisation is granted it is valid for a maximum period of 3 years and is subject to renewal thereafter.

1112 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 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 sapssubmit@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~~

~~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, ~~fax, or~~ e-mail ~~or by post to the address above:~~

Tel: +353 1 676 4971

Fax: +353 1 676 7836

E-mail: scientificanimalprotection@hpra.ie

E-mail: sap@hpra.ie

Fees:

Currently there are no fees for this application. However, authorised breeder/supplier/user establishments are currently subject to annual fees. Please see the 'Guide to Fees for Scientific Animal Protection', which can be found under the SAP Guides and Forms section at www.hpra.ie.

APPENDIX 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.

Breeder – any natural or legal person breeding animals referred to in Annex I of 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.

Procedure – any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or 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. This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition, but excludes the killing of animals solely for the use of their organs or tissues.

Project – a programme of work having a defined scientific objective and involving one or ~~multiple~~more procedures.