HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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.

CONTENTS

1 SCOPE

This guidance is intended to assist applicants in completing the HPRA 'Application for authorisation of breeder/supplier/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 (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 suitably qualified 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 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 proportion of inspections 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. Separate advice on the content and construct of the SMF is outlined in the HPRA 'Guide to Preparation of a Site Master File (SMF) for Breeder/Supplier/Users under Scientific Animal Protection Legislation', available on the HPRA website, under Regulation and Scientific Animal Protection (at www.hpra.ie/regulation/scientific-animal-protection/guidance-documents).

3 DEFINITIONS

Refer to Appendix 1 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.

The HPRA endeavours to complete the assessment of breeder/supplier/user applications within 90 calendar days. It should be noted that this timeline does not include the time taken for the receipt and validation of the applications by the HPRA. Applications are not validated as eligible for HPRA scientific animal protection (SAP) assessment until all necessary documentation has been provided. Furthermore, the time taken by applicants to respond to any queries raised or satisfactorily address outstanding non-compliances (e.g. from inspection cases) is not part of the assessment timeline (the system 'stops the clock' on applications for the duration of the period when satisfactory responses to queries are awaited).

5 SECTION A - BREEDER/SUPPLIER/USER 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.

If approved, the breeder/supplier/user authorisation document will specify all establishment locations where breeding/supplying/using is authorised to take place. Therefore, all establishment locations must be 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.

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 welfare of animals involved in procedures and projects undertaken is protected.

In these cases, 'User only' should be selected and the relevant species included.

6 SECTION B - PERSONNEL DETAILS

The Directive and the Regulations 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/suitably qualified expert under this section.

Specific training requirements apply for the roles outlined in sections 6.2 to 6.5 of this guide, and these can be found in the European Commission's common education and training framework located on the Publications office of the European Union website (at https://op.europa.eu/en/).

6.1 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 as defined in Regulation 44 of the Regulations should be provided. This person will be legally responsible for ensuring compliance with the terms and conditions of the breeder/supplier/user authorisation and for governing procedures, personnel, premises and equipment.

The compliance officer 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.

6.2 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 (DV) 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 expertise in relation to animal welfare, care and veterinary matters.

The curriculum vitae (CV) as it relates to the professional education and training of the DV 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 DV, and this person must meet EC training requirements.

The breeder/supplier/user will be expected to have a contract in place with the practitioner that specifies how the responsibilities for animal welfare required by the legislation are to be/being undertaken and how that veterinarian will provide input to the animal welfare body (AWB). The naming of a DV 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 DV or suitably qualified expert is expected to have oversight and awareness of all issues which affect research animals, and 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 DV or suitably qualified expert in the application form. This person is the individual charged with advisory duties in relation to the welfare 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 name a DV or suitably qualified expert who has overall responsibility for advising on the welfare and treatment of the animals and inputting their advice and recommendations to the AWB.

6.3 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 (animal care and welfare officer). This person is also required to form part of the AWB 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 officers (ACWO). In each case the appropriate contact details for each of the ACWO(s) 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. If not directly employed, this individual would be expected to have a contractual relationship with the user and to be a member of the AWB.

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

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 (information officer). 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 CV 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.

6.5 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 (training officer).

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. 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 training and competency to do so expertly and professionally. The CV as it relates to the professional education and training of the training officer(s) should be provided with the application.

7 SECTION C - ANIMAL WELFARE BODY

The scientific animal protection legislation requires an AWB to operate in each breeder/supplier/user establishment, in accordance with Article 26 of the Directive and Regulation 50 of the Regulations. At a minimum, the AWB shall consist of the ACWO(s) and in the case of a user, at least one scientist. In practice therefore, there must be at least two members of the AWB in each breeder/supplier/user establishment. The DV or suitably qualified must provide input to the AWB, with the HPRA strongly advising they are an active member. The DV's input must be documented and available on request during inspection. The HPRA recommends that the AWB should contain sufficient members to allow for expert input, proper understanding and a fruitful discussion of the issues. The duties of the AWB are set out in Article 27 of the Directive and Regulation 50(2) of the Regulations and further information can be found in the European Commission Guidance on animal welfare bodies and national committees, located on the Publications office of the European Union website (at https://op.europa.eu/en/publication-detail).

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

8 SECTION D - SITE MASTER FILE

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

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

The SMF 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, including the legally designated personnel as referenced in section 6 above. The SMF provides the HPRA with details relating to the premises, equipment and procedures and must be kept up to date. It is also used as a reference by the HPRA inspectorate.

Separate guidance on the format and content of the SMF for breeder/supplier/users authorised under scientific animal protection can be found on the HPRA website, under Regulation and Scientific Animal Protection.

9 SECTION E - DECLARATION AND UNDERTAKING

The declaration and undertaking must be signed by the person(s) indicated in section 6.1 of this guide, 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 terms and conditions set out in the declaration and in the authorisation (if granted). If multiple compliance officers are listed, signatures are required from each compliance officer.

10 MAKING AN APPLICATION

10.1 Checklist

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

- Breeder/supplier/user establishment application form, duly completed and signed

- SMF
- CVs which demonstrate the relevant qualifications and training of the:
  - compliance officer(s)
  - designated veterinarian or suitably qualified expert
  - animal care and welfare officer(s)
  - information officer(s)
  - training officer(s)

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

10.2 Naming convention

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

- Application form: to be used for the application form
- SMF: to be used for the site master file
- CVCO: to be used for the compliance officer's CV
- CVDV: to be used for the DV's CV
- CVACWO: to be used for the animal care and welfare officer's CV
- CVIO: to be used for the information officer's CV
- CVTO: to be used for the training officer's CV
- CV2: to be used for the deputy project manager's CV (where applicable)

Note: where there are multiple people appointed to a role, the subsequent CVs should be numbered, e.g. CVACWO; CVACWO2, CVACWO3, etc.

- Appendix (where applicable)
- Cover letter (where applicable)

The following table shows an example of how the files should be named for a hypothetical breeder/supplier/user application:

DOCUMENT	FILE NAME
Breeder/supplier/user application form	EAN_Application form
The SMF	EAN_SMF
The compliance officer's CV	EAN_CVCO
The second compliance officer's CV *(if relevant)*	EAN_CVCO2
The DV's CV	EAN_CVDV
The animal care and welfare officer's CV	EAN_CVACWO

DOCUMENT	FILE NAME
The information officer's CV	EAN_CVIO
The training officer's CV	EAN_TO
Cover letter	EAN_Cover letter

10.3 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. 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. For further information nominated persons can email cesp@hma.eu.

Applications can also be submitted by standard email to the HPRA at sapsubmit@hpra.ie.

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 breeder/supplier/user applications submitted can be made by telephone to +353 1 676 4971 or email at sap@hpra.ie.

10.4 Fees

Currently there are no fees for this application. However, authorised breeder/supplier/user establishments are currently subject to annual fees. Please see the 'HPRA Guide to Fees for Scientific Animal Protection', which can be found on the HPRA website under Regulation and Scientific Animal Protection.

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 more procedures.

Suitably qualified expert – A designated person charged with advisory duties in relation to the well-being and treatment of the animals.