VETBIONET

Veterinary Biocontained facility Network for excellence in animal infectiology research and experimentation

Deliverable D4.4

VetBioNet Guidance on Implementation of the 3Rs and EU Animal Experimentation Directive

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Executive Summary

The VetBioNet infrastructure project is focusing on innovation in animal infectious diseases research. An important aspect of the networks work is to explore some of the cross-cutting issues that related to both the members responsibilities and how animal research is conducted.

An important aspect of the Network is to explore the application of the 3Rs and relate this to the implementation of EU Directive 2010/63/EU in order to enhance further knowledge-sharing and provide guidance on VetBioNet's partner communities response to and support for the further development of EU national regulations and policies.

This document (Deliverable 4.4) draws together a number of issues related to the Directive 2010/63/EU and sets outs activities conducted across the VetBioNet network to a support work that related to the Implementation of the 3Rs and EU Directive 2010/63 on the Protection of Animals used for Scientific Purposes. To effectively achieve reflection, practice and implementation, five distinct but not mutually exclusive activities were undertaken:

1. Development of a 3Rs resource database;
2. Development of a 3Rs events calendar;
3. An overview and update on the implementation of Directive 2010/63/EU;
4. Development of a series of National Legislation Information Sheets;
5. Animated short films on the project's website explaining research ethics in this field
6. Analysis of the recent review of the implementation of the Directive 2010/63/EU and identification of issues for the VetBioNet infrastructure network

In addition to these activities, a key aspect of the implementation of the Directive has been related to training provision. A number of new collaborative education initiatives have been recently launched (e.g. ETPLAS), however, some of these activities are focused at the strategy level, developing overarching guidance, so it is important to develop and provide specific training that supports areas of research while maintain pan-European standards that can support harmonization across Europe. As such VetBioNet will deliver two further 3Rs and Experimental Design Training School in 2021/2022. These training Schools, delivered in partnership with 3Rs organisations, on "Ethics, 3Rs and Experimental Design Training" and will be Federation of European Laboratory Animal Science Associations (FELASA) accredited to further support pan-European harmonisation.

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All of these activities are conducted with broad and targeted input from the VetBioNet partners. This document also outlines some of the issues that relate to VetBioNet work going forward. Further work will be included in activities and discussion of key issues related to recommendations for improvements in implementation of 3Rs initiatives and knowledge sharing will be further taken up in the work of VetBioNet.

VetBioNet Team involved:

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1. Introduction

Within the VetBioNet infrastructure project, focusing on innovation in animal infectious diseases research, one of the key objectives is to review and support the application of the 3Rs and relate this to the implementation of EU Directive 2010/63/EU in order to enhance further knowledge-sharing and provide guidance on VetBioNet's partner communities response to and support for the further development of EU national regulations and policies. This document (Deliverable 4.4) draws together several activities conducted to address this objective and as such serves as a support document highlighting guidance on Implementation of the 3Rs and EU Directive 2010/63 on the Protection of Animals used for Scientific Purposes (https://ec.europa.eu/environment/chemicals/lab_animals/legislation_en.htm).

To effectively achieve the objective, five distinct but not mutually exclusive activities were undertaken:

1. Development of a 3Rs resource database;
2. Development of a 3Rs events calendar;
3. An overview and update on the implementation of Directive 2010/63/EU;
4. Development of a series of National Legislation Information Sheets;
5. Animated short films on the project's website explaining research ethics in this field [1]

All of these activities are conducted with broad and targeted input from the VetBioNet partners. This document outlines each of these activities and discusses their importance and makes related recommendations for improvements in implementation of 3Rs initiatives, knowledge sharing and understanding of national legislation in relation to the implementation of Directive. The recommendations relate to issues specific to infectious disease research, but the majority are applicable to the wider animal research community.

Within the European Union the use of animals in scientific research is governed by Directive 2010/63/EU. Directive 2010/63/EU came into force on 22 September 2010 and replaced the original 1986 Directive 86/609/EEC on the protection of animals used for scientific purposes. When the Directive was updated it firmly enshrined the principles of the 3Rs (Replacement, Reduction and Refinement), ethics review, and enhanced transparency, into the core of the legislation (See Annex 1). The scope was widened to include mammalian foetuses in their last trimester of intrauterine development and cephalopods as well as animals used for the purpose of higher education

[1] https://www.vetbionet.eu/watch-the-new-vetbionet-videos-on-youtube/. (Accessed 09/12/2020)

and training. Clinical veterinary practice, animal health monitoring and field trials for the registration of veterinary medicines are excluded from the scope of the Directive. Furthermore, the use of non-human primates was further restricted, and the exemptional use of stray/wild animals was further defined.

The development and application of the revised Directive (2010/63/EU; https://ec.europa.eu/environment/chemicals/lab_animals/legislation_en.htm) has three key objectives:

- to ensure efficient functioning of the EU internal market and enhance competitiveness and innovation of the EU research, both public and privately funded, through the creation of a level playing field;
- to ensure high standards of welfare for animals still used for scientific purposes; and
- to improve transparency to the public on the use of live animals for scientific purposes in the EU.

This aim to improve transparency reflects that in recent years there has been increasing focus on openness and transparency agendas in relation to animal experimentation (Williams, 2017). Openness contrasts starkly to the secrecy that for many decades has been claimed to surround animal experimentation. A secrecy that appears to be linked to a lack of trust across the significant positions regarding laboratory animal use. Animal researchers argued that forms of concealment are necessary for security reasons – following decades of extremist and sometimes violent animal-rights activity, whereas anti-vivisectionists frame the secrecy as a way to conceal activities that are unethical or cruel – as evidenced by a number of exposés (McLeod 2018). However, as the instances of extremism have declined the animal research community has increasingly begun to identify with transparency and openness as a key means of improving public acceptance of animal experiments and overcoming misinformation (Jump 2014).

Indeed, transparency is recognised as key to developing and maintaining public trust (Curry 2018) and as a means of demonstrating an institution or organisation is more ethical, more honest or more trustworthy (Worthy 2018), although it is acknowledged it can also pose severe difficulties for scientists particularly in this era of widespread access to and interaction with social media (Lewandowsky and Bishop 2016). Research institutes have supported initiatives and have developed approaches to greater transparency, such as the implementation of the Basel Declaration (Basel Declaration Society, 2011) and development of the ARRIVE guidelines

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(Kilkenny et al, 2010). A number of these have been initiated within specific country settings but have had implications for the European research community. These initiatives, although not resulting from the drafting and implementation of EU Directive, are nonetheless part of the same movement to embed good practice principles, collaboration and great harmonization across the research community.

An important change within in the new Directive which is both a reflection of changing practice and as well as a driver of change in itself is the increasing prominence and more specific targeted and documented application of the 3Rs. The concept of the 3Rs; Replacement, Reduction and Refinement was originally introduced by Russell and Burch in 1959. They argued for a more humane approach to scientific research involving animals through the principles of: **Replacement** – of methods which use conscious living vertebrates with any scientific method employing non-sentient material; **Reduction** - of the number of sentient animals used in each experiment or for a specific purpose; and **Refinement** – to reduce to an absolute minimum the amount of distress imposed on those animals that are still used (Russell and Burch 1959). In recent times the definitions of the 3Rs have evolved slightly to reflect current scientific and ethical thinking and have become integral to the regulation of animal experimentation around the world which is explicitly written into Directive 2010/63/EU. As well as being a legal requirement to apply the 3Rs in all animal research, documented and reflective application of the 3Rs it is particular important practice in the field of infectious disease research. As Hobson-West (2009) has presented the value of 3Rs approach is characterized through three conceptualizations of its value, either as:

- An ethical concept setting out a moral imperative or alternatively as a process for managing ethical dilemmas that arise in research involving animals;
- A scientific concept that relates to experimental design and ensuring the validity of the scientific method
- A political concept that may present a way to promote consensus in a controversial domain.

Given the potentially severe nature of many of the animal models for the study of infectious diseases and sometimes limitations on housing, husbandry and care imposed by high biocontainment, finding innovate ways to apply the 3Rs principles to infectious disease research is essential to ensure good practice and high ethical standards are maintained.

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The agenda for the development of regulation-related and 3Rs resources was set at the Year 2 meeting (in UK). This has been informed by the suggested priorities and key issues for the network members that were collected through the e-survey (using an e-voting system and anonymised feedback) at the roundtable meeting in Brussels and the Year 2 annual meeting in UK. These consultation events established a number of priorities for the 3Rs and Directive activities that are set out in the later section 2. Further roundtable discussion was facilitated at the VetBioNet Annual Meeting in Spain. All of this input supported the analysis that has resulted in the development of the tools and exchange of knowledge that is intended to support harmonization and the work of the VetBioNet partners and the wider research community.

The aim of this paper is therefore to provide a brief update on the implementation of the Directive and signpost key issue to support the identification of useful resources and/or information to assist with understanding, applying and complying with the regulations and implementing the 3Rs that relates to the Directive. Therefore before setting out the activities, tools and issues relevant for the field of animal health research, key aspects of the Directive are set out in Section 2.

2. Legislation Overview and Update

The aim of this section is to provide a brief update on the implementation of Directive 2010/63/EU and signpost any useful resources and/or information to assist with understanding, applying and complying with the regulations to support the objectives of the VetBioNet project and its stakeholders.

2.1. Directive Review

Directive 2010/63/EU was fully introduced on 1 January 2013 and like all EU legislation included a requirement for a review, which had to be completed by 10 November 2017 (Article 58). The aim of the review was to assess the progress towards the three key goals of the Directive.

The review process began with targeted stakeholder consultations during 2016 involving the user community (those who breed, supply or use animals), Member State authorities and other EU-level stakeholder organisations. To promote a balanced response, national animal welfare organisations were also invited to contribute. Unfortunately, due to the relatively early timing of the review and the Directive's partly delayed transposition into some Member States national legislations there is only limited experience of the implementation of the new regulations. Therefore, the review focussed on assessing the impacts of the Directive based only on preliminary findings. However, the limited data available did highlight some useful and interesting points which are summarised here. The review report (European Commission 2017a) and the associated Commission Staff Working Document (European Commission 2017b) provide the full details.

Overall the review found that the Directive's framework is generally considered to be a sound foundation for the protection of animals used for scientific purposes. There are indications that the impact of the Directive varies among Member States. However, this is largely due to the greater differences in national legislation prior to transposition and implementation of this Directive.

Olsson *et al* (2016, p. 356), investigated the implementation of the Directive prior to the official review and found that '*Overall when an issue is clearly described in sufficient detail in the Directive, with little room for different interpretations, transposition is likely to produce similar standards across the different member states*' for example, the very specific minimum standards for laboratory housing and care. However, they also propose that: '*Harmonisation, on the other hand, is likely to be less successful when the Directive is less specific and when implementation relies on infrastructures that are highly variable and for which little common regulation exists*' (Olsson *et al* 2016, p. 356), with the considerable diversity between Member States as regards their approach to project evaluation and authorisation being a prime example of when the Directive has provided detailed guidelines on what should be covered by an evaluation but not how it should be undertaken. Respondents to the consultation for the review identified that some aspects of the Directive are developing and working well, such as the Animal Welfare Bodies (AWBs), which are positively contributing to the improvement of animal use and care practices. Other positive effects include raising standards in research practice, improved 3Rs awareness, promotion of culture of care, growing recognition of the link between animal welfare and good science, and increasing transparency. In contrast there have been some areas highlighted as requiring further attention, including the efficiency and consistency of project evaluation (although EU guidance on this was generally well distributed by most Member States) and authorisation processes, as well as access to, and quality of information on the use of animals and the availability of alternatives.

In terms of the designated veterinarians and other veterinarians involved, there is some concern that their role and tasks are not sufficiently clear in some countries, such that limited returns on costs could be incurred. However, veterinarians with expertise in laboratory animal medicine are having a significant impact in animal welfare oversight and the education and training of other staff. Furthermore, the inclusion of the designated veterinarian on AWBs is viewed as particularly valuable and an advisory role is mandatory. A number of professional societies[2] support the further development of laboratory animal medicine and such building a supportive community of practices is a key aspect of the effective implementation of the Directive.

[2] The European Society of Laboratory Animal Veterinarians (ESLAV) http://eslav-eclam.org/eslav and European College of Laboratory Animal Medicine (ECLAM) https://eclam.eu/ . (Accessed 09/12/2020)

Education and training is an area where useful insight was gained. Benefits of education and training stipulations include: better model selection, better experimental design, better animal health and welfare, better recognition of pain, distress and suffering, and better understanding of animal behaviours and needs. Although the legal requirements focus on competence for a variety of tasks and responsibilities (including animal care, and setting up procedures as well as competence in carrying out procedures (Art. 23 2010/63/EU), however, it was reported that there is considerable variation between Member States exist regarding requirements on competence of personnel, with many users unaware of EU guidance on training. There are also some challenges with regards recognition and implementation of the role of 'person responsible for the provision of species-specific information' (art 24). The review report recommends that efforts should be made by all relevant stakeholders to improve availability and access to, and variety of, training opportunities essential for obtaining the requisite competences in different knowledge areas, techniques and species.

Many Member States have increased their activities in promoting alternatives e.g. increasing research funding, development of 3Rs centres, supporting educational events and other information dissemination efforts. In the last five years further funding has been invested by the EC to support the use of alternatives, such as funds (approx. 1 million euros) made available by European Parliament (EP) to develop knowledge sharing activities to promote alternatives to animal use[3].

However, four key issues were identified that are hindering more rapid uptake of alternatives (European Commission 2017a):

1. lack of knowledge;
2. insufficient communication/dissemination of information;
3. acceptability and;
4. cost

The issues of acceptability relates to not all alternative methods having been validated for relevance, robustness or reproducibility which is a significant barrier to uptake. The concern about a lack of knowledge of alternatives is also related to a lack of visibility. Users also highlighted the need for easier searching methods, and better availability of information on alternatives as well as requesting experts to help find information on alternatives relevant to their field of work. The report calls for increased efforts to improve awareness of available applicable alternatives – interpreted in the widest

[3] EU Parliament-funded (Pilot Project [Agreement No: 07.027741/2018/794340/SUB/ENV.B2]). (Accessed 09/12/2020).

sense to include Replacement, Reduction and Refinement of animal use – and appropriate training and tools to facilitate their efficient use by all involved in the process.

The Directive has a specific focus on non-human primate (NHP) use in science, in particular it will only allow (after an appropriate transition period) the use of NHPs that are the offspring of animals bred in captivity or that are sourced from self-sustaining colonies.

The current deadline for this requirement is November 2022 as set out in Directive Annex II. Article 10 of the Directive stipulates a feasibility study be conducted to assess the deadline and propose amendments where necessary. The key findings of the feasibility study are published in the review report, which concludes that the dates set in Annex II do not need to be altered. The report also draws on the conclusions of the *SCHEER Report on the need for non-human primates in biomedical research, production and testing of products and devices* (SCHEER 2017; for more details see below) to note that no phasing-out timetable for the use of NHPs will be proposed at this stage.

The overall conclusion of the review is that no amendments to the Directive are proposed at this stage. However, the Staff Working Document contains several recommendations for different stakeholders to take up, as appropriate, with the common aim of improving the attainment of Directive objectives. In terms of further progress reviews, the data on the practical implementation of the Directive by Member States was due in 2018. In addition, National statistical data were published for the first time in 2015, but trends of animal use at EU level only became available in 2019 and Information on retrospective assessments of projects will become available from 2019. Therefore, a full REFIT (Regulatory Fitness and Performance) evaluation of the Directive will be undertaken after 2019 when better information is available and sufficient time has lapsed for the Directive's implementation to enable assessment of any changes in welfare and use practices.

2.2. Guidance Documents

To aid Member States with implementing the Directive the European Commission published several guidance documents, two of which are mentioned above. These documents are freely available to download[4] and in all the official languages of the EU, there are also posters to accompany them. The guides were developed with key stakeholders to help all parties involved or interested in animal research in their different roles to apply the principles of Directive 2010/63/EU correctly.

[4] European Commission Animals used for Scientific Purposes website at: http://ec.europa.eu/environment/chemicals/lab_animals/pubs_guidance_en.htm (accessed 09/12/2020).

The guidance documents cover the following topics:

- Animal Welfare Bodies and National Committees
- Education and Training Framework
- Inspections and Enforcement
- Project Evaluation and Retrospective Assessment
- Severity Assessment Framework

In addition to the Commission guidance some individual Member State authorities have produced their own advice. For example, approaches have been set out in the UK and The Netherlands.

In the UK the Home Office Animals in Science Regulation Unit (ASRU) has worked with stakeholders and relevant experts to develop a series of Advice Notes to help UK scientists to correctly interpret and implement the UK legislation (the Animals [Scientific Procedures] Act 1986), which resulted from the transposition of Directive 201/63/EU. The advice notes are available to download on the UK Government website[5] and cover the following topics:

- Household products testing ban advice note
- Guidance on the use of human material in animals
- Use, keeping alive and re-use advice note
- Harm-benefit analysis advice note
- Re-homing and setting free advice note
- Working with animals taken from the wild advice note
- Code of practice for the care and accommodation of animals
- Efficient breeding of genetically altered animals
- Severity classification of genetically altered animals
- Recording and reporting the actual severity of regulated procedures

The Netherlands National Committee for the protection of animals used for scientific purposes has published guidance documents (also in English)[6] on the following topics:

- Indicators, management and utilisation of data for monitoring laboratory animal use and 3R alternatives, part 1
- Genetically modified animals killed in stock
- Transition to non-animal research – About the possibilities for phasing out animal procedures and stimulating innovation without laboratory animals
- Rehoming of former laboratory animals
- Alternative methods for killing laboratory animals

[5] UK Animal research: technical advice website at: https://www.gov.uk/guidance/animal-research-technical-advice (accessed 0612/2020). (Accessed 09/12/2020)
[6] https://english.ncadierproevenbeleid.nl/ (Accessed 09/12/2020)

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- Preventing, recognizing and combating pain in laboratory animals
- Synthesis of Evidence in laboratory animal research
- Indicators, management and utilisation of data for monitoring laboratory animal use and 3R alternatives, part 2
- Procedures using cats or dogs
- Motivation by restriction? Starting points for controlled fluid and food intake in neurocognitive research from a 3Rs perspective,
- Genetically modified animals. Died or killed before use in breeding programmes or animal procedures - Part - 2 Quality criteria

Furthermore, the Council on Animal Affairs (advisory to the Minister of Agriculture, NL) has published advice on animal research for the livestock sector[7] .

The need for further information on legislation and key regulatory has been raised as a key issue for the VetBioNet partners and the development of this information is discussed below with the availability of VetBioNet member country specific guidance in the National Legislation Information Sheets described below (Section 3).

2.3. SCHEER Opinion

As noted previously the European Commission referred to *The Scientific Committee on Health Environmental and Emerging Risks (SCHEER) Final Opinion on the need for non-human primates in biomedical research, production and testing of products and devices* (SCHEER 2017) in the review of the Directive. SCHEER was requested by the European Commission to review recent evidence to update the 2009 Opinion of the same name. This updated Opinion responds to six main issues in the mandate and highlights the many scientific approaches that could significantly contribute to the replacement, reduction and refinement (3Rs) of Non-Human Primates (NHP) studies and tests. However, the SCHEER members and a panel of external experts from a range of backgrounds concluded that:

> '*there are significant issues that go beyond scientific rationale that prevent widespread adoption and development of alternatives for NHP laboratory use and these are discussed with suggestions of the opportunities to overcome them*.'

They also noted that '*although the current state of knowledge does not permit to propose a timetable for phasing-out the use of NHPs in Europe, the Opinion provides recommendations on how to advance 3Rs for NHP use, such as through alternative methods, training, improvement of techniques and protocols, sharing of knowledge and removal of barriers*' (SCHEER 2017, p.2). When reviewing the national statistics it is interesting to note,

[7] https://english.rda.nl/publications/publications/2019/3/20/animal-procedures-for-the-livestock-sector. (Accessed 09/12/2020)

that the core justification for the use of NHPs is that they model directly for the human species in a way that is not possible with other models and approaches. However with reference to the interests of the VetBioNet partners, animal disease research is typically done with target animal species and some model species, but not NHP as their use relates to human biology and medicine and is not justifiable or needed in this particular field.

2.4. Changes to the Statistics on Animal Use

With the revision of the Directive there has also been a modernisation of the requirements regarding recording and reporting information on animal use in scientific research. Article 54(2) of Directive 2010/63/EU requires that '*Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures…*'.

In May 2012 the Commission published a common format for submitting the required information, Commission Implementing Decision 2012/707/EU (European Commission 2012). Annex II of the Decision describes the categories for which annual statistics should be collected and provides more details for some of the categories to aid understanding and accuracy. 2014 was the first year in which Members States had to collect animal use data in this revised format and they were required to publish them in 2015 and every year thereafter.

This harmonise approach to animal use data collection and the annual reporting is a valuable resource. In order to support the VetBioNet members it was suggested, by the VetBioNet Advisory Board and a number of members, that some coordinate information on national mechanisms and figures would be helpful. This was proposed to be in the form national information sets with information on how to access information on structures, processes and contacts. There a set of Legislation Information Sheets (described below Section 4) have been developed to provide information on availability and on how to access the annual statistics for each of the VetBioNet member countries. The Commission was required to publish the compiled EU data for the first time in November 2019 and then every three years following this. The *2019 Statistical Report COM (2020) 16/1* and the accompanying *Commission Staff Working Documents* can be accessed on the European Commission Animals used in Scientific Procedures website[8]

[8] European Commission Animals used for scientific purposes website at: https://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm (accessed 09/12/2020).

The new data are not directly comparable with the previous EU Statistics (2011 and before). There have been several changes with introduction of new categories as well as new species (cephalopods) that have significantly changed the scope of the reporting obligations. Some of the important changes to note include collecting details for the actual severity for all procedures. To facilitate this detailed information on all uses of animals must be reported (including re-uses) rather than only the first use and the data are for procedures completed as opposed to procedures started.

In addition to the inclusion of cephalopods, information on free-feeding larval forms (e.g. tadpoles) and for genetically altered animals is now collected. Reporting of genetically altered animals is further broken down into animals which show a harmful phenotype (i.e. a harmful physical defect) and animals which do not show a harmful phenotype. Greater detail is collected on the place of birth of non-human primates. For the first time, information is collected on whether non-human primates were wild caught or captive bred. For captive bred non-human primates, information is also collected on the number of generations that they have been purpose bred in captivity, or if they were born in a closed breeding colony. There is also more detail about the specific legislation involved in regulatory testing. Further information on individual Member States' statistical reports and in some cases additional guidance on the collection and reporting process can be accessed through the European Commission website[9].

Following, the Commission Implementing Decision 2012/707/EU has been replaced by the MISSION IMPLEMENTING DECISION (EU) 2020/569 of 16 April 2020 establishing a common format and information content for the submission of the information to be reported by Member States pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes and repealing Commission Implementing Decision 2012/707/EU. This document sets common formats for both statistical reporting and Non-Technical Summaries for licensed projects and forms the legal basis to implement provides a central, open access EU database for the publication of this documentation starting 20121. This will provide broad access to information relevant for professionals, policy makers and public alike.

[9] European Commission Animals used for scientific purposes website at: https://ec.europa.eu/environment/chemicals/lab_animals/member_states_stats_reports_en.htm (Accessed 09/12/2020)

2.5. National Committees

Under Article 49 of the new Directive each Member State had to establish a National Committee for the Protection of Animals Used for Scientific Purposes. The National Committee is responsible for advising the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice. They are also required to exchange information on the operation of animal-welfare bodies and project evaluation and share best practice within the Union. Contact details and in most cases website links for each Member State National Committee are available on the European Commission website[10].

The Directive review Staff Working Document (European Commission 2017b) indicated that the establishment of National Committees and their ability to fulfil their role has been problematic in many Member States. The structure, membership, responsibilities and activities of National Committees vary significantly among Member States as do the resources made available to perform their functions. In response to these concerns the reviewers recommended that:

> '*Urgent focus is needed by National Committees on their key task to establish a coherent approach to project evaluation in particular in Member States with multiple competent authorities tasked with project evaluation.*
>
> *The Commission services, Member States and National Committees should engage in discussions to develop appropriate tools for this purpose*' (p. 43).

And that;

> '*Member States should facilitate and resource National Committees where this is not yet established, or where it is not fully functional, to ensure that its role and tasks are fulfilled as these tasks play key roles in the attainment of the overall objectives of the Directive*' (p. 68).

However, the review also noted that there are some National Committees that are flourishing with the development of guidance material and the creation of networks with and sharing practices among Animal Welfare Bodies (AWB's). For example, the National Committee in the UK (the Animals in Science Committee) has developed AWB Regional Hubs to facilitate information exchange and identification of best practice.

[10] European Commission Animals used for scientific purposes website at: https://ec.europa.eu/environment/chemicals/lab_animals/nc_en.htm (Accessed 09/12/2020)

2.6. Animal Welfare Bodies

In Articles 26 and 27, Directive 2010/63/EU sets out the mandatory establishment of Animal Welfare Bodies (AWBs) for each breeder, supplier and user of research animals. As noted above the requirement for AWBs has been welcomed by Member States, users and stakeholder organisations. The AWBs are largely seen as having a significant positive impact on improving the culture of care, animal welfare and in some cases scientific quality. Where concerns have been raised these involve issues with expertise, resources and having sufficient authority. As mentioned above the Commission has provided guidance on the composition and functioning of the AWBs (European Commission 2014) and the review indicates that most users found this to be useful. Considering the Directive review the Commission also recommend the following in relation to AWBs:

- Establishments and Member States (through inspection) should ensure that all core tasks of the AWB are being fulfilled.
- Member States should clarify roles and responsibilities of the AWB and project evaluation, in particular where there may be some integration or overlap with following the development of projects, including application of the Three Rs and project evaluation process.
- Senior management of the establishment should ensure that the AWB has sufficient resources and empowerment to carry out the required tasks.
- Establishments could consider the addition of the Designated Veterinarian as a full member of the AWB.

2.7. PARERE Network

Under Article 47(5) of Directive 2010/63/EU '*Member States shall nominate a single point of contact to provide advice on the regulatory relevance and suitability of alternative approaches proposed for validation*'. The Preliminary Assessment of REgulatory RElevance (PARERE) Network links all these contact points together.

The Network is hosted by the Union Reference Laboratory for Alternatives to Animal Testing - EURL-ECVAM under Directorate-General Joint Research Centre of the European Commission. The details of the ministry or department and the relevant person that act as the PARERE contact point in each Member State are provided on the European Commission website[11].

Further information on the role of the Network, the representatives to PARERE and its meetings and operations can be found on the ERUL-ECVAM website[12].

[11] European Commission Animals used for Scientific Purposes website at: http://ec.europa.eu/environment/chemicals/lab_animals/parere_en.htm (Accessed 09/12/2020)
[12] European Commission EU Science Hub; EU Reference Laboratory for alternatives to animal testing website at:

3. Development of Resources related to the 3Rs and Legislation

In recent years two European Commission Reports, Holley *et al* (2016) and European Commission (2017a), have found that significant improvements in the communication of information on 3Rs resources and the development of alternatives are needed. To focus attention on the availability and utilisation of 3Rs knowledge sources, the Joint Research Centre (JRC) created an inventory of knowledge sources[13] and are now undertaking a study to provide an initial overview of 3Rs education and training opportunities being offered at university and professional levels[14].

There are currently a number of initiatives that are developing and delivering resources in order to respond to the broader animal research community needs. However, in response to the implementation of the Directive, the outcomes of the review of the Directive and the more specific needs of the VetBioNet members, a set of mixed format tools and resources have been developed as part of the VetBioNet work for this deliverable.

These set of tools and resources are:

- 3Rs Knowledge Resources
- 3Rs Networking Resources
- 3Rs Events Calendar
- 3Rs Knowledge Exchange Activities
- National Legislation Information Sheets
- Development of further training opportunities

This activities are discussed below.

https://eurl-ecvam.jrc.ec.europa.eu/about-ecvam/scientific-advice-stakeholders-networks/parere/parere-network (Accessed 09/12/2020)

[13] European Commission Joint Research Centre Data Catalogue; Inventory of 3Rs knowledge sources website at: http://data.jrc.ec.europa.eu/dataset/jrc-eurl-ecvam-eurl-ecvam-3rs (Accessed 09/12/2020)

[14] European Commission EU Science Hub; Mapping education and training on the 3Rs website at: https://ec.europa.eu/jrc/en/science-update/education-and-training-3rs (Accessed 09/12/2020)

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3.1. 3Rs Knowledge Resources

There are now a notable number of 3Rs resources and tools that exist and some are very usable with the Commission and national bodies highlighting key resources [15], however some resources are uncoordinated, under-utilised and suffer from a lack of sharing and communication within and between different sectors and communities. More importantly these resources can be generic and not tailored to the needs of specific research communities, such the area of animal infectious diseases. In addition, as 3Rs methods become increasingly available, resources are constantly changing, and new ones are becoming accessible on a regular basis.

In order to help VetBioNet members and the wider scientific community particularly working in animal infectious disease to stay abreast of important 3Rs knowledge and resources, a new and evolving VetBioNet 3Rs Networking Resource has been developed to support the members work.

This is now available on the VetBioNet website. The resources have been mapped and evaluated and are available to download individually from the VetBioNet website and an excel spreadsheet is also available for reference.

3.2. 3Rs Networking Resource

This 3Rs Networking Resource provides information on 3Rs organisations and networks including; location, links, contact information and a summary of applicable activities. A second section details 3Rs Tools that are available online including relevant; databases, training material, guidelines, applications and journals. The resource is designed to be searchable and dynamic. It will be updated on a regular basis (bi-annually; March and September) and any direct contributions are more than welcome.
The resource can be accessed here: http://www.vetbionet.eu/3rs-network-and-tools-database/.

3.3. 3Rs Events Calendar

A further approach to support and improve the uptake of approaches and communication of information on the 3Rs is attendance at scientific events. Therefore, an events calendar has been compiled, which brings together relevant information on sector specific conferences, workshops, symposia

[15] Useful resources listed and linked on the European Commission's web page: https://ec.europa.eu/environment/chemicals/lab_animals/index_en.htm (Accessed 09/12/2020)

and training (but not accredited training, see ETPLAS[16] for this) which focus on disseminating developments in Replacement, Reduction and Refinement.

At present the events covered are international but with a significant emphasis on European locations, with the calendar currently spanning to 2022. When available, links to event websites and registration information is included. The calendar is intended to be a dynamic resource and will be updated at least bi-annually (March and September). Every effort has been made to find as many relevant events as possible and to include information that relates to events that have moved from face-to-face due to the challenges of COVID-19 restrictions. The Members are regularly encourage to add to the list and suggestion events.

The calendar can be accessed on the VetBioNet website[17] here: https://www.vetbionet.eu/wp-content/uploads/2019/12/VetBioNet-Resource2-Event-database-VER3-@26-11-19.xlsx. Other online resources have also been added to this list to support the Members who are able to travel to attend events.

3.4. 3Rs Knowledge Exchange Activities

In order to support the exchange of topical and current information related to the 3Rs, training and Directive relate-policy developments. In order to highlight interesting specific developments and activities to the members a series of news articles have been produced which have been published in the VetBioNet newsletter and on the website.

Specifically the news items published to date are:

- Newsletter Item (1) New 3Rs Centres;
- Newsletter Item (2) Harm-Benefit Analysis;
- Newsletter Item (N3) 3Rs Centres;
- Newsletter Item (4) 3Rs training events;
- Newsletter Item (5) Refinement Resource;

[16] Education and Training Platform for Laboratory Animal Science – ETPLAS Website at: https://www.etplas.eu/index.php?id=4325 (Accessed 09/12/2020)

[17] VetBioNet calendar of events: https://www.vetbionet.eu/wp-content/uploads/2019/12/VetBioNet-Resource2-Event-database-VER3-@26-11-19.xlsx. (Accessed 09/12/2020)

- Newsletter Item (6) University of Nottingham Hosts VetBioNet Experimental Design Training Course in January 2019;
- Newsletter Item (7) Review of humane endpoints application;
- Newsletter Item (8) Positive outcomes from VetBioNet/FRAME Training School;
- Newsletter Item (9) Paper on need to fully Implement the 3Rs.

3.5. National Legislation Information Sheets

Members of the VetBioNet have identified that even basic information on individual Member States' animal research legislation and related project evaluation and ethical review can be very fragmented and difficult to find and access. This inability to identify the correct processes and requirements can create time delays and potentially barriers to free movement of researchers, tissues and samples and to multi-site project collaboration.

To address this issue and to meet the aim of delivering Guidance on the implementation of the Directive a series of Legislation Information Sheets have been produced.

The aim of the each of the National Legislation Sheets is to provide a one-stop quick reference guide to each European VetBioNet partner country's legal requirements for animal research, including an outline of the project evaluation process, where to find useful guidance documents and related information (e.g. annual statistics), and important contact details and websites.

Creating National Legislation sheets across a number of countries requires the mapping and analysis of significant documents in national languages. Therefore drawing from and expanding previous work that has become out of date, the National Sheets have been adapted from, as well as expand upon, reports of the were produced by the EC funded ANIMPACT project (European FP7 grant agreement no. 602616), with kind permission of Dr Anna Olsson, Coordinator of ANIMPACT.

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Each Sheet has been reviewed and verified for accuracy by a relevant member of VetBioNet. However in order to ensure that the National Sheets remain relevant for the members, all sheets will be reviewed and updated annually. With further use the sheets will also be adapted and added as Members identify any additional needs. The National Legislation sheets that have been developed are:

- Denmark
- France
- Germany
- Ireland
- Italy
- The Netherlands
- Poland
- Spain
- Switzerland
- UK

Table 1 provides a summary of the available Information Sheets with indications of the information provide. The full documents (see final section of each Sheet for verification status) are included here in Appendix 1. The National Sheets are also provided on the VetBioNet website as downloadable pdf files.

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Table 1	Summary of National Legislation Information Sheets									
Information Available	Country									
	CH	DE	DK	ES	FR	GB	IE	IT	NL	PO
National Law	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Regulation & Authorisation Process	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Licensing Process	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Project Evaluation: 1. Geographical Organisation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2. Evaluators	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3. Project Submission	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4. Fees	x	✓	✓	✓	x	✓	✓	✓	✓	✓
5. Guidelines for Project Evaluation	✓	x	x	x	x	✓	✓	x	✓	x
6. Follow-Up of Projects' Authorisation	x	✓	✓	✓	✓	✓	✓	✓	✓	✓
Published National Information:										
1. Annual Statistics	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2. Competent Authority Report	x	x	x	x	x	✓	x	x	✓	x
3. Non-Technical Summaries	x	✓	✓	✓	✓	✓	✓	✓	✓	✓
Official Contact Points and Websites	x	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 1: Summary of 10 National Legislation Information Sheets

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3.6. Development of further training opportunities

As identified in the review of the Directive 2010/63/EU, further provision and improved access to, and variety of, training courses is needed. VetBioNet committed to deliver a Training School on "Ethics, 3Rs and Experimental Design" as part of the programme of work and this was delivered in January 2019 by the UNOTT team, in collaboration with VetBioNet Members and external 3R partners. This Training School was very well received (see reporting D5.6).

Although under the Directive the responsibility for competencies is held at the Member State level, the development of training guidance and material is an important collaborative activity for the community of professionals across Europe regarding animals (to be) used for scientific purposes. New initiatives such as the Education and Training Platform for Laboratory Animal Science (ETPLAS) represent an important step in improving training provision. Some initiatives are focused at the strategy level, developing overarching guidance, so it is important to develop and provide targeted training that supports specific areas of competence while implementing pan-European standards that can support harmonisation across Europe and also the mobility of qualified personnel.

For this reason and with the recognition of the importance of training within the impact assessment of the Directive 63/2010/EU, VetBioNet has committed in the later phase of the VetBioNet work to provide further training with relevance for this field. In order to further support the application of the 3Rs as part of the work of VetBioNet, two further 3Rs and Experimental Design Training School have been planned for 2021 /22. These training Schools will deliver "Ethics, 3Rs and Experimental Design Training" and will be Federation of European Laboratory Animal Science Associations (FELASA) accredited to support pan-European harmonisation. This should provide further opportunities to support VetBioNet activities to apply the 3Rs principles and good practice approaches in experimental design.

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4. Recommendations for further VetBioNet activities and knowledge sharing

Building on the analysis, drawing on the desk-based components and the discussion across a series of events within the network, a series of issues have been identified for further reflection and that can form the focus of additional activities within time of the funded network and in the longer term. In addition, some of the worked conducted for the deliverable will be taken forward and supported within the network activities in order to update resources, build on VetBioNet members experiences of working within and supporting the development of the regulatory framework.

In terms of the current resources, the following activities will be maintained and extended:

- In order to the support the exchange of information, the 3Rs resource database which is hosted in VetBioNet website will be further updated;

- In order to identify opportunities to exchange information and further network with colleagues within the laboratory animal science and infectious disease community, the 3Rs events calendar which is hosted on VetBioNet website will be further updated;

- The team responsible for this deliverable will further update the VetBioNet community on any new developments in the Directive 2010/63/EU or in national activities that relate to implementation;

- The series of National Legislation Information Sheets will be reviewed and update in 2021

- The role of media resources such as the animated short films, will be reviewed and additional resources will posted on the project's website

- Further developments in policy-related the revision of or implementation of the Directive will be shared with the members through the VetBioNet newsletter and annual meetings.

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To further identify aspects that can be taken forward and support the overarching objectives of the VetBioNet work, a series of specific and additional activities will be run as part of the networks activities. These activities build on the outcomes of the report, highlighting the key aspects, and will further focus on knowledge sharing and activities that can support harmonization approaches. Specifically the work will be taken forward in the following activities:

- Providing a VetBioNet opportunity to exchange approaches to Transparency and Open Science in Infectious Disease Research. This activity will look at the new non-Technical Summary requirements under the new amendment to the Directive as well as examples of Transparency and VetBioNet members experiences of transparency approaches. This will also explore the quality of public information

- Working with the WP1 team and the researchers who have conducted trans-national access project, the challenges and value of the regulatory approval system will be reviewed. This activity should help to identify some of the ways in which further international and EU mobility can be supported.

- A forum for the exchange of Animal Welfare Bodies (AWB) approaches and the role of the Ethical Review Process (ERP) will be organized. This will further explore the value and the challenges of separating the AWB and ERP process. This will be linked to the work to create 'Safe Spaces' for examination of objectives, process and practice in animal infectious disease research (also see Deliverable 4.6)

- Highlighting the need to build on activities that need to complement the legal requirements and boundaries of the implementation of the Directive, VetBioNet will organize an event to examine the need to support "Culture of Care" approaches. This will be linked to the work to create 'Safe Spaces' for examination of objectives, process and practice in animal infectious disease research (also see Deliverable 4.6)

- This work will be taken forward with the provision of further training on the 3Rs. Two additional 3Rs and Experimental Design Training School will be organized and run in 2021 /22.

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6. APPENDIX 1

How Directive 2010/63 drives best practices, 3Rs alternatives and transparency regarding the protection of animals (to be) used for scientific purposes.

6.1. Best practices

Are regulated for all animal husbandry and care in all licensed establishments, important elements are:

- Species and life forms protected (Article 1)
- Methods of killing (Article 6)
- Extra restrictions on the use of non-human primates, animals from the wild, endangered species, feral and stray animals (Articles 7 to 9 and 11)
- The requirement that listed species are purpose bred in licensed establishments (Article 10)
- Sharing biomaterials (Article 18)
- Setting free or rehoming of animals (Articles 19 and 29)
- Requirements for the authorization of establishments (Article 20), including named officers (Articles 24 and 25) and institutional Animal Welfare Body (Articles 26 and 27)
- Requirements for installations and equipment for animal accommodation (Articles 22 and 33)
- Competence of personnel tasked to take care of animals and/or to set up or carry out animal procedures (Article 23)
- Identification of animals and record keeping (Articles 30 to 32)
- The functioning of a National Committee for the protection of animals used for scientific purposes in each Member State (Article 49)

6.2. 3Rs

Are regulated for all scientific uses of animals, important elements are:

- Threshold severity to define a procedure under the Directive (Article 1)
- The principles of Replacement, Reduction and Refinement
- Purposes listed (exclusively), Article 5 (general) and Article 8 (non-human primates)
- Choice of methods to minimize animal use (Article 13) and animal suffering (Articles 13 and 14)
- Classification of severity of procedures (Article 13) for the purposes of project license application evaluation (Articles 37 to 39), retrospective assessment (Article 39) and statistical reporting (Article 54), but also for limiting re-uses of animals (Article 16), competence

of personnel (Articles 23 and 24), animal welfare oversight (Articles 24 to 27)
- Provisions for alternatives replacing animal uses, to use tissues instead (Articles 1 and 18), development of such alternative methods by members states (Article 47) and by the Union Reference Laboratory (Article 48).

6.3. Transparency

Is regulated for all scientific uses of animals and breeders/suppliers, important elements are:

- The publication of a Non-Technical Summary of a project when licensed (Article 43)
- The supplementation of the NTS with the outcome of retrospective assessment (Article 39)
- Harmonized annual statistical reporting on animals used, the purposes of the work and severity outcomes (Article 54, implementing decision 2020/569/eu)
- Periodic reports on breeding programs of genetically altered animals (implementing decision 2020/569/eu)

6.4. Impact

These elements together provide for high animal welfare standards and promote a culture of care within establishments. The assessment of severity of procedures is highly instrumental to promote the refinement of procedures. Internal animal welfare management is empowered by the furthering of competence of personnel, the establishment of Animal Welfare Bodies and the requirement of a designated veterinarian. Public sources of information on animal uses for scientific purposes have been greatly enriched, European databases to be implemented in 2021.

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7. APPENDIX 2: National Legislation Information Sheets

7.1 COUNTRY: DENMARK

7.2 COUNTRY: FRANCE

7.3 COUNTRY: GERMANY

7.4 COUNTRY: IRELAND

7.5 COUNTRY: ITALY

7.6 COUNTRY: THE NETHERLANDS

7.7 COUNTRY: POLAND

7.8 COUNTRY: SPAIN

7.9 COUNTRY: SWITZERLAND

7.10 COUNTRY: UNITED KINGDOM

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7.1 COUNTRY: DENMARK

Animal Research Legislation Information Sheet

COUNTRY: DENMARK

1. IMPLEMENTATION OF DIRECTIVE 2010/63/EU

The Directive was transposed into national legislation with a new law; The Executive Order of the Animal Testing Act (Bekendtgørelse af lov om dyreforsøg), available at: https://www.retsinformation.dk/Forms/R0710.aspx?id=162938.

The legislation is implemented by the Ministry of the Environment and Food.

2. REGULATION AND AUTHORISATION PROCESS: MAIN ACTORS

2.1 Ministry: Ministry of Food, Agriculture and Fisheries (Veterinary and Food Administration).

2.2 Competent authority: Ministry of Food, Agriculture and Fisheries (Veterinary and Food Administration).

2.3 Entity responsible for the project authorisation: Animal Experiments Inspectorate (AEI) is the national entity under the Ministry of Food, Agriculture and Fisheries, constituted by a Secretariat and the Board of/Council for Animal Experiments. The secretariat, which is responsible for the day-to-day keeping of the AEI, comprises 5 employees (Head of secretariat, two academic staff members, head clerk and one student). The Board/Council manages the AEI.

3. LICENSING PROCESS

Two tier licensing system:

1. Permits to carry out experiments involving animals
2. Permission to breed and deliver experimental animals

Permits and permissions are issued by the AEI. An application for a permit for animal testing shall be submitted to the Animal Research Inspectorate. Application is via an online system: https://dyreforsoegstilsynet.fvst.dk/Pages/default.aspx.

4. PROJECT EVALUATION ACCORDING TO ARTICLE 38 OF DIRECTIVE 2010/63/EU

4.1 Geographical organization of the project evaluation process
The evaluation is conducted at a national level, by the Council for Animal Experiments, a national committee under the AEI. The applications are assessed at the council meetings where it is decided whether the application is approved or needs elaboration.

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4.2 Evaluators

The evaluation is conducted by Council for Animal Experiments. Amendments to permissions may be accepted by the secretariat if they do not substantially differ from what the Council has accepted. The applications are prepared by the Secretariat and analysed by the Council.

4.2.1 Evaluators' characterization

The Council consists of eleven experts from relevant subject areas. The council members are appointed by the Minister of Environment and Food. The head of the council is required to be a judge. In addition, one council member is appointed after consulting the Danish Council for Independent Research for Medical Sciences, one member is appointed after consulting the Danish Council for Independent Research for Technology and Production Sciences, one member is appointed after consulting the Danish Health Authority, one member is appointed after consulting the Confederation of Danish Industry, one member is appointed after consulting the disease fighting NGOs, one member is appointed after consulting The Danish Animal Ethics Council and four members are appointed after consulting the Animal Welfare Organizations. The council members are appointed for four years.

The Council composition and member details are available on the AEI webpage at: https://www.foedevarestyrelsen.dk/english/Animal/AnimalWelfare/The-Animal-Experiments-Inspectorate/Pages/default.aspx.

4.3. Project submission

The protocols are submitted using an online application system, AIRD, available at: https://dyreforsoegstilsynet.fvst.dk/Pages/default.aspx (the applicants must request access to the system to create and submit the application).

Various guidelines for submitting applications including how to use the online system are available in Danish on the Danish AEI website here: https://www.foedevarestyrelsen.dk/Dyr/dyrevelfaerd/Dyreforsoegstilsynet/Sider/Ansoegning-og-indberetning.aspx. Some of these guidelines will soon be available in English on the English AEI website at: https://www.foedevarestyrelsen.dk/english/Animal/AnimalWelfare/The-Animal-Experiments-Inspectorate/Pages/pplying_for_permits_and_reporting_statistics.aspx.

4.4. Fees

The fee for to obtain a license for animal experiments is 1, 2.500DKK is payable. For each of the following commenced years, and additional 500kr must be paid. Information on the fees can be found in the legislation (in Danish) here: https://www.retsinformation.dk/Forms/R0710.aspx?id=162938.

4.5. Guidelines for project evaluation

Besides what is described in the legislation, there are no specific guidelines for the Council on how to conduct the project evaluation.

4.6. Follow-up of projects' authorisation (i.e. inspections, retrospective review, etc.)

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The AEI also conducts the inspections [the Council members often participate in the inspections] and is responsible for the follow-up of the projects' authorisation.

5. PUBLISHED NATIONAL INFORMATION ON ANIMAL USE

5.1. Annual Statistics on Animal Use

Extensive data in English and commentary in Danish (only for 2016) for 2014-onwards available here: https://www.foedevarestyrelsen.dk/Dyr/dyrevelfaerd/Dyreforsoegstilsynet/Sider/Statistik.aspx. Statistics with English commentary are available upto 2016 (currently) at: https://www.foedevarestyrelsen.dk/english/Animal/AnimalWelfare/The-Animal-Experiments-Inspectorate/Pages/Statistics_and_our_annual_report.aspx.

5.2. Competent Authority Report

The AEI no longer publish an annual report.

5.3. Non-Technical Summaries

Non-technical summaries available from 2013 onwards (no search function) in Danish on the Minsitry Website here: https://dyreforsoegstilsynet.fvst.dk/PublishedApprovals/Pages/default.aspx#/.

6. OFFICIAL CONTACT POINTS AND WEBSITES

Competent Authority Website: https://www.foedevarestyrelsen.dk/english/Animal/AnimalWelfare/Pages/default.aspx

National Contact Point: Christin Lia, Email: chrli@fvst.dk

National Committee Website: The National Committee for the Protection of Animals used for Scientific Purposes: https://www.foedevarestyrelsen.dk/english/Animal/AnimalWelfare/The_National_Committee_for_the_Protection_of_Animals_used_for_Scientific_Purposes/Pages/default.aspx

National Committee Contact: Chair: Christine Lydia Nelleman, Email: Cne@food.dtu.dk

PARERE Network Contact: Environmental Protection Agency, Marie Louise Holmer, Email: mlh@mst.dk

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This document was created by Dr Michelle Hudson-Shore with the assistance of Prof Kate Millar and Joshua Cantrell, University of Nottingham with assistance from VetBioNet colleagues.

If you have any comments, or suggestions for updating or improving this document please contact Dr Hudson-Shore at: michelle.hudson-shore@nottingham.ac.uk or kate.millar@nottingham.ac.uk

VERSION 2

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This information sheet was adapted and updated from reports of the ANIMPACT project (European FP7 grant agreement no. 602616) produced in 2017 (which are available here: http://animpact.eu/news-publications/wp3-results) with kind permission of Dr Anna Olsson, Coordinator of ANIMPACT. Dr Olsson can be contacted at: olsson@ibmc.up.pt.

7.2 COUNTRY: FRANCE

COUNTRY: FRANCE

1. IMPLEMENTATION OF DIRECTIVE 2010/63/EU

The regulation in France (articles R214-87 to R214-137 of the French rural code) has been updated by the 2013-118 decree and five orders from February 1st 2013, published on February 7th, according to the 2010/63 directive from the EU. This regulation is under the responsibility of the French Ministry of Agriculture. The amended legislation is available at: https://www.recherche-animale.org/sites/default/files/c_rural_2013.pdf.

2. REGULATION AND AUTHORISATION PROCESS: MAIN ACTORS

2.1 Ministry: Ministry of Higher Education, Research and Innovation
2.2 Competent authority: Inspecteur de santé publique vétérinaire Référente nationale expérimentation animale (Veterinary public health inspector National referent animal experimentation)
2.3 Entity responsible for the project authorisation: Ministry of Higher Education, Research and Innovation.

3. LICENSING PROCESS

Two tier licensing system:

1. Authorisation to experiment on live animals is required (Project authorisation)
2. All breeding centres, suppliers and users must have authorisations (conformity of the buildings and of the employees' expertise)

The Ministry of Higher Education, Research and Innovation issues project licences. For further information see the Ministry website (in French) here: http://www.enseignementsup-recherche.gouv.fr/cid70597/l-utilisation-des-animaux-a-des-fins-scientifiques.html.

4.1 Geographical organization of the project evaluation process
The project evaluation is done on at a national level by a dedicated secretariat within the departments of the Ministry of Higher Education and Research, which is responsible for centralizing project authorization applications, registering them and sending them, after verification of their completeness and compliance, to the local ethics committees concerned. It also collects the corresponding opinions and the issuance of project authorizations. The project must have a favourable ethical evaluation conducted by the local ethics committee in order to be authorised.

4.2 Evaluators
The Minister responsible for research grants project authorisations. The ethical evaluation of projects is carried out by the Ethics Committee in Animal Experimentation/Ethics Committee for Animal Testing under which the user establishment falls.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N°731014

4.2.1 Evaluators' characterization
Ethic committees evaluate every research project that uses animals. The French Rural code sets the mission, structure and function of ethic committees. A favourable ethical evaluation is necessary to obtain authorization for the project to be carried out. The committees are created at the establishment's suggestion and approved by the Minister in charge of research. A committee must be composed of a minimum of five people with various competences, including a person with competence in the field of the design of experimental procedures about animals; a person with competence in the field of carrying out experimental procedures about animals; a person with skills in at least one of the following areas (animal care, killing of animals); a veterinarian; a person not specialized in matters relating to the use of animals for scientific purposes. These people cannot participate in a deliberation in which they would have an interest, at the risk of invalidating the decision. Links to the Regional Ethical Committees can be found here: http://ethique.ipbs.fr/creea.html and a pdf list here: http://cache.media.enseignementsup-recherche.gouv.fr/file/utilisation_des_animaux_fins_scientifiques/22/1/comiteethiqueea17_juin2013_257221.pdf.

4.3. Project submission
Authorisation requests are registered directly online via a specific computer application; Project Authorization using Animals for Scientific Purposes or (APAFiS). For access to the system (requires a login) users should contact the head of their establishment.

For further information or to apply without using the electronic system contact:

Secretariat Project Authorization at: autorisation-projet@recherche.gouv.fr.

The link to APAFiS and further information is available on the Ministry website at: http://www.enseignementsup-recherche.gouv.fr/cid70597/l-utilisation-des-animaux-a-des-fins-scientifiques.html.

4.4. Fees
No information available.

4.5. Guidelines for project evaluation
There are no specific guidelines for project evaluation but the related regulations are all available at on the Ministry website here: http://www.enseignementsup-recherche.gouv.fr/cid70597/l-utilisation-des-animaux-a-des-fins-scientifiques.html.

4.6. Follow-up of projects' authorisation (i.e. inspections, retrospective review, etc.)
Breeders, suppliers and users are inspected on a regular basis according by joint order of the Ministers responsible for Agriculture and Research and the Minister for Defence.

5. PUBLISHED NATIONAL INFORMATION ON ANIMAL USE

5.1. Annual Statistics on Animal Use
Detailed Excel spreadsheet for 2010 then extensive data with commentary (in French) for 2014-onwards, available here: http://www.enseignementsup-

recherche.gouv.fr/cid70613/enquete-statistique-sur-l-utilisation-des-animaux-a-des-fins-scientifiques.html.

5.2. Competent Authority Report
Not available.

5.3. Non-Technical Summaries
Non-technical summaries available in a browsable format in French from 2013 onwards on the Ministry website here: http://www.enseignementsup-recherche.gouv.fr/cid85210/resumes-non-techniques-des-dossiers-notifies.html.

6. OFFICIAL CONTACT POINTS AND WEBSITES

Competent Authority Website: Not available.

National Contact Point: Sandryne Bruyas, Dr vétérinaire, Email: sandryne.bruyas@agriculture.gouv.fr.

National Committee Website: National Committee for Ethical Thinking on Animal Testing (Comité national de réflexion éthique sur l'expérimentation animale [CNREEA]): http://www.enseignementsup-recherche.gouv.fr/cid70598/l-encadrement-reglementaire-de-l-utilisation-d-animaux-a-des-fins-scientifiques.html

National Committee Contact: Chair: Hélène Combrisson, Email: hcombrisson@vet-alfort.fr

PARERE Network Contact: Ministry for Education and Research, Virginie Vallet-Erdtmann, Email: virginie.vallet-erdtmann@recherche.gouv.fr

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7.3 COUNTRY: GERMANY

Animal Research Legislation Information Sheet

COUNTRY: GERMANY

1. IMPLEMENTATION OF DIRECTIVE 2010/63/EU

The German Animal Welfare Act ("Tierschutzgesetz") was amended and a supplementary regulation, Ordinance for the protection of experimental purposes or other animals used for scientific purposes ("Tierschutz-Versuchstierverordnung") was created. The German Animal Welfare Act and the new regulation are available at: http://www.gesetze-im-internet.de/tierschg/TierSchG.pdf and http://www.gesetze-im-internet.de/tierschversv/TierSchVersV.pdf. The Competent authority is responsible for implementing the Act.

2. REGULATION AND AUTHORISATION PROCESS: MAIN ACTORS

2.1 Ministry: Federal Ministry of Food and Agriculture Animal Welfare Unit (Bundesministerium für Ernährung und Landwirtschaft Referat Tierschutz).
2.2 Competent authority: District Government, Regional Council (Bezirksregierung, Regierungspräsidium)
2.3 Entity responsible for the project authorisation: District Government, Regional Council

3. LICENSING PROCESS

One tier licensing system:

1. project permit for animal testing

Approval is issued by the Regional Council with advice from a local Animal Protection Committee.

4. PROJECT EVALUATION ACCORDING TO ARTICLE 38 OF DIRECTIVE 2010/63/EU

4.1 Geographical organization of the project evaluation process
Before submitting an application the project must be reviewed by the institutional Animal Welfare Officer ["Tierschutzbeauftragter", a designated veterinarian with expertise in laboratory animal medicine who helps in the design of the applications in the requesting research institute]

Project authorisation is regional. The applications must be submitted to the competent authority, i.e. the corresponding office of the Regional Council. Who decides about the applications in each competent authority is regulated by the specific "Land" law and is partly different in the 16 "Lands". Germany has 16 states ("Länder") and each "Land" has public authorities that are responsible for the project authorisation and notification.

For an ethical evaluation of the experiment's purpose, a local animal protection committee/commission works alongside the Regional Council office. The advice of

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the animal protection committee/commission is not binding for the office in charge of the approval.

NOTE: In the field of the Federal Armed Forces, the responsible agencies of the Federal Armed Forces shall be responsible for implementing the Act and the ordinances issued on the basis thereof. The Federal Ministry of Defence shall appoint a commission to assist the competent agencies in deciding whether to authorize planned experiments. The majority of the members of the commission must possess the expertise in veterinary medicine, medicine or any other discipline of natural science needed to assess experiments on animals. The commission shall also include members from nominee lists of animal welfare organizations, with the experience needed to assess animal welfare issues. The competent agency shall inform the commission immediately of all applications for authorization of planned experiments and give the commission an opportunity to give its opinion within a reasonable time-limit. Account shall be taken of the security interests of the Federal Armed Forces. If animal experiments are to be performed by order of the Federal Armed Forces, the commission shall also be notified and be given an opportunity to give its opinion before placing the order.

4.2 Evaluators

The evaluation is conducted by the competent authority (see above for difference if Armed Forces are involved). The Animal Protection Committee/Commission assists the competent authority in the evaluation process. Each relevant authority has its own Commission.

4.2.1 Evaluators' characterization

The majority of the Animal Protection Committee/Commission members must possess the expertise in veterinary medicine, medicine or any other discipline of natural science needed to assess experiments on animals. The commissions shall also include members from nominee lists of animal welfare organizations and with the experience needed to assess animal welfare issues. These members must make up one-third of the commission.

4.3. Project submission

An example of the standard form (in German) can be viewed on the District Government of Upper Bavaria's website here: http://www.regierung.oberbayern.bayern.de/formulare/gesundheit/tier/ or downloaded directly here: https://www.regierung.oberbayern.bayern.de/imperia/md/content/regob/internet/dokumente/formulare/f_bereich5/sg_55-2/fb-tsch-k03-02-v05_genehmigungsantrag_anzeige.doc.

Check Regional Council in which work is to be carried out for correct form and where to submit it.

4.4. Fees

The fees depend on the aim of the institution that applies for project evaluation ("profit vs. "non-profit" aim).

4.5. Guidelines for project evaluation

Not available.

4.6. Follow-up of projects' authorisation (i.e. inspections, retrospective review, etc.)

This responsibility is regulated by the specific "Land" law and is partly different in the 16 "Lands".

5. PUBLISHED NATIONAL INFORMATION ON ANIMAL USE

5.1. Annual Statistics on Animal Use

Extensive data and commentary (in German) is available for 2015 onwards, links to data tables for 2009-2014 are available at the end of each of the 2015 onward reports. Available on the Competent Authority website here: https://www.bmel.de/DE/Tier/Tierschutz/_texte/TierschutzTierforschung.html.

5.2. Competent Authority Report

Not available.

5.3. Non-Technical Summaries

Non-technical summaries available in German from 2013 onwards in a searchable database managed by BfR here: https://www.animaltestinfo.de/.

6. OFFICIAL CONTACT POINTS AND WEBSITES

Competent Authority Website:
https://www.bmel.de/EN/Homepage/homepage_node.html

National Contact Point: Dr Katharina Kluge, Email: 321@bmel.bund.de

National Committee Website: National Committee for the Protection of Animals Used for Scientific Purposes for the Federal Republic of Germany (Nationalen Ausschusses zum Schutz von für wissenschaftliche Zwecke verwendeten Tieren): https://www.bfr.bund.de/en/national_committee.html

National Committee Contact: Chair: Professor Dr Andreas Hensel, Vice chair: Professor Dr Reiner Wittkowski, Email: nationaler-ausschuss-tierschutzgesetz@bfr.bund.de

PARERE Network Contact: ZEBET, Bundesinstitut fur Risikoberwertung ZEBET Alternativmethoden zu Tierversuchen, Email: 94@bfr.bund.de

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7.4 COUNTRY: IRELAND

Animal Research Legislation Information Sheet

COUNTRY: IRELAND

1. IMPLEMENTATION OF DIRECTIVE 2010/63/EU

The directive is transposed into the Irish national law, through the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 (S.I. No. 543 of 2012), available at: http://www.hpra.ie/docs/default-source/3rd-party-documents/si-543-(changed)-of-2012.pdf?sfvrsn=2, with the amendment the European Union (Protection of Animals used for Scientific Purposes) (Amendment) Regulations 2013 (S.I. No. 434 of 2013), available at: http://www.hpra.ie/docs/default-source/3rd-party-documents/si---434-2013.pdf?sfvrsn=2

The implementation of the legislation is overseen by the Health Products Regulatory Authority (HPRA).

2. REGULATION AND AUTHORISATION PROCESS: MAIN ACTORS

2.1 Ministry: Ministry/Department of Health
2.2 Competent authority: The HPRA – Health Products Regulatory Authority
2.3 Entity responsible for the project authorisation: The HPRA – Health Products Regulatory Authority

3. LICENSING PROCESS

Three tier licensing system:

1. Breeder/supplier/user authorisations: if you are intending to breed, supply and/or use animals for scientific or educational purposes
2. Project authorisations: to perform scientific procedures involving the use of animals
3. Individual authorisations: if you are involved in carrying out scientific procedures on animals; acting as a project manager for a project authorisation as well as individuals performing euthanasia of animals

The HPRA issues each of these three authorisations. Guides and forms for each type of authorisation are available on the HPRA website here: https://www.hpra.ie/homepage/veterinary/scientific-animal-protection/authorisations.

4. PROJECT EVALUATION ACCORDING TO ARTICLE 38 OF DIRECTIVE 2010/63/EU

4.1 Geographical organization of the project evaluation process
The formal project evaluation and authorisation is conducted at a national level, by the HPRA – Health Products Regulatory Authority. However, the HPRA encourages a previous evaluation by a local institutional ethical committees. The ethical review might be conducted either by each individual user establishment

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(can be within the Animal Welfare Body [AWB]), or by a committee mandated to act on behalf of a group of user establishments. In the case of the latter, it would be necessary for the ethics committee to have a formal contract in place with the user establishments involved before protocol submission so that the recommendations and conclusions of the ethics committee are binding on the parties concerned. If the local evaluation is included there is no fee for the standard application. There are approximately 20 ethics committees in Ireland.

The Ethics Committees that are responsible for reviewing the proposed use of animals at a local level have a role in ensuring that research conducted at the user establishment is in line with the ethos of that establishment. In the case of certain user establishments, they are also required to support the publication of research outcomes in peer reviewed literature. Ethics committees consider the study design, procedures planned and evaluate situations where there might be a risk that the use of animals could be in conflict with the best welfare interests of the animals involved. They are instrumental in ensuring that the 3R principles (replacement, reduction and refinement) are applied in a meaningful manner. Therefore, they play a key role in ensuring high standards of animal welfare and in assessing the harm-benefit balance of any proposed study. The HPRA wishes to ensure that before new project applications are submitted to the HPRA for mandatory evaluation, that a preliminary ethical review has already been conducted. This is seen to be in the best interests of animal welfare and in the overall efficiency of the process.

4.2 Evaluators

The project evaluation is conducted by the HPRA. However, to complement this assessment, the HPRA encourages prior evaluation by institutional ethics committees (this is encouraged through several measures but is not mandatory). In the HPRA *Guide to Ethics Committee Assessment of Project Applications under Scientific Animal Protection Legislation* (link given below) they state that; "The HPRA is conscious that, as the competent authority under the legislation, it has a duty and legal responsibility to perform its own project evaluations. However, the HPRA understands the value of the role of establishment ethics committees and wishes to encourage their continued involvement into the future." (p.11).

The applicant must provide all documentation required to the HPRA. Administrative personnel check to ensure that the documents supplied are in accordance with the stated requirements. The evaluation is conducted by technical personnel who ensure the Non-technical Project Summary (NTPS) report is correct. The Management Committee of the HPRA (Heads of individual Departments plus the Chief Executive) are the body which are ultimately responsible for all authorisation decisions of the organisation. They are Veterinary practitioners or PhD scientists. All staff have received appropriate training in the conduct of project evaluation. After the evaluation, administrative personnel upload the approved NTPS reports to the website.

4.2.1 Evaluators' characterization

The *Guide to Ethics Committee Assessment of Project Applications under Directive 2010/63/EU and S.I. No. 543 of 2012*, the HPRA describes several recommendations for the composition of the ethics committees (but these are not mandatory). The recommendations are:

The committee must have at least 6 persons (but preferably substantially more to provide more robust scrutiny of proposed projects and to allow for occasional absences of members). All persons involved in the ethics committee are expected to be familiar with, and be able to provide evidence (e.g. signed and dated records of having read and understood relevant documents and reading material), that they fully understand the 3R principles.

There must be a chairperson and a vice-chair. The chairperson should be a person of standing or with significant responsibilities in the institution, such as a president or vice-president of research, dean, professor, director or senior executive with a demonstrable track record in dealing with complex issues and able to chair meetings where different perspectives are being sought, while able to forge consensus.

The expertise that an ethics committee would be expected to include are: the designated veterinarian; the animal care and welfare officer; one or more representative(s) of the research community, or those with current or recent experience in the conduct of procedures in animals; a public interest representative independent of the research being conducted at the user establishment (i.e. a "lay" person); a statistician or person with expertise in statistical analysis (where relevant).

It is recommended that additional participants are included to enhance the value of the ethics committee's assessment. Such members might include: an ethicist or member of an ethical review group for clinical trials in humans; a patient representative; a specialist in a particular animal species being investigated, or suitably qualified expert and additional animal technicians or members of the research community.

4.3. Project submission

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. Nominated persons can contact cesp@hma.eu for further information.

Applications can also be submitted by standard e-mail to sapsubmit@hpra.ie.

Further information on the process can be found in the *Guide to Project Applications under Scientific Animal Protection Legislation* available at: https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/aut-g0098-guide-to-project-applications-under-scientific-animal-protection-legislation-v11.pdf?sfvrsn=28

4.4. Fees

The HPRA does not charge for project fees, except in the following cases:
- For projects without ethical approval: 2.000€
- For fast track applications - within 21 days: 2.000€.

Information on these and other fees is available here: https://www.hpra.ie/homepage/about-us/publications-forms/guidance-documents/item?id=4060f925-9782-6eee-9b55-ff00008c97d0&t=/docs/default-source/publications-forms/guidance-documents/fin-g0007-guide-to-fees-for-scientific-animal-protection-v9

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4.5. Guidelines for project evaluation

The HPRA *Guide to Ethics Committee Assessment of Project Applications under Scientific Animal Protection Legislation* are available on the HPRA website (updated in February 2019) here: http://www.hpra.ie/homepage/about-us/publications-forms/guidance-documents/item?id=2060f925-9782-6eee-9b55-ff00008c97d0&t=/docs/default-source/publications-forms/guidance-documents/aut-g0116-guide-to-ethics-committees-assessment-of-project-applications-v2.

4.6. Follow-up of projects' authorisation (i.e. inspections, retrospective review, etc.)

The HPRA is responsible for the follow-up of the project authorisation. They do this through a number of mechanisms, including compliance inspections (the Ethics Committee's functioning is also supervised by the HPRA inspections). The inspections to the user establishments also have fees for inspections conducted in response to suspected non- compliance e.g. follow-up inspections, for cause inspections (per day, per member of the inspection team: 1.640€ or part of day, per hour, per member of the inspection team: 235€). No fees will apply to routine and compliance inspections.

5. PUBLISHED NATIONAL INFORMATION ON ANIMAL USE

5.1. Annual Statistics on Animal Use

Extensive data and commentary in English available from 2013 onwards (prior to this were published by Department of Health) on the HPRA website here: http://www.hpra.ie/homepage/veterinary/scientific-animal-protection/statistical-reporting.

5.2. Competent Authority Report

Not available.

5.3. Non-Technical Summaries

Non-technical project summaries are available in a browsable format from 2013 onwards from the HPRA website here: http://www.hpra.ie/homepage/veterinary/scientific-animal-protection/authorisations/non-technical-project-summaries.

6. OFFICIAL CONTACT POINTS AND WEBSITES

Competent Authority Website:
https://www.hpra.ie/homepage/veterinary/scientific-animal-protection

National Contact Point: Dr J.G. Beechinor, Veterinary Director, Email: jgb@hpra.ie

National Committee Website: National Committee for the Protection of Animals Used for Scientific Purposes: http://www.hpra.ie/homepage/veterinary/scientific-animal-protection/national-committee

National Committee Contact: Chair: Michael C. Gaynor, Email: NCSAP@hpra.ie

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PARERE Network Contact: Veterinary Sciences Centre, UCD School of Veterinary Medicine, University College Dublin, Prof. Alan W. Baird, Email: alan.baird@ucd.ie

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7.5 COUNTRY: ITALY

COUNTRY: ITALY

1. IMPLEMENTATION OF DIRECTIVE 2010/63/EU

The Directive is transposed into the national legislation through the new law Legislative Decree 4 March 2014, n. 26 "Implementation of the Directive n. 2010/63 / EU on the protection of animals used for scientific purposes " (Decreto Legislativo 4 marzo 2014, n. 26 - Attuazione della direttiva 2010/63/UE sulla protezione degli animali utilizzati a fini scientifici). Available in Italian here: http://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=48988. The regulation is implemented by the Ministry of Health.

2. REGULATION AND AUTHORISATION PROCESS: MAIN ACTORS

2.1 Ministry: Ministry of Health
2.2 Competent authority: Ministry of Health
2.3 Entity responsible for the project authorisation: Ministry of Health with advice from the Higher Institute of Health (Istituto Superiore di Sanità [ISS])

3. LICENSING PROCESS

Two tier licensing system:

1. Project authorisation
2. User establishment authorisation

The Ministry of Health is responsible for issuing authorisation. Project authorisation application guidelines are available in Italian here: http://www.salute.gov.it/portale/ministro/p4_8_0.jsp?lingua=italiano&label=servizionline&idMat=SA&idAmb=PA&idSrv=SPE&flag=P, and establishment authorisation guidelines are available here: http://www.salute.gov.it/portale/ministro/p4_8_0.jsp?lingua=italiano&label=servizionline&idMat=SA&idAmb=PA&idSrv=SPEST&flag=P.

4. PROJECT EVALUATION ACCORDING TO ARTICLE 38 OF DIRECTIVE 2010/63/EU

4.1 Geographical organization of the project evaluation process

Firstly, the evaluation is conducted at an institutional level, by the institutional animal welfare body, the Organismo Preposto al Benessere degli Animali (OPBA). After this step, the applications are submitted to the national competent authority, the Ministry of Health, who authorises/rejects the projects after an evaluation conducted by the ISS or other technical-scientific bodies according to the subjects pertaining to the project, or to the Higher Health Council in cases where primates, dogs, cats and specimens of endangered species are used

4.2 Evaluators

The evaluation is conducted at a first level by institutional committees [OPBA] and at, a second level, by individual experts at the ISS (there are about 25 – 30

evaluators distributed in different departments and with different backgrounds/expertise - e.g. biologists, pharmacologists, toxicologists).

4.2.1 Evaluators' characterization
The minimum composition of the OPBA described in the Directive and in the Italian Decree is: - The person or persons responsible for the welfare and care of the animals, the designated veterinarian and a scientific member.

Additional guidelines regarding the composition and functioning of the OPBA are to be issued/approved.

4.3. Project submission
Project submission can be made online using the National Databank for Animal Testing, which requires log in details and can be found on the Ministry website here: https://stabulari.izs.it/stabulari/login.

4.4. Fees
Currently there are no fees for project evaluation. The fee for establishment authorisation is € 774.69 (details can be found on the establishment authorisation guidelines page above)

4.5. Guidelines for project evaluation
There are no specific guidelines for the evaluators regarding how to conduct the project evaluation.

4.6. Follow-up of projects' authorisation (i.e. inspections, retrospective review, etc.)
The Ministry of Health is responsible for the follow-up of projects' authorisation and for inspections.

5. PUBLISHED NATIONAL INFORMATION ON ANIMAL USE

5.1. Annual Statistics on Animal Use
Moderate data without commentary is available in Italian from 2007, here: http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=4400&area=sanitaAnimale&menu=sperimentazione.

5.2. Competent Authority Report
Not available.

5.3. Non-Technical Summaries
Non-technical summaries available for 2014 and 2015 in Italian in a browsable format here:
http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=4399&area=sanitaAnimale&menu=sperimentazione.

6. OFFICIAL CONTACT POINTS AND WEBSITES

Competent Authority Website:
http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=sanitaAnimale&menu=sperimentazione

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National Contact Point: Giovanni Botta, Ufficio VI Benessere Animale, Email: sanita.animale@sanita.it

National Committee Website: Comitato nazionale per la protezione degli animali usati a fini scientifici (National Protection Committee animals used for scientific purposes): No website currently available.

National Committee Contact: Chair: Rodolfo N.Lorenzini, Email: rodolfo.lorenzini@iss.it

PARERE Network Contact: Centro di Referenza per i Metodi Alternativi (Reference Center for Alternative Methods), IZSLER, Dr Guerino Lombardi, Email: guerino.lombardi@izsler.it

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7.6 COUNTRY: THE NETHERLANDS

Animal Research Legislation Information Sheet

COUNTRY: NETHERLANDS

1. IMPLEMENTATION OF DIRECTIVE 2010/63/EU

The Directive was transposed into the Dutch national legislation in December 2014. The new legislation is available at: https://wetten.overheid.nl/BWBR0003081/2014-12-18. This regulation is under the responsibility of the Ministry of Agriculture, Nature and Food Quality.

2. REGULATION AND AUTHORISATION PROCESS: MAIN ACTORS

2.1 Ministry: Ministry of Agriculture, Nature and Food Quality, Department of Animal Supply Chain and Animal Welfare
2.2 Competent authority: Central Authority for Scientific procedures on Animals [Centrale Commissie Dierproeven] (CCD).
2.3 Entity responsible for the project authorisation: Central Authority for Scientific procedures on Animals (CCD) with advice from the established Animal Experiments Committees (DECs).

3. LICENSING PROCESS

Two tier licensing system:

1. Institutional permits for the breeding and supply, or use, of animals for scientific purposes.
2. project permit for animal use for scientific purposes

1. The CCD is the central body that is solely authorised to grant project permits for scientific procedures on animals. The CCD is an Independent Administrative Body (ZBO) that was established by law. The laws and regulations stipulate that the CCD is independent and impartial. More information can be found on the CCD website: https://www.centralecommissiedierproeven.nl/.

The institutional licenses for the breeding and supply, or use, of animals for scientific purposes are granted by the Dutch Food and Consumer Product Safety Authority (NVWA).

4. PROJECT EVALUATION ACCORDING TO ARTICLE 38 OF DIRECTIVE 2010/63/EU

4.1 Geographical organization of the project evaluation process
The project evaluation is firstly conducted at an institutional/local level by one of the established DECs (https://www.centralecommissiedierproeven.nl/onderwerpen/themas/dierexperimentencommissies). The DEC gives advice to the CCD. Subsequently, the application is evaluated by the CDD for authorisation at a national level. DECs assess whether the importance of the research (or training) outweighs the

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harms to the animals, and how the 3Rs are implemented. The key task of the DEC is to ethically review applications for animal use for scientific purposes. The CCD recognizes DECs and monitors their functioning. The Dutch Association of Animal Experiments Committees (NVDEC) is an association of all DECs in the Netherlands. There are about 15 DECs in the Netherlands before these are submitted. This review focuses on technical aspects such as feasibility and the application of best practices. The application needs to be signed by the institutional representative.

4.2 Evaluators

The evaluation is firstly reviewed by the institutional AWB, then an ethical review is conducted by a DEC, resulting in an ethical review report, and then by the CCD. The CCD is solely authorised to grant project permits for scientific procedures on animals.

4.2.1 Evaluators' characterization

A DEC consists of at least seven members with expertise in the areas of: the different scientific disciplines and scientific applications for which the animals will be used. This also includes replacement, reduction and refinement (the 3R's) in these areas; design of tests, including statistical aspects; animal testing practice or, where necessary, veterinary practice with wild animals; keeping, caring for and treating animals of species that will be used; ethics; research animals and their protection. At least two members are not involved in scientific procedures on animals. In addition to the chairman, at least half of the members may not have an employment relationship with the institution's permit holder for which an advice is issued.

The CCD comprises five experts. The CCD's composition, background, expertise, representation and interests are published on the website of the CCD at: http://www.centralecommissiedierproeven.nl/over-ccd/samenstelling-ccd.

The decision-making process is further supported by a secretariat consisting of skilled staff with a technical (such as PhDs), administrative or legal background.

4.3. Project submission

The protocols are submitted for evaluation by digital submission in a secured ICT-system (NetFTP), followed by a signed application-form. Instructions on using the NetFTP are found here: https://www.centralecommissiedierproeven.nl/onderwerpen/aanvraag-vergunning/documenten/formulieren/15/5/18/instructie-netftp.

Instructions on completing the application are found here: http://www.centralecommissiedierproeven.nl/onderwerpen/aanvraag-vergunning.

Applying for an establishment licence at the NVWA is done by e-mail to: chd@nvwa.nl.

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4.4. Fees

DECs charge variable fees for advice. Internal DECs are mostly paid by the institutions. The charge for other applicants can cost up to 3500 euros. CCD fees are between 884 - 1389 euro (modifications of existing projects) and 884 – 1940+ or more euros (new projects), depending on the number of types of procedures in annexes).

4.5. Guidelines for project evaluation

There are guidelines for how the DEC should perform its evaluation: "Practical guide to the ethical evaluation framework for the use of laboratory animals", available here: https://www.centralecommissiedierproeven.nl/onderwerpen/dierexperimentencommissie-dec/documenten/formulieren/16/6/6/ethisch-toetsingskader. The CCD use the EU guidelines on project evaluation. There is also a "Guide to the definition of the project", which helps researchers, the Animal Welfare Bodies (IvDs) and the Animal Experiments Committee (DECs) to define clear and concise project applications, available at: https://www.centralecommissiedierproeven.nl/documenten/formulieren/16/6/6/invulling-definitie-project.

4.6. Follow-up of projects' authorisation (i.e. inspections, retrospective review, etc.)

The follow-up is conducted by CCD (retrospective review, advised by a DEC) and by the Netherlands Food and Consumer Product Safety Authority (NVWA) (inspection and registration)**.** Civil servants designated by the Minister are tasked with oversight of compliance with the legislation. The inspector is authorised to enter a licensed establishment but also a private residence without the consent of the occupant and take with him the necessary equipment.

5. PUBLISHED NATIONAL INFORMATION ON ANIMAL USE

5.1. Annual Statistics on Animal Use

Extensive data and commentary is analysed and published by the NVWA in Dutch, available here: https://www.nvwa.nl/onderwerpen/dierenwelzijn/dierproeven-voor-onderzoek/eisen-aan-instellingen-voor-het-uitvoeren-van-dierproeven

5.2. Competent Authority Report

CCD publishes an Annual Report detailing its activities. Available online from 2015 onwards at: https://www.centralecommissiedierproeven.nl/over-ccd/jaarverslag.

5.3. Non-Technical Summaries

Non-technical summaries available in Dutch, from 2014 onwards in a searchable format on the CCD website: https://www.centralecommissiedierproeven.nl/onderwerpen/niet-technische-samenvatting.

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6. OFFICIAL CONTACT POINTS AND WEBSITES

Competent Authority Website:
https://www.centralecommissiedierproeven.nl/

National Contact Point: Katharina Kardinal-Janke, Email: k.kardinal@minez.nl

National Committee Website: Nationaal Comité advies dierproevenbeleid (NCad) (Netherlands National Committee for the protection of animals used for scientific purposes): https://www.ncadierproevenbeleid.nl/.

National Committee Contact: Chair: Henk Smid, Email: NCad@minlnv.nl

PARERE Network Contact: RIVM, Betty C. Hakkert, Phd, Email: Betty.Hakkert@rivm.nl

This document was created by Dr Michelle Hudson-Shore with the assistance of Prof Kate Millar and Joshua Cantrell, University of Nottingham and Dr Martje Fentener van Vlissingen, Erasmus University Medical Centre, The Netherlands, with assistance from VetBioNet colleagues.

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VERSION 3

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7.7 COUNTRY: POLAND

Animal Research Legislation Information Sheet

COUNTRY: POLAND

1. IMPLEMENTATION OF DIRECTIVE 2010/63/EU

The Directive was transposed into national law through the Act of 15 January 2015 on the protection of animals used for scientific or educational purposes (Journal of Laws, item 266) on November 10, 2015 (”USTAWA z dnia 15 stycznia 2015 r. o ochronie zwierząt wykorzystywanych do celów naukowych lub edukacyjnych”). The Ministry of Science and Higher Education implement the regulation.

2. REGULATION AND AUTHORISATION PROCESS: MAIN ACTORS

2.1 Ministry: The Ministry of Science and Higher Education.
2.2 Competent authority: The Minister of Science and Higher Education appoints the National Ethical Committee for Experiments on Animals which nominates members of Local Ethics Committees.
2.3 Entity responsible for the project authorisation: Local Ethical Commissions for Experiments on Animals.

3. LICENSING PROCESS

Three tier licensing system:

1. Project Licence - Permission to conduct animal experiments
2. Individual permit for performing animal procedures
3. Register of breeding, supplying and user establishments

Breeders, suppliers and users are authorised by the Veterinary Inspection and registered by the Ministry of Science and Higher Education. The Minister of Agriculture and Rural Development describes the minimum requirements for establishments and conditions of care of animals kept in the establishment.

Projects and individuals are authorised by the Local Ethical Commission.

4. PROJECT EVALUATION ACCORDING TO ARTICLE 38 OF DIRECTIVE 2010/63/EU

4.1 Geographical organization of the project evaluation process

The project evaluation and authorisation is conducted by the 11 Local Ethical Commissions. The National Ethics Committee (NEC) supervises these Commissions. The geographical scope of these committees is determined by the Regulation of Ministry of Science and Higher Education. The rationale for the geographical scope of the committees is to provide the effective work of Local Ethical Commission and guarantee conducting the evaluation process and granting the experiment authorisation within 40 days. The establishments’ location and the number of experiments carried out are taken into account in the definition of the Commissions’ geographical scope. The NEC is a national

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committee that i) serves as an appeal instance when a Local Ethical Commission refuses granting of project authorisation; ii) provides opinions on issues concerning protection of animals used for scientific or educational purposes for breeders, suppliers and users; iii) develops good practices for users concerning planning and caring out the procedures, on applying principle of replacement, reduction and refinement and on alternative methods; iv) appoints and dismiss members of Local Ethical Commission.

Information on location and composition of the National Ethical Committee for Experiments on Animals is available in Polish on the Ministry website here: http://www.bip.nauka.gov.pl/krajowa-komisja-etyczna-do-spraw-doswiadczen-na-zwierzetach-lokalizacja-i-sklad/.

Local Ethical Commissions for Experiments on Animals list is available here: http://www.bip.nauka.gov.pl/lokalne-komisje-etyczne-do-spraw-doswiadczen-na-zwierzetach-lokalizacje-i-sklady/.

4.2 Evaluators

The project evaluation is conducted by one of the 11 Local Ethical Commission.

4.2.1 Evaluators' characterization

The Local Ethical Commission are composed by 12 members: six representatives of biological, pharmaceutical, medical, agricultural or veterinary sciences with a degree or a PhD and knowledge and experience of using animals for research or educational purposes; three representatives of the humanities or social sciences, in particular in ethics, philosophy or law, among them one representative of an organization with the protection of the patients' rights as a statutory goal; and three representatives of NGOs with animal protection as a statutory goal.

The NEC (National Ethics Committee) is composed of 15 members: nine representatives of biological, pharmaceutical, medical, agricultural or veterinary sciences with a degree or a PhD and knowledge and experience in using animals for research or educational purposes; three representatives of the humanities or social sciences, in particular in ethics, philosophy or law; and three representatives of NGOs with animal protection as a statutory goal.

4.3. Project submission

There is no online platform for submitting the applications. The applications are submitted to the Local Ethical Commission by email or in paper form. There are two forms of applications: a regular administrative procedure and a simplified administrative procedure. From January 2019 there are also new forms for modifying the project licence all available on the ministry website in Polish here: http://www.bip.nauka.gov.pl/dokumenty-wymagane-do-ubiegania-sie-o-zgode-na-przeprowadzenie-doswiadczenia/.

Form for a regular procedure is available in Polish on Ministry website here: http://www.bip.nauka.gov.pl/g2/oryginal/2018_12/99c07f760093343e9ed0d23587bb76b0.docx.

Form for a simplified procedure is available in Polish on the Ministry website here:

http://www.bip.nauka.gov.pl/g2/oryginal/2018_12/bbb86049e552eb2e90fe93cfda6bcc57.docx.

Forms for individual permission to conduct procedures are available in Polish on the ministry website here: : http://www.bip.nauka.gov.pl/dokumenty-wymagane-do-ubiegania-sie-o-zgode-na-przeprowadzenie-doswiadczenia/.

4.4. Fees
There are no fees; the project evaluation is free of charge.

4.5. Guidelines for project evaluation
Not available.

4.6. Follow-up of projects' authorisation (i.e. inspections, retrospective review, etc.)
The Local ethical Commissions are responsible for the retrospective assessment. The inspections of breeders, suppliers and users are carried out by the Veterinary Inspection.

5. PUBLISHED NATIONAL INFORMATION ON ANIMAL USE

5.1. Annual Statistics on Animal Use
Basic data available in polish from 2011 onwards on the Ministry website here: http://www.bip.nauka.gov.pl/sprawozdania_zwierzeta/.

5.2. Competent Authority Report
Not available

5.3. Non-Technical Summaries
Non-technical summaries available in Polish from June 2016 onwards from the Ministry website here: http://www.bip.nauka.gov.pl/streszczenia-nietechniczne/.

6. OFFICIAL CONTACT POINTS AND WEBSITES

Competent Authority Website: https://www.gov.pl/web/nauka/

National Contact Point: Dr Anna Passini, Email: anna.passini@nauka.gov.pl

National Committee Website: National Ethical Committee for Experiments on Animals: http://www.bip.nauka.gov.pl/krajowa-komisja-etyczna-do-spraw-doswiadczen-na-zwierzetach-lokalizacja-i-sklad/

National Committee Contact: Chair: Elzbieta Kampanowska-Jezierska, Email: zwierz@nauka.gov.pl

PARERE Network Contact: Krajowe Centrum Metod Alternatywnych do Oceny Toksyczności (KCMA IMP), Maciej Stepnik, Email: mstep@imp.lodz.pl

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7.8 COUNTRY: SPAIN

Animal Research Legislation Information Sheet

COUNTRY: SPAIN

1. IMPLEMENTATION OF DIRECTIVE 2010/63/EU

The directive is transposed into national legislation through the Royal Decree 53/2013 from February 1st: http://cea.unizar.es/normativa/RD53_13Proteccion%20animales%20utilizados%20en%20experimentacion.pdf, Law 32/2007 from November 7th: http://cea.unizar.es/normativa/Ley32_2007.pdf and Royal Decree 1386/2018, of November 19: https://www.boe.es/boe/dias/2018/11/20/pdfs/BOE-A-2018-15797.pdf, which modifies Royal Decree 53/2013, of February 1, which establishes the basic rules applicable for the protection of animals used in experimentation and other scientific purposes , including teaching. The Ministry of Agriculture, Food and Environment is the point of contact for the purposes of compliance with this royal decree.

2. REGULATION AND AUTHORISATION PROCESS: MAIN ACTORS

2.1 Ministry: Ministry of Agriculture, Food and Environment.
2.2 Competent authority: Regional Competent Authorities.
2.3 Entity responsible for the project authorisation: Regional Competent Authorities.

3. LICENSING PROCESS

Two tier licensing system:

1. Project authorisation (three types of project)
2. The breeders, suppliers and users and their establishments must be authorized by the competent body prior to the start of their activities.

Authorisation is done by the Competent Authority prior to the start of activities. The breeders, suppliers and users must register in the General Register of Livestock Farms, created and regulated by Royal Decree 479/2004, of March 26, which establishes and regulates the General Livestock Register, and, where appropriate, in a specific register for such purposes.

4. PROJECT EVALUATION ACCORDING TO ARTICLE 38 OF DIRECTIVE 2010/63/EU

4.1 Geographical organization of the project evaluation process

The project evaluation is not centralised to one place/body. In order to communicate and request authorization for a project, the user or the person responsible for the project must present the project proposal to the regional Competent Authority, accompanied by the report of the institutional Ethics Committee of Animal Experimentation (OEAB), a copy of the project evaluation

request, and at least the corresponding information from among those listed in annex X, and in the case of type II and III projects, of the non-technical summary provided in article 36 of this royal decree.

The request for evaluation of the project shall be addressed to the Authorized Body (órgano habilitado) appointed by the Competent Authority, freely chosen by the applicant, from among those listed in the list of Authorized Bodies. The evaluation of each project will be carried out by the Authorized Body (órgano habilitado). The OEABs can be appointed to conduct the project evaluation if they meet additional requirements and there are also some external Authorised Bodies that are not connected to any institution. After the evaluation the final authorisation is always performed by one of the regional Competent Authority.

A List of Competent Authorities can be found here:
https://www.mapa.gob.es/es/ganaderia/temas/produccion-y-mercados-ganaderos/Puntos%20de%20contacto%20de%20acuerdo%20al%20art%C3%ADculo%2041%20del%20RD%2053%202013_tcm30-104706.pdf

A list of Authorised Bodies can be found here:
https://sede.micinn.gob.es/portal/site/eSede/menuitem.df29f2378d5d10a0cee63510223041a0/?vgnextoid=4625f3781efed310VgnVCM1000001d04140aRCRD&vgnextchannel=26d0f3781efed310VgnVCM1000001d04140aRCRD&vgnextfmt=formato1&lang_choosen=es

4.2 Evaluators
The evaluation is always conducted by the Authorised Bodies.

4.2.1 Evaluators' characterization
An Authorised Body should include the minimum composition of: at least the person or persons responsible for the welfare and care of the animals; a scientific member; the designated veterinarian; other researchers that aren't connected with the project that will be assessed and one person with expertise in animal welfare without direct relation with the user or the project.

4.3. Project submission
There is no national standard form. Competent Authorities operate at a regional level (administrative regions) and these regional administrative regions may have different procedures. So check the with local Authority. Usually, there is a template that the researchers must complete and send to the Authorised Body. The process is reviewed electronically, through e-mail. There may be some web-based systems in some institutions.

4.4. Fees
There are no standard fees. The project evaluation could have costs for the applicants if it is conducted by an external Authorised Body (in this case, an evaluation could cost between 200 and 500 euros).

4.5. Guidelines for project evaluation
There are no specific national guidelines for the evaluators on how to conduct the project evaluation, but a link is provided to the European Commission Project Evaluation Guidance Document.

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4.6. Follow-up of projects' authorisation (i.e. inspections, retrospective review, etc.)

The authorized body will carry out a retrospective evaluation. Animal testing ethics committees may also, when determined by the competent body, be appointed bodies authorized to carry out the evaluation and retrospective evaluation, provided that they meet the requirements.

5. PUBLISHED NATIONAL INFORMATION ON ANIMAL USE

5.1. Annual Statistics on Animal Use

Basic data in Spanish 2009 - 2013. Then moderate data and commentary in Spanish from 2014 onwards. Available on the Ministry website here: https://www.mapama.gob.es/gl/ganaderia/temas/produccion-y-mercados-ganaderos/bienestanimal/en-la-investigacion/Informes_y_publicaciones.aspx.

5.2. Competent Authority Report

Not available.

5.3. Non-Technical Summaries

Non-technical summaries available (no date range) in Spanish in a searchable format on the Ministry web site here: https://www.mapa.gob.es/app/resumenesnotecnicos/DataProvider/Consulta.ashx.

6. OFFICIAL CONTACT POINTS AND WEBSITES

Competent Authority Website:
https://www.mapa.gob.es/es/ganaderia/temas/produccion-y-mercados-ganaderos/bienestanimal/en-la-investigacion/default.aspx

National Contact Point: Email: ceeba@magrama.es

National Committee Website: Spanish Committee for the protection of animals used for scientific purposes (Comité español para la protección de los animales utilizados con fines científicos [CEPAFIC]): https://www.mapa.gob.es/es/ganaderia/temas/produccion-y-mercados-ganaderos/bienestanimal/en-la-investigacion/CEPAFIC.aspx

National Committee Contact: Chair: Fernando Miranda Sotillos, Email: ceeba@mapama.es

PARERE Network Contact: DG de Recursos Agricolas y Ganaderos, Ministerio de Medio Ambiente y Medio Rural y Marino, Email: ceeba@magrama.es

This document was created by Dr Michelle Hudson-Shore with the assistance of Prof Kate Millar and Joshua Cantrell, University of Nottingham with assistance from VetBioNet colleagues.

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VERSION 2

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7.9 COUNTRY: SWITZERLAND

Animal Research Legislation Information Sheet

COUNTRY: SWITZERLAND

1. IMPLEMENTATION OF DIRECTIVE 2010/63/EU

Implementation of Directive 2010/63/EU is not applicable here as Switzerland is not a Member State of the EU. The legal requirements for the authorisation procedure for animal experiments and laboratory animal facilities are laid down in the Animal Protection Act (AniPA) and the Animal Protection Ordinance of 23 April 2008 (AniPO), available in French here: AniPA, https://www.admin.ch/opc/fr/classified-compilation/20022103/index.html and AniPO, https://www.admin.ch/opc/fr/classified-compilation/20080796/index.html#id-6.
The Federal Council is responsible for implementing this legislation.

2. REGULATION AND AUTHORISATION PROCESS: MAIN ACTORS

2.1 Ministry: The Federal Council
2.2 Competent authority: Federal Food Safety and Veterinary Office (FSVO)
2.3 Entity responsible for the project authorisation: The Cantonal Veterinary Office

3. LICENSING PROCESS

Two tier licensing system:

1. Project authorisation – each individual experiment must be approved
2. Laboratory animal facility approval

Authorisation for both of these is given by the Cantonal Veterinary Office. See the FSVO website for more information here: https://www.blv.admin.ch/blv/en/home/tiere/tierversuche/antrag-bewilligung-tv.html.

Application forms and guidance are available on the FSVO website (under forms) here: https://www.blv.admin.ch/blv/en/home/tiere/tierversuche/forschende.html.

4. PROJECT EVALUATION ACCORDING TO ARTICLE 38 OF DIRECTIVE 2010/63/EU

4.1 Geographical organization of the project evaluation process

Experiments in grade 0 (no harm) will be evaluated directly by the Cantonal Veterinary Office. Applications with all other grades are forwarded to the Cantonal Commission for Animal Experiments for an assessment. The decision of the Cantonal Veterinary Office will usually follow the Commission's recommendation. In case the Cantonal Veterinary Office comes to a different

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decision as the Commission, it has to defend its decision towards the Committee. The applicant, the Cantonal Commission for Animal Experiments, and the Federal Food Safety and Veterinary Office are informed about the decision of the Cantonal Veterinary Office. These parties can object to the decision during an appeal period of 30 days after the licence was granted. The animal experiments may only be started after this period pf 30d if no objections have been received.

The cantonal committee on animal experimentation examines the application, clarifies any questions with the researchers and gives a recommendation: rejection, conditional acceptance (e.g. fewer animals must be used) or acceptance. The licence is issued by the cantonal veterinary office. Researchers can appeal against the decision. The FSVO then examines the cantonal veterinary office's decision and may request amendments.
In the event of any complex or controversial issues, the veterinary authority can turn to the Federal Committee on Animal Experimentation.
The period of validity of a licence to conduct animal experiments is limited to three years (Art. 141 AniPO). For further information see the FSVO website at: https://www.blv.admin.ch/blv/en/home/tiere/tierversuche/antrag-bewilligung-tv.html.

4.2 Evaluators

The ethical trade-offs between the probable suffering of experimental animals and the expected benefits for humans are assessed by the cantonal animal testing commissions.

4.2.1 Evaluators' characterization

The cantonal animal testing commissions. They are made up of members who are independent of the applicants: experts on the keeping of animals, animal protectionists, researchers and laypeople.

4.3. Project submission

The e-Tierversuche online application can be used to manage applications, authorisations, reports and announcements relating to animal experiments. The application for authorization to carry out animal experiments must be submitted using the computer system. When the situation warrants, the cantonal authority may accept paper applications if they are presented according to the FSVO.1 template form.
More information on accessing the system can be found on the FSVO website here: https://www.blv.admin.ch/blv/en/home/tiere/tierversuche/forschende/e-tierversuche.html.

4.4. Fees

No information available.

4.5. Guidelines for project evaluation

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Various guidelines for conducting harm-benefit analysis are available on the FSVO website here: Guidance on weighing of interests and dignity: https://www.blv.admin.ch/blv/en/home/tiere/tierversuche/schweregrad-gueterabwaegung.html.

4.6. Follow-up of projects' authorisation (i.e. inspections, retrospective review, etc.)

Not known.

5. PUBLISHED NATIONAL INFORMATION ON ANIMAL USE

5.1. Annual Statistics on Animal Use

Detailed statistics, commentary and an interactive search/visualisation tool are available in French or German from 1997 onwards on the Federal Council website at: http://www.tv-statistik.ch/fr/communique-de-presse/.

5.2. Competent Authority Report
Not available

5.3. Non-Technical Summaries
Not available.

6. OFFICIAL CONTACT POINTS AND WEBSITES

Competent Authority Website:
https://www.blv.admin.ch/blv/en/home/tiere/tierversuche.html

National Contact Point: Not Known

National Committee Website:
Federal Commission for Animal Experiments, website not available.

National Committee Contact: Not known

PARERE Network Contact: Not applicable.

This document was created by Dr Michelle Hudson-Shore with the assistance of Prof Kate Millar and Joshua Cantrell, University of Nottingham with assistance from VetBioNet colleagues.

If you have any comments, or suggestions for updating or improving this document please contact Dr Hudson-Shore at: michelle.hudson-shore@nottingham.ac.uk or kate.millar@nottingham.ac.uk

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7.10 COUNTRY: UNITED KINGDOM

Animal Research Legislation Information Sheet

COUNTRY: UK

1. IMPLEMENTATION OF DIRECTIVE 2010/63/EU

The directive has been transposed into the national law through the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 - No. 3039 (ASPA, from 18th December 2012). The amended legislation is available at: https://www.gov.uk/government/publications/animals-scientific-procedures-act-1986-amendment-regulations. ASPA is implemented by the Home Office in England, Scotland and Wales and by the Department for Health, Social Security and Public Safety in Northern Ireland.

2. REGULATION AND AUTHORISATION PROCESS: MAIN ACTORS

2.1 Ministry: Home Department of the UK Government
2.2 Competent authority: Animals in Science Regulation Unit (ASRU), Home Office
2.3 Entity responsible for the project authorisation: Animals in Science Regulation Unit (ASRU), Home Office

3. LICENSING PROCESS

Three tier licensing system:

1. personal licence for each person carrying out procedures on animals
2. project licence for the programme of work
3. establishment licence for the place at which the work is carried out.

Licences are issued by the Home Office in England, Scotland and Wales and by the Department of Health, Social Services and Public Safety (DHSSPSNI) in Northern Ireland. Detailed guidance on the application process for each type of licence and for specific roles (e.g. persons responsible for compliance) can be found here: https://www.gov.uk/government/collections/animal-testing-and-research-applying-for-licences.

4. PROJECT EVALUATION ACCORDING TO ARTICLE 38 OF DIRECTIVE 2010/63/EU

4.1 Geographical organization of the project evaluation process
From 1 January 2013, the local establishment ERPs were replaced by animal welfare and ethical review bodies (AWERBs). All applications, whether for a new project licence, or amendments to an existing licence, must be reviewed by the AWERB at the establishment where the work is going to take place (if the work will occur in more than one establishment, the researcher needs to arrange the review at each establishment). The AWERB advises the establishment licence holder whether to support the project proposal. Project applications are sent, once endorsed by the establishment licence holder (PELh or PEL holder)

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(previously known as the certificate holder), to the Animals in Science Regulation Unit (ASRU), at the Home Office. A central licensing team deal with administration of the application and it is sent to the assigned Inspector for that specific establishment.

Project evaluation is then undertaken by the Inspectors who may also refer to other Inspectors, the Animals in Science Committee or to independent assessors. The requirement for referral depends on the severity of the work in the application, species to be used, and whether or not the work is contentious e.g. the public or Ministers may have particular concern. Advice from the Inspector(s) and the other sources if relevant, is provided to the Secretary of State. His/her officials then grant or refuse the licence based on the advice. After review/evaluation by the AWERBs, both the evaluation and authorisation is undertaken at a national level by Home Office officials.

4.2 Evaluators

The evaluation is firstly conducted by the AWERBS and then by the Animals in Science Regulation Unit Inspectors, who give advice to Officials responsible for the authorisation, acting on behalf of the Secretary of State.

4.2.1 Evaluators' characterization

Considering the user establishments, ASPA specifies that the AWERBs must have, as full members, at least one of the establishment's Named Animal Care and Welfare Officers (NACWO), at least one of the Named Veterinary Surgeons (NVS) and also include a scientific member. They are also expected to take into account the views of people who do not have responsibilities under ASPA, as well as one or more persons who are independent of the establishment. Inspectors may also attend meetings of the AWERB from time to time as part of their responsibilities for monitoring compliance with the legislation.

There are approximately 22 Inspectors operating in the UK. They are required to have medical or veterinary qualifications. Inspectors often have both clinical and research experience and frequently have postgraduate qualifications such as PhDs and specialist diplomas. All Inspectors are required to have medical or veterinary degrees. They frequently have additional certificates, diplomas and PhDs and come from diverse clinical and research backgrounds.

4.3. Project submission

Evaluation by AWERBs is a local process, which is administered in various ways at establishments, and occurs before the project is evaluated at the Home Office. The project licence application is submitted online via the Animals Scientific e-Licensing (ASPeL) system. Guidance on completing an application and a template form are available at: https://www.gov.uk/government/publications/animal-testing-and-research-apply-for-a-project-licence. Projects are programmes of work, which address a specific aim and objectives, using one or more protocols to achieve those objectives. It should be noted that projects are not authorised by individual experiment, rather a five-year programme (or shorter) is authorised, which could consist of several protocols.

4.4. Fees

There are no fees for project authorisation but there are charges for other parts of the licensing process (establishment licences and for each personal licensee at the establishment with primary availability).

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N°731014

4.5. Guidelines for project evaluation

There are guidelines regarding the role of the AWERB issued by the competent authority, in the Guidance on the Operation of the Animals (Scientific Procedures) act 1986 (see Appendix A). Also, "A resource book for lay members of ethical review and similar bodies worldwide 3rd edition January 2015" and the "Guiding principles on good practice for Animal Welfare and Ethical Review Bodies 3rd Edition – September 2015" are available from the RSPCA website at: https://science.rspca.org.uk/sciencegroup/researchanimals/ethicalreview/keyresources/-/articleName/Key_resources_ethical_review.

Inspectors evaluate the projects in accordance with requirements of the legislation. The cornerstone of the evaluation is the harm-benefit analysis which is described in Appendix I of the Guidance to ASPA and in the "The Harm–Benefit Analysis Process New Project Licence Applications Advice Note: 05/2015", available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/660238/Harm_Benefit_Analysis__2_.pdf.

4.6. Follow-up of projects' authorisation (i.e. inspections, retrospective review, etc.)

Inspectors are responsible for inspecting the establishments and determining whether the work is compliant with ASPA. Retrospective assessment is undertaken by the AWERBs who then submit to the Inspectorate. The Inspectorate makes a final evaluation of the retrospective assessment.

5. PUBLISHED NATIONAL INFORMATION ON ANIMAL USE

5.1. Annual Statistics on Animal Use

Extensive data with commentary and time series tables, published since 1987. Available online from 2002 onwards: https://www.gov.uk/government/collections/statistics-of-scientific-procedures-on-living-animals.

5.2. Competent Authority Report

ASRU publishes an Annual Report detailing its activities, including numbers of inspections and legislative non-compliance cases, engagement activities and development of guidance documents. Available at: https://www.gov.uk/government/collections/animals-in-science-regulation-unit-annual-reports.

5.3. Non-Technical Summaries

Non-technical summaries available from 2010 onwards here: https://www.gov.uk/guidance/research-and-testing-using-animals#non-technical-summaries.

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6. OFFICIAL CONTACT POINTS AND WEBSITES

Competent Authority Website: https://www.gov.uk/guidance/research-and-testing-using-animals

National Contact Point: Mr Will Reynolds, Email: william.reynolds10@homeoffice.gsi.gov.uk

National Committee Website: Animals in Science Committee (ASC): https://www.gov.uk/government/organisations/animals-in-science-committee

National Committee Contact: ASC Secretariat Email: asc.secretariat@homeoffice.gsi.gov.uk

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