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# Animal Welfare Committees in the European Research Area

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# Foreword

The use of animals in scientific experiments has rightly been highlighted on many occasions. It is among the most sensitive topics relating to bio-medical research.

There is a consensus that animals deserve a treatment orientated to the minimisation of suffering, and based on the respect and protection of welfare and integrity. All these elements need to be taken into account in research, not only because the protection of animals is rightly promoted by animal protectionists, but also because a responsible use of science requires ethical considerations to be accounted for and embedded into research practices. The justification for the use of animals in research, together with seeking opportunities for Replacement with 'non-sentient' material, Reducing the number of animals used and/or Refining the procedures (the 'Three Rs'), are key elements to be considered.

The ethical assessment of research protocols involving the use of animals is usually carried out by animal welfare committees. These committees, which are not mandatory under EU legislation\*, have, however, been set up in most EU countries. Animal welfare committees have the potential to contribute efficiently to the protection of the animals used for scientific and experimental purposes and especially to the implementation of the Three Rs principle.

Through action 34 of the Action Plan 'Science and Society', adopted by the European Commission in December 2001, a study was launched to carry out a comparative analysis of the Animal Welfare Committees present in the European Research Area. The study also intends to establish a Directory of existing Animal Welfare Committees in this area. The collection of this information and its critical analysis are important steps in contributing to the work of Animal Welfare Committees by providing information at a European level.

I would like to offer my thanks to Professors Frans Stafleu and Jan Vorstenbosch of the Ethics Institute at Utrecht University who have written the report, and to all the Animal Welfare Committees who kindly responded to the survey.

I encourage members of Animal Welfare Committees to study this report and to make use of the Directory, to contact their colleagues across national borders, to exchange experiences and best practices, and to develop joint activities on specific topics of common interest, such as training activities or workshops.

The Commission services, for their part, will act as a catalyst by disseminating the information and by promoting ongoing information exchange between Animal Ethics Committees. They will keep addressing all relevant parties involved and pursue a climate of confidence building, in particular between animal welfare organisations, industry and the scientific community.

Janez Potočnik  
EU Commissioner for Science and Research

\*Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes.



# Index

<b>General Summary</b>	7
<b>Chapter 1. Introduction: Scope, Objectives and Methods of the Study</b>	11
<b>Chapter 2. General State of Affairs Concerning AWCs in the European Research Area</b>	
2.1 Reasons for setting up AWCs	13
2.2 AWCs per country and their legal status	14
2.3 The evolution of AWCs	14
<b>Chapter 3. Procedural Aspects of AWCs</b>	
3.1 Institutional affiliation and advisory relations of AWCs: local, regional, national AWCs	17
3.2 Tasks of AWCs	19
3.3 The composition of AWCs	20
3.3.1 Expertise and qualifications of members	20
3.3.2 Independence	22
3.3.3 Protection of members of AWCs	23
3.4 Working procedures	24
3.4.1 Communication	24
3.4.2 Prospective/retrospective review	25
3.4.3 Deliverables	25
3.4.4 Transparency	26
<b>Chapter 4. Substance and Elements of the Review Process</b>	
4.1 The scope of the review	29
4.2 Scientific review: validity, necessity and value of procedures	30
4.3 Reviewing the Three Rs: opportunities for Replacement, Reduction of numbers, Refinement of experimental procedures	32
4.4 Ethical review: harms and benefits of experiments	32
4.5 Review of legal requirements and of facilitatory conditions: additional tasks of AWCs	34

<b>Chapter 5. Conclusions and Recommendations</b>	37
<b>Appendix A: Directory of Contact Persons and Addresses of Animal Welfare Committees in the European Research Area</b>	41
<b>Appendix B: Tables with Results of the Questionnaire</b>	53
<b>Appendix C: Opinions of Respondents on AWCs</b>	79
<b>Appendix D: Characteristics per Country</b>	85
<b>Appendix E: Literature</b>	109

# General Summary

Animal Welfare Committees (AWCs) are not mandatory under EU legislation. However, in most European Research Area countries, some system of AWC exists, often of a mandatory character. Their main purpose is the protection and improvement of the welfare of animals used in scientific procedures. The study described in this report examined and analysed the way AWCs operate throughout Europe and formulated some conclusions concerning best practices.

In particular, the objectives of the study were:

- To establish a directory containing the names of contact persons and addresses for AWCs in the European Research Area. The EC Directory currently consists of 78 contact addresses of institutes and/or persons of national, regional and/or local AWCs in 24 European member states, candidate countries and associated countries.
- To provide a description, analysis and evaluation of AWCs in the European Research Area. For this purpose, information was obtained through questionnaires, personal e-mail contact, the Internet, national Animal Welfare Acts and other sources of information, such as publications, brochures and application forms.

The most common remit of AWCs is a prospective review of the ethical and technical aspects of research protocol applications involving vertebrate animals and a recommendation, given to the licenceholder, or the authorities, concerning the acceptability – with regard to legal, scientific and ethical standards – of the proposal under consideration. Furthermore, the remit often includes an assessment and recommendation concerning the accommodation, husbandry, breeding and care of laboratory animals and the management of the facilities. The review is, in most cases, limited to vertebrate animals. Sometimes species (primates) or cases (transgenic animals) receive special attention.

AWCs operate on a local, regional or national level, often in some sort of combination. The most common system is a local AWC combined with a national committee. In Northern and Western EU countries, systems that combine a national AWC with local/regional committees seem well established, legally and institutionally. Other regions are in the process of developing a system.

The number of members varies from 10-15 for national to 4-10 members for local and regional AWCs. Members include scientists with expertise in the field of animal research, veterinarians, scientists with other relevant expertise such as ethicists, lawyers and alternatives experts, representatives from the authorities, such as inspectors, and lay persons. Independence of judgment is often protected by a ruling that members have different backgrounds and/or (some) members are not affiliated to the organisation involved. Meetings and recommendations from the AWCs are not usually open to the public. An appeal by the applicant, to either a governmental authority or a national committee, is possible most of the time.

The review covers scientific-technical and ethical elements. The technical elements concerns 1) the aim and necessity of the study, 2) the validity of using animals and the scientific quality of the experiment, and 3) the opportunities for Replacing the procedure with non-sentient 'material', Reducing the number of animals used and/or Refining the procedures –

the 'Three Rs' (Russel+Burch, 1959). This technical review is the backbone of the review process. The ethical element concerns a harm-benefit evaluation, and judgment of the moral acceptability of the procedure.

Respondents were invited to voice their opinion concerning the functioning of the AWC in their countries. In countries with mandatory AWCs, this legal status is valued positively. The fact that protocols are reviewed by a committee consisting of independent and competent members from different scientific disciplines was generally regarded as positive. The absence of a formal status was considered a serious drawback. Negative judgments also related to the fact that the process is time-consuming and bureaucratic, and may slow down research. In some countries, it appeared to be difficult to find enough competent members for the AWCs.

The controlling and preventive effect of AWCs is an important asset, because researchers are required to account for the scientific and ethical implications of the use of animals in their research. However, there are important differences between AWCs. These differences may originate in the legal and political system, in the public opinion concerning the treatment and status of animals in countries, and/or in the choice of advisory tasks (scientific, ethical and legal) with which the AWCs are commissioned. They may also concern the composition of AWCs – for instance the inclusion of lay members or representatives of the animal protection movement.

A number of problems relating to these differences were identified:

1. Affiliation of local committees to research institutes and companies facilitates information and communication, quick procedures, and an evaluation that is sensitive to the specific context of the experiments. However, it may compromise the impartiality of the review. This effect may be counteracted to a certain extent by selecting the members of AWCs based on criteria of independency, as well as on criteria of expertise. Regarding the procedures of composing committees and selecting members, as well as with regard to the safeguarding of independent judgment, further information, clarity and discussion is needed.
2. Procedures concerning transparency and public accountability differ and are sometimes a matter for controversy. A more thorough evaluation of the procedural aspects must take into account the relation between procedures and composition on the one hand, and the expectations with regard to specific elements of the review (scientific and ethical) and various conceptions of independency on the other. This evaluation also has to take into account the fact that animal experiments are often contested, sometimes aggressively so, and therefore protection of the privacy of members, security issues and confidentiality are at stake.
3. With regard to the elements of the review, there are consequential differences between the scientific review, the application of the Three Rs concept and the ethical evaluation. The Three Rs review seems the least problematic because AWCs at the local level seem well composed and equipped to see to this aspect. However, whether an AWC has the expertise and mandate to judge the scientific value and/or necessity of animal experiments, and what the relation is to the judgment of other stakeholders, is a matter of discussion.

4. The process of ethical review and evaluation remains largely in the dark. Respondents mentioned no sources that they consult for this evaluation. Ethical evaluation does not rely on expertise but on views, reasons and arguments of a moral kind. Many problems of a principally conceptual, moral and political nature seem to be at stake in this process of evaluation. The valuation and balancing of harm and benefits is a very complex and difficult matter. Nevertheless, it also touches on the recognition of moral pluralism that is the basis of the liberal-democratic order, and on the relation between moral considerations, and the rights and equality of market parties and stakeholders. It is doubtful whether AWCs, especially local AWCs, can claim the authority to break new ground on these large political and ethical issues. Perhaps they should signal to the public and politicians the difficulties they have in ethically evaluating some categories of animal experiments, which subsequently can become the subject of a broader national AWC evaluation and/or political decision-making process.

Politicians and policy-makers should be aware of these implications and support initiatives to reach a more informed and reflective level of discussion on these matters. In view of the differences and problems, and in view of the importance of developing 'best practices' and harmonisation of procedures and standards, more information and examination, as well as an exchange of experiences and ideas, is needed.

It is concluded that most countries of the European Research Area have established AWCs and that their remit is comparable. AWCs seem to contribute effectively to the protection of animals used in scientific procedures in research and regulation. However, in practice, there are differences in the way AWCs operate and there are some notable and principled issues concerning the tasks and authority of AWCs. A European network should be instrumental in developing the recognised value of AWCs and in sorting out the complexities of different assignments. The composition of AWCs should be balanced with a range of expertise and clear warranties of independency. Further development of professionalism of the members is needed. For 'ethical awareness' to be developed, direct contact between AWCs and stakeholders, such as researchers, is recommended. It is also recommended that AWCs be given a basis in national and European law, that there is a right of appeal, and that all animal experiments, at least with vertebrates, should be reviewed considering the Three Rs opportunities and the harm-benefit proportion, although the reviews on both these counts does not necessarily have to result in recommendations that are equally compelling. It is suggested that the three elements of the review are carefully kept in view and that the composition, procedures and instruments of AWCs reflect awareness of the demands and limitations of each of these assignments.



# Introduction: Scope, Objectives and Methods of the Study

In this document, the results of a study on Animal Welfare Committees (AWCs) in the European Research Area are reported. Information on the existence and functioning of AWCs was acquired and analysed for all 25 Member States of the EU, with the exception of Malta and Luxembourg, for which no contact person was found. Bulgaria and Turkey were included in the survey, whereas Romania and Croatia were not. Iceland, Israel, Norway and Switzerland were added for reasons of comparison.

The objectives of the study were:

- to establish a directory containing the names of contact persons and addresses for AWCs in the European Research Area;
- to provide an analysis of the remit, operating procedures, composition and institutional affiliation of AWCs;
- to provide an evaluation of the functioning of AWCs in the European Research Area and to draw conclusions concerning best practices, bottlenecks and recommendations.


Information was obtained from the following sources:

- a questionnaire specifically developed for the purpose of this study;
- e-mail contact with key persons in the relevant countries;
- the Internet, especially websites of official organisations and various stakeholders;
- national animal welfare legislation;
- publications, brochures, and application forms concerning AWCs (see Appendix B, table 1 data acquisition for detailed information).

The questionnaire contained questions about legislation, review, procedures, composition, transparency, communication and opinions on the functioning of AWCs. During 2003, it was sent to 81 stakeholders in the countries mentioned above, mainly contact persons of AWCs, representatives of animal protection organisations and of scientific organisations. Fifty-one replies were received, a 65% response.

Today, most countries have introduced laws to regulate the use of animals in scientific procedures. In the European Union, two important regulations apply for the use of animals in research and regulation: The Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (Council of Europe, ETS 123), and the Directive for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (86/609/EEC). These regulatory systems have the following general objectives (van Zutphen 1993):

- To define legitimate purposes for which laboratory animals may be used;
- To ensure competence of all persons involved in animal experimentation;
- To limit animal use where alternatives are practicably available;
- To prevent unnecessary pain or distress to animals;
- To provide for the inspection of facilities and procedures;
- To ensure public accountability.



Although AWCs are not mandatory under the EU legislation (Directive 86/609/EEC), they may play an important role in reaching these objectives by reviewing, discussing and evaluating scientific procedures. A revision of the Directive 86/609/CE is now under discussion. In the proposals for the revision of the Directive, the implementation of mandatory AWCs in EU countries is considered. The analysis and evaluation of this study is meant to contribute to the process of decision-making on this matter.

The data and results of the study are reported and analysed along the following lines. Chapter 2 contains a general reflection on the purposes, functions and reasons for setting up AWCs and their actual presence and status in the countries examined. Some notable trends and developments are discussed. Chapter 3 elaborates in more detail on the procedural aspects of AWCs and treats matters of affiliation, composition, working procedures, transparency and accountability. Chapter 4 is about the substance and content of the review process, and discusses the differences between legal, scientific and ethical reviews and the implications of these differences.

An additional objective of the study was to establish a Directory for contacts within the European Research Area (ERA). This Directory consists of 78 contact addresses of institutes for national, regional and/or local AWCs in ERA countries. Those approached have given their permission to be included in the EC Directory as a contact person for their country. Contact persons are members of a local or regional AWC, a national board or committee, or of a competent authority such as a Ministry. No names of persons are included for reasons of confidentiality. The EC Directory is restricted to information about institutes, giving addresses, e-mail addresses, telephone and fax numbers and, if available, websites. In case a contact person could not be found, the address of a competent authority has been given, such as a government department or a national committee. Despite repeated efforts, it was not possible to establish contacts for some countries. These may be included at a later stage.

# General State of Affairs Concerning AWCs in the European Research Area

## 2.1 Reasons for setting up AWCs

AWCs are intended to protect and promote the interests and welfare of animals used in scientific procedures. Generally, they contribute in four ways to this end:

1. By inspecting whether legal requirements, (for instance, concerning competencies of staff) are complied with;
2. By reviewing the reasons and conditions that determine the validity, necessity and worthiness of a scientific procedure or project;
3. By reviewing the opportunities for applying the Three Rs principle: to Replace the procedure with a method or strategy which uses non-sentient material, to Reduce the number of animals used in the procedure, and to Refine the procedures so as to make animals suffer less;
4. By making an ethical assessment of the ratio between the harm done to the animals and the possible benefits of the procedure for man (and sometimes animal).

AWCs fit into a more general climate of increased concern for animals. This climate may differ from country to country because it is influenced and reinforced by a number of factors. For the questionnaire, we selected the European directive, the public debate in a country, the role of the animal protection movement and awareness in the scientific community as possible sources of motivation to set up AWCs.

### Results

The European directive and awareness of the scientific community are mentioned most often, the public debate much less (only by five respondents). Some respondents (Portugal) indicate all influences as being relevant. Others only mention one, such as the UK (the European directive). Some respondents did not answer this question.

### Analysis and evaluation

These results do not permit significant conclusions. The four 'motives' cannot be prised apart. The responses, for instance that awareness of the scientific society is deemed more important than outside pressures, are to some extent explainable as artefacts of the questionnaire. The fact that the UK and the Netherlands, which both have influential and well-organised animal protection movements, do not mention these organisations as an influence reinforces this impression.

The European directive is often mentioned, although this directive does not mention, yet, AWCs. An explanation for this could be that the general objectives of the directive are such that the installation of AWCs is quite in line with these objectives. The fact that political or legal action is initiated is, without doubt, one of the driving forces behind the evolution of AWCs into serious institutions.

## 2.2 AWCs per country and their legal status (Appendix B, table 2)

### Results

All 25 EU Member States, except Greece, have introduced AWCs for the review of animal experiments. In most countries, AWCs have a legal basis, with the notable exception of France and Ireland. Legal status means that there is a formal regulation concerning AWCs, which states that a recommendation from the AWC is mandatory before a project licence is issued, or before the carrying out of an experiment is legal. In most cases this recommendation is not binding, which means that the applicant has the freedom to overrule the recommendation, or that there is an appeal procedure. In Denmark, Italy, Portugal and Slovenia there are mandatory national committees; other countries have mandatory local committees. In countries where AWCs do not have legal status, AWCs may exist as a result of the initiative of local institutes in order to meet scientific standards, in response to criticism from the public and/or because funding organisations require ethical review. In some cases, non-mandatory AWCs precede mandatory committees, for instance in Estonia and Bulgaria, where regulation is under preparation.

### Analysis and evaluation

Animal experiments are an essential part of an extensive scientific practice with important societal implications, such as the legally regulated testing of possibly toxic substances. Due to the high standards set for science, there is already a system in place in most countries that reviews the scientific validity of animal experiments. In view of the international character of science and regulation, it is likely that countries throughout Europe will develop comparable systems of control and evaluation for legal and scientific matters. International scientific contacts and regulatory structures will facilitate the spread of institutions such as AWCs. However, legal systems, the institutionalisation and extent of scientific practice, as well as societal and ethical concern about animals, differ across European countries and might lead to different social and legal implications.

## 2.3 The evolution of AWCs

As will become clear in the elaboration of the procedural and substantial aspects of the functioning of AWCs, there are a number of differences between AWCs in various countries. The most important of these differences can broadly be construed as 'steps' in developing AWCs to serious, authoritative institutions.

Six important stages of development can be distinguished:

1. Whether or not the existence of AWCs at some level is *mandatory* by law. This is clearly the case in most countries and it seems just a matter of time before other countries follow.
2. Whether or not *all* animal experiments in a country are reviewed. In the fully developed form of an AWC system, all scientific procedures involving *vertebrate* animals are reviewed.

3. Whether or not AWCs have a balanced *composition*, with the relevant expertise present, and with clear rules for the *independence* of members.
4. The *status* of the recommendations. An uncommitting recommendation is now rare and, in many cases, a positive recommendation is legally required.
5. The *extent* of the review. An (extra) control of the scientific aspects of the experiment and a review of the opportunities to Replace, Reduce or Refine the experiment are found in all countries. In addition, an ethical assessment of the experiment in terms of the harm-benefit proportionality is found in the majority of countries. Other tasks might be assigned, such as a review of the housing of the animals, the promotion of ethical awareness of researchers and the public, or the introduction of a 'culture of care'.
6. The *professional* competence and attitude of members and organisations. Professionalism includes training the members and providing a financial contribution to support the functioning of AWCs.

These six steps seem to indicate an evolution of AWCs in the direction of a set of 'best practices' or a model, which represents AWCs as formal, legally based, professional institutions with a strong mandate and a clearly defined scope of recommendation and judgment. However, this picture does not do justice to the complexities and differing views regarding AWCs. Relative to the various elements of the remit and the implications of recommendation and judgment, some of these steps can be evaluated more positively while others are more ambiguous. For some of these developments it may be not a matter of time, but of choice, whether a particular format of AWC will stabilise. On principled as well as practical grounds, it is understandable that major differences between models of AWCs may develop. These differences may originate in the legal, social, cultural or ethical system of particular countries as well as in the kind of advisory tasks (scientific, ethical and legal) with which the AWCs are commissioned.

A more extensive remit and more formal authority for the recommendation given by AWCs may have important consequences of a practical and legal nature. For instance, if AWCs have the legal authority to dismiss experiments and procedures as being morally unacceptable, this is bound to have significant consequences for the rights of licenceholders and scientific researchers. This authority could probably only be sustained when the procedural and legal requirements, imposed on AWCs, are much higher than they seem to be currently. This again will involve higher financial and practical costs, both for AWCs and for the applicant. Seeking a balance between safeguarding the stakes and rights that scientists, companies, patients and consumers may claim regarding scientific procedures with animals on the one hand, and the protection of the interests of animals on the other, is the central challenge that AWCs have to meet. We will see how AWCs try to meet this challenge by examining the procedural and substantial aspects of their nature and functioning.



# Procedural Aspects of AWCs

In this chapter, we describe and discuss constitutional and procedural aspects of AWCs, leaving out the substance of the review and evaluation as far as possible, as this will be dealt with in the following chapter. Procedural elements that are central to the nature and functioning of AWCs are institutional affiliation, advisory relationships, the remit, the composition, and policy concerning transparency and public accountability.

## 3.1 Institutional affiliation and advisory relations of AWCs: local, regional and national AWCs

Three ways of institutional affiliation and location of AWCs are found, which are sometimes related to different mandates and tasks: local or institutional AWCs, regional AWCs and national AWCs. The advisory relationships and appeal procedures are closely bound up with these levels of organisation.

### Results

The most common system found is that of a local or institutional AWC combined with a national committee (15 out of 26). In 4 of the 26 countries, mostly small countries, only national committees exist (Cyprus, Denmark, Norway and Slovenia). A regional system, combined with national or local committees, is found in France, Germany, Spain and Sweden.

The most common situation is where the review of particular animal experiments and the recommendation on the acceptability of the experiment is a matter for local AWCs. Small organisations sometimes make use of the services of the AWC of another institution. The national AWC functions as an instance of appeal (the Netherlands) and/or reviews specific kinds of experiments (for instance with severe suffering of animals) or experiments with particular species of animals (Italy). Sometimes national committees review research programmes of a larger scale (Denmark) or give recommendation to the government on general matters of animal experimentation.

The advisory relationship and affiliation of local committees is generally with the institutional licence-holder regarding animal experiments. Licences are issued by the government. In practice, the recommendation is often addressed to the individually responsible researcher or manager. Sometimes the recommendation is given by a local committee to a national committee, which decides on the acceptability of the experiment. In the case of national and regional committees, the recommendation is mostly given to the Governmental Authority, which then decides on the matter. In many countries, this authority is the Ministry of Health or the Ministry of Agriculture (see Appendix A, table 5.1 for the details per country).

Appeal procedures are found in all countries in which AWCs have a legal mandate. An appeal against a recommendation from the AWC can be lodged either by the licence-holder, in the case of a negative recommendation, or by the AWC if the recommendation is not accepted by the applicant. Usually an appeal is lodged either with the relevant national authority, for instance the Veterinary Inspector or the Home Office, or to a national AWC. In cases where AWCs have a more informal status, there is rarely a formal possibility of appeal if the recommendation is ignored. (For more complete information on these appeal procedures, see Appendix B, table 4)

### **Analysis and evaluation**

Animal experiments take place within three kinds of institutions:

1) universities and research institutes, 2) research and testing institutions that are under governmental responsibility, and 3) private commercial companies. Each of these bodies is characterised by a specific mission, purpose, way of organisation and institutional set-up. This particularity may serve as an argument that AWCs are best affiliated to institutions: this facilitates adequate information and communication, as well as an evaluation that takes into account the specific context of the animal experiments to be reviewed. Another reason is that it allows for quick and reliable procedures, which are important for the functioning of organisations.

There are, however, also arguments against affiliating to an institution, based on the impartiality of reviews and the small number of experiments carried out by organisations, and it could be that AWCs might be better located on a regional or national basis, or set up as a layered system.

The decision where to locate AWCs and how to structure the relations between types of AWCs is bound up with the following considerations:

- The number of animal experiments. In some countries, the scale of animal experimentation is too limited for a system of local committees to be efficient. One national, or a few regional ones, suffice.
- The existing political and constitutional order in a country. Certain countries (notably Germany and Switzerland), with strong federal or regional constitutional traditions, locate committees on a regional level.
- The general opinion concerning the desirability of centralisation or decentralisation of societal decisions.
- Whether the review is confined to a particular animal experiment, as described in a research protocol, or is about research projects or research programmes of a general character. In the first instance, it is hardly possible for a national AWC to review experiments in detail, especially where large numbers of experiments are carried out. Many countries decide to have a division of labour between local and national committees: local committees review particular experimental protocols and monitor the conditions under which they are conducted, while national committees concentrate on more general and/or ethically sensitive issues, and/or function as a Court of Appeal.
- The presence of a procedure of appeal. If an appeal is not possible and a positive recommendation about an animal experiment is mandatory, then the elementary requirements of due procedure, as well as opportunities for more extensive, thorough and independent review and establishment of norms, are missing.

If a harm-benefit evaluation and ethical assessment is explicitly required from AWCs then, for reasons of impartiality of moral judgement, it might be argued that the evaluation should be made by an AWC that is not affiliated to an organisation, which has a major interest in the procedures being accepted. If the emphasis is laid on reviewing the possibilities of Replacement, Reduction and Refinement, then this reason seems less relevant, because this review is more science-based and is often in the interest of the licence-holder.

Two recent developments confirm that a system of division of labour, between decentralised institutional AWCs and a more independent and authoritative (national) AWC with respect to aspects, levels and objects of review, is desirable. Until recently, Denmark and the UK have had centralised systems but have started to install local committees as well. In the Netherlands, which has a system of institutional AWCs, the decision about the acceptability of the making of transgenic animals lies with a national committee, which reviews larger programmes of research and their ethical justification. These developments demonstrate the attempt to relate several aspects of the review of animal experiments (scientific, Three Rs, ethical and social) to bodies that are best equipped and mandated to deal with them in relation to requirements such as informativeness, knowledgeability, professionalism, independence, societal involvement and moral authority.

### 3.2 Tasks of AWCs

Regarding the remit of AWCs, four tasks are considered:

1. To *review* research protocol applications involving vertebrate animals concerning:
  - compliance with legal regulations
  - scientific soundness of the research design
  - necessity of the research
  - competence and experience of researcher and animal care-staff
  - opportunities for reducing the number of animals used, preventing or relieving pain and distress to the animal and the use of non-animal alternatives (Three Rs)
  - ethical aspects – weighing the harm to the animals against the benefits of the experiment.
2. To give *recommendation* on these matters to:
  - the authorities on licencing the research
  - the director of the facility on permitting the research
  - the researcher on improvement of the design.
3. To *assess* and *recommend* concerning accommodation, husbandry, breeding and care of laboratory animals, the training of staff and the management of the facilities.
4. To *stimulate* the ethical *discussion* and the ethical *awareness* on the use of animals in research.

### Results

The review and evaluation of scientific procedures, and the recommendation regarding experiments, is generally the central assignment of AWCs. Only Belgium mentions the stimulation of ethical discussion, while Spain, Belgium and the UK refer also to the assessment of management. Often, the assessment of animal accomodation and the staff's training are also mentioned.

## Analysis and evaluation of the results

The results show a clear hierarchy in the tasks of AWCs, at least of the local or institutional type. The review of the protocols of animal experiments and the recommendation on the acceptability come first, while the assessment and recommendation on general facilities and conditions of experiments are of secondary importance, maybe because they are (also) taken care of by other authorities. But, as the review has several components (scientific, Three Rs and ethical), it is not immediately clear whether all these components receive equal attention. However, there seems to be a general belief that animal experiments should be reviewed and evaluated on the level of particular experiments, not (just) on the more aggregate level of programmes.

For national AWCs, this picture may differ, especially in countries where they are combined with a system of local AWCs. The task of the national AWC will be to discuss issues that are more general. It could function as a body in which more generic norms for animal experiments are considered and proposed, either by way of stimulating debate or by establishing standards and codes of best practice.

## 3.3 The composition of AWCs

The size of local and regional committees varies from four to ten members, national committees number between 10 and 15. The term of office varies from two to four years, although it is sometimes renewable. The numbers reflect both the need for representation of essential expertise and the need for a broad support of the judgments and recommendation. The composition of AWCs is one of the essential procedural matters. It is connected with other elements, especially the remit, and is of great importance for the status of the recommendation and trust that the general public puts in AWCs.

We concentrate on two sets of issues: regarding the expertise and qualifications of members, and regarding the independence of the members. The results and analysis apply mainly to local and institutional AWCs.

### 3.3.1 Expertise and qualifications of members (Appendix B, table 6.1-6.5)

#### Results

The kinds of experts who are regularly mentioned as imperative for the functioning of AWCs are:

- Experts in scientific experimental design and method (statisticians, methodologists), particularly experts in methods of animal experimentation (animal laboratory scientists);
- Experts in veterinary science and practice, animal husbandry and care. These are generally veterinarians, but also ethologists and animal welfare scientists. Often, these are laboratory animal scientists, specialising in animal diseases, animal behaviour, surgery and medical applications, specifically related to the use of animals in scientific procedures;
- Experts in research: scientists, depending on the area of research – medicine, biology, zoology, other natural sciences, neuroscience and physiology, clinical researchers, zoo technicians, animal welfare experts.

This expertise concerns animal laboratory research in the strict sense. Other members have other sorts of expertise and qualifications that are relevant for animal experiments. Three categories can be distinguished:

- Scientists with expertise relevant to the regulations concerning animal experiments, such as lawyers, ethicists, and experts in alternatives to animal experiments;
- Representatives of institutional authorities, such as civil servants from the relevant ministries, veterinary inspectors, or the director of the institution/facilities;
- 'Laymen', a category best described negatively as not belonging to the former categories. They are supposed to have an outsider's view on animal experimentation. Members from the animal protection movement are considered laymen, although they may have a scientific background. A layperson may also be a scientist, for instance a sociologist, a theologian, an ethicist or a biologist. In universities, students may be members of AWCs. In some countries, such as France, Ireland, Latvia and Sweden, members of the public who have no ties with the animal protection movement are AWC members.

### **Analysis and evaluation**

The variety of qualifications and expertise reflects the complexity of, and some of the problems with, the remit of AWCs. The review of the scientific validity and value of the research, of the specific requirements from the point of view of animal laboratory science, of the possibilities to improve the protection of animals by applying the Three Rs principles, and the review and evaluation from a moral point of view: each requires specific competencies and attitudes. In the ethical evaluation, they are also intertwined.

It is generally acknowledged that scientifically unsound or useless animal experiments, or procedures that can be replaced or refined, are immoral. But judgments on these matters may be contentious. In many institutions, a scientific review is assigned to a research committee, a research manager or the head of the research group. Conflicts may thus arise between the judgment of the AWC and other authorities. As science is often a key argument in the review, it is important to sort out powers and competencies in this matter.

Scientific research may be valid and worthwhile from a strictly scientific point of view, and still be considered unjustified, because the degree of animal suffering that is involved is disproportionately great compared to the expected value and benefits of the experiment. This evaluation, however, is a complicated matter involving difficult judgments of probability and morality, which can only be given by taking into account the wider context that will determine the meaning and purpose of the particular scientific procedure under consideration.

The expertise mentioned in the second set of categories is of a different kind than that in the first. It is a matter of the 'insider' expertise of those actively involved in animal experiments and science, versus the 'outsider' view of those who are not. If all sorts of expertise and views are taken on board in an AWC, a complicated communication is to be expected, especially regarding the ethical evaluation that is bound to be influenced by the professional and personal views of its members.

Given the wide variety of backgrounds, expertise and viewpoints, and the complexity of the review, more knowledge about the dynamics of the process of deliberation and decision-making that are going on in AWCs is needed. As animal experiments are part of complicated and specialist scientific practices and processes, there is a tendency to emphasise the 'objective' scientific aspects, which are often hard for nonprofessionals and outsiders to understand. Outsiders may prefer to be silent about their doubts, because of the difficulties of grasping the scientific point of the particular experiment within a wider context. There is also a danger that members who have served a long time on an AWC have disproportionately greater power or influence. For reasons of fair and equal judgment, this is not desirable.

### 3.3.2 Independence (Appendix B, table 7)

The independence of the members is an important issue, especially in institutional AWCs, which often include a number of members who are on the payroll of an institution or company. This fact might not only hinder the committee in reaching fair and balanced moral judgments, but could also negatively influence the commitment to applying the Three Rs, and the independent judgment of the scientific quality of procedures.

#### Results

The strategies, by which AWCs cope with these problems, can be categorised by two broad concepts: person-related independence, and collective or procedure-related independence.

Examples of claims of person-related warranties of independence are:

- some members are laymen;
- some do not have any interest in animal experiments;
- some come from outside the affiliated institute or have no relation with the authority that issues the licences;
- members receive no payment;
- some members are publicly accountable as civil servants.

Examples of claims of procedure-related or collective warranties are:

- the committee is composed of members from different scientific backgrounds;
- members come from different institutions and bodies with different interests (industry, research funds);
- members are appointed by (or their appointment has to be confirmed by) an independent authority;
- the meetings are closed, so one can speak freely. Individual opinions are not communicated outside the committee;
- central elements of the review process, such as decisions and motivations, are public;
- the review is anonymous.

#### Analysis and evaluation

More clarity is needed on the concept of independence and its relation to the functions and expectations regarding AWCs. The person-related notions of independence involve three conditions, which are sometimes convergent, conflicting and unrelated:

- Independent in a 'social-cultural' sense: supposedly outsiders who do not have a background in animal experiments and science, have a non-biased, independent view on the matter.
- Independent in an economic sense: members who are not affiliated to the institute as an employee or receive no payment, are supposed to be able to judge free from interest.
- Independent in the sense of 'free from a direct conflict of personal or professional interests' (this may often be subsumed under the previous point).

The procedure-related notions of independence combine one or more of these ideas with the formal process of selecting and appointing members, and with the general idea that the presence of a plurality of viewpoints and interests will lead to an independent and impartial recommendation, because the recommendation will incorporate this plurality. The ambiguity of the notion of independence is further shown by the argument that because the meetings are closed, members may speak freely and independently, unhindered by pressure from outside. However, that independence is sometimes said to be hindered by the fact that the documents are made public.

Matters of independence of judgment also have to be sorted out in relation to the various aspects of the review. With regard to the ethical evaluation, the interpretation and meaning of independence is more difficult, because there seems to be no consensual framework of standards and principles to judge the moral acceptability of animal experiments, while moral values and ideals are central to personal identities and often strongly felt. With regard to scientific value and validity and the application of the Three Rs, things might be different.

Currently, there is no recognisable 'best practice' for the composition of AWCs. The expertise and qualifications mentioned all seem important and even necessary from relevant points of view. The presence of experts, who are knowledgeable about the technical and scientific matters of experiments and research, is particularly important. Though, for their judgment to be trustworthy, it is important that they have no strong interests in the proposals under consideration and that they are selected and appointed according to a clear and transparent procedure. Besides, AWCs should consist of a substantial number of members with different backgrounds and independent positions, and the recommendations should be made public and accessible.

### 3.3.3 Protection of members of AWCs

#### Results

The protection of the members of an AWC is an issue because, in some countries, an intimidating and even violent animal protection movement is active. Protection is given by holding meetings in private and keeping names of members and other data confidential. Meetings (especially at the local level), which, for reasons of confidentiality of scientific and economic information, are also the most sensitive, are generally not open to the public. Names of the members of AWCs are generally treated as confidential. Finland and Switzerland are exceptions.

## **Analysis and evaluation**

One of the drawbacks of the measures taken to warrant protection of members is that they may reinforce the impression that members are not prepared to account for their judgments, because they are influenced by the interested parties. Moreover, stressing the negative influence of abolitionists' groups may distract attention from the fact that there may also be undue influence and pressure on the judgment of members of local AWCs within the institution, especially on those who are in the pay of the organisation. The concern for protection and confidentiality may undermine the credentials of AWCs as trustworthy and impartial bodies for supervising the quality and acceptability of animal experiments.

There is a need for an exchange of experiences and ideas between AWCs in Europe concerning these tensions and measures of protection and confidentiality, which are relative to issues of independence and public accountability. This matter is closely linked to the issue of transparency, which will be discussed below.

## **3.4 Working procedures**

How do AWCs reach a recommendation? Regarding the formal relationship of AWCs to applicants, please refer to Chapter 3.1. In this section, we treat aspects of communication with stakeholders such as researchers, the deliverables of AWCs and the transparency and public accountability of recommendations.

### **3.4.1 Communication (Appendix B, table 8)**

#### **Results**

AWCs usually discuss and recommend in the form of a written application (protocol) of a particular format. The protocol contains the relevant information about the procedure and the motivation as to why it is necessary. Often the researcher is invited to attend the meeting to provide further information and answer questions in person. In some countries (France, Austria and the UK), this is standard procedure. Extra information is also collected by phone, fax and e-mail, either by the secretary or by a designated member. When the review process takes place locally, personal contacts are more common. The recommendation is generally given in writing.

#### **Analysis and evaluation**

There is a difference between AWCs, which rely more on formal procedures and written requests for more information, and AWCs, which seek personal communication with researchers for information and motivation. The difference reflects a tension between, firstly, an approach which stresses distance, impartiality and a formal criteria of review, and secondly, an approach which tries to acquire information by way of an interview with the researcher, and to arrange for a broader consultation of the motives and reasons of the researcher. Implementing improvements in the experimental protocol, for instance regarding the Three Rs, may be easier if it is possible to refer to the interview with the researchers or biotechnicians involved.

These working procedures may often be the consequence of contingent, practical and institutional possibilities (administrative, personal and financial) and of traditions rather than principled reasons. It is important to be aware of the possible conflicts of interest and psychological factors that might unduly influence decisions in the case of more personal contacts. Adverse effects of purely formal relations are practical difficulties in developing a reliable picture of the research and reaching workable decisions, and a tendency to stress the bureaucratic and legal, not the moral purport of the review and evaluation. Different aspects of the review (scientific and ethical) may well invite different evaluations of these arguments. In any case, adequate administrative and financial support for AWCs is important for the reliability and quality of working procedures and recommendations.

#### **3.4.2 Prospective/retrospective review (Appendix A, table 14)**

The review is usually prospective, resulting in a recommendation about the procedure or project that is to be performed. There are some retrospective reviews, especially with regard to the review of facilitary conditions and the assessment of levels of suffering in ongoing experiments.

##### **Analysis and evaluation**

While AWCs ought to be careful not to become a 'policing' institution, it is important that ongoing and retrospective reviews, especially with regard to the scientific and Three Rs performance of researchers, are taken up in a (more) systematic and serious way. AWCs ought to keep themselves informed about the actual developments, and about the difficulties and achievements related to animal experiments. This applies to the Three Rs performance, but also to the scientific performance. Every three years in Sweden, the licence to conduct animal experiments needs to be renewed, based on a review of the reported research results and data. This procedure might be a means to achieve more comprehensive appreciations of the quality and acceptability of animal experimentation.

#### **3.4.3 Deliverables (Appendix B, table 9)**

The deliverables of AWCs consist of minutes, written recommendations, annual reports and lay summaries. The most common records kept are those of the written recommendations. Lay summaries are found in Finland, Belgium, Ireland, UK and Denmark. In addition, annual reports are prepared at a national or institutional level, or both.

##### **Analysis and evaluation**

The issue of deliverables is important in three respects. First, a reliable and comparable (between countries) system of acquiring information on AWCs' performance and procedures is an important source of information for national and European policy. Secondly, the requirements concerning recording and registering minutes, recommendations and summaries may be quite different. For instance, it is important whether the recommendation is confined to 'positive' or 'negative', or whether written motivations for the recommendation are mandatory. For the credibility of AWCs, it is important that the substance of the deliberation leading to the recommendation is made public. Thirdly, public 'visibility' of AWCs and their accountability are closely connected, but may not combine easily because the dynamics of publicity may counteract a balanced judgment and motivation.

#### 3.4.4 Transparency (Appendix B, table 10)

With regard to transparency and the public character of the activities of AWCs, we have to distinguish between:

1. Accessibility of meetings of AWC to the public, or for specified groups of non-AWC members.
2. Disclosure of specific written documents: protocols, minutes, recommendations, annual reports, etc.

#### Results

Meetings of institutional or local AWCs are not open to the public (Latvia is an exception) but meetings can be attended by members of the civil service or the inspectorate. Meetings of national AWCs are sometimes open to the public.

With regard to disclosure of written documents, the situation differs between countries and types of document. Annual reports, with data of a more general nature, are generally available. Documents that are more specific, such as protocols, are generally not made public, neither are the minutes. With a recommendation, there is a difference between a general account (the number of recommendations made, positive/negative) and a specific list, which is related to the experiments. A general overview is often incorporated in the annual report. However, a more specific list of recommendations and motivations is rarely available, probably because the relationship with the protocols is too narrow and the information contained is confidential, either for scientific or industrial reasons. This is also the reason why members are generally obliged to keep information and documents about AWC proceedings confidential. Guidelines concerning the work of AWCs are available in many countries (table 10.1). Legislation in Finland gives the public or interested parties, such as animal protectionists, access rights to protocols and/or the decisions of the AWC, but confidential information is not included.

#### Analysis and evaluation

From the point of view of politics and ethics, and the interface between science, industry and society, the transparency of AWC activities and performance is a crucial matter. The picture of the state of affairs of European AWCs in this regard is confusing and incomplete. One of the reasons for the confusion is that there are different interpretations of transparency, different items of disclosure, as well as ways and levels of 'going public' or making things accessible.

There are essentially three problems to consider:

1. conflicts between transparency and rights of confidentiality of interested parties;
2. conflicts between security matters and 'going public';
3. relationship between arguments for particular kinds of disclosure and conceptions of the main tasks and functions of AWCs.

Regarding the third issue, if AWCs are conceived as institutions, which are designed to build bridges and trust between science and society in the sensitive area of ethical and humane treatment of laboratory animals, some degree of transparency and public accountability is unavoidable. Public accountability is also crucial to the development of common principles, procedures and standards to prevent large differences and inequality between AWCs in different organisations and countries. It is essential that this discussion on common standards and harmonisation is carried out, because it is important to safeguard conditions of equality under which market parties and scientific institutions operate, and to foreclose unverifiable 'shopping around' to get approval from AWCs, both within the European Union and globally.



# Substance and Elements of the Review Process

The review process generally focuses on the following four aspects of the animal experiment under consideration:

- the scientific aspects of the experiment (validity, value, necessity);
- the application of the Three Rs principle: the opportunity to Replace, Reduce or Refine parts of or the whole experiment;
- the ethical review and evaluation;
- the formal and legal requirements, and the conditions for conducting experiments, such as the competencies of the personnel and the quality of the facilities.

We will first present the results and discussion on the types of scientific procedures with animals that AWCs are supposed to review. Decisions about including or excluding particular categories of experiments, and/or of species, reflect the framework and assumptions that determine the ethical evaluation of AWCs.

## 4.1 The scope of the review (Appendix B, table 11, 12 and 13)

The range of the experiments to be reviewed may be broader or more limited in several respects:

- specific experiments or *procedures* are excluded from review, or receive special attention;
- specific *species* of animals are excluded or receive special attention;
- the *level* of aggregation of procedures may differ. Local AWCs mostly review particular experiments or a series of experiments, but ethical evaluation is often meaningless without taking into account the broader context that determines the necessity and significance of the experiment, such as the purpose and value of the scientific project or programme.

### Results

Usually AWCs review all scientific procedures (at the protocol and/or project level) involving *vertebrates*. Experiments with invertebrates are, as a rule, excluded. Sweden is an exception, as it also reviews experiments with invertebrates. In some countries, decapods, cephalopods and octopi are included. Scientific work with larval, foetal, and embryonic stages is sometimes exempted from review (e.g. Spain). In Italy, *only* experiments with cats, dogs, non-human primates and experiments without the use of anaesthesia are legally subject to review. (For further information, see Appendix B, table 11)

Some scientific procedures with vertebrates are excluded from review. Killing animals for *in vitro* work is not subject to review in Belgium, Germany and the UK. In Denmark, field studies and some dietary studies do not need to be reviewed. In Germany, regulatory tests,

vaccinations, withdrawal of blood samples and other diagnostic measures to detect human diseases and defects, or to test serum are exempt from ethical review. In Norway, clinical veterinary procedures, marking, withdrawal of blood samples, collection of secretion, breeding, rearing, feeding and environmental procedures are exempt from review. (For further information, see table 12)

Categories that receive special review in some countries are procedures involving severe suffering (Ireland), the making of genetically modified animals (the Netherlands and Norway have special national committees to monitor this) and, lastly, procedures with certain species of animals (for example cats, dogs, non-human primates).

Applications may be reviewed at project or procedure/protocol level. At the project level, detailed information about the procedures is often not available, and the review of the Three Rs (Reduction, Replacement and Refinement of animal experiments) cannot be carried out adequately. With information available only at the procedural level, an ethical evaluation, based on a harm-benefit analysis of the significance of the experiment in a broader sense, becomes difficult. (For further information, see table 13)

### **Analysis and evaluation**

The basic moral assumption of the review of AWCs is that the protection of the welfare and interests of *sentient* animals is vital. However, Sweden, which reviews procedures with invertebrates, is an exception and there are indications that factors other than sentience, such as animal integrity and the human-animal relationship, are considered in the ethical evaluation. The inclusion or exclusion of larvae, foetus and embryos is controversial, and we are awaiting further scientific evidence on the experiential capacities of animals in these stages. As the protection and care of experimental animals cannot reasonably be confined to the episode of the experiment itself, we think that it is appropriate to extend the review to the use of sentient animals in all stages. This applies specifically to transgenic animals.

Considerations on these inclusions need special attention and should be the starting point of a broader, as well as an in-depth, discussion on the frameworks of moral principles and standards, which either implicitly or explicitly determine the decisions of AWCs.

## **4.2 Scientific review: validity, necessity and value of procedures**

The scientific review of animal experiments or projects is a complex matter. Firstly, it has to be considered that there are three different areas of science-based animal use: fundamental research, applied research, and a set of various uses such as testing and the acquisition of biological material, which are more or less standard and non-experimental. Standards for scientific review differ for each of these areas. Secondly, a scientific review may be about the methodological validity of a single experimental design, about the necessity and value of the specific procedure within the broader framework of a project, or about the scientific value – for instance its novelty – of the project. These types of judgment involve different criteria and are not equally objective. Finally, the correct use (selection, preparation, interpretation of results) of animals in science is a complex issue, which requires specific scientific expertise.

## Results

Whether an AWC has the expertise and should have the power to perform a scientific review of the procedure or project seems to be a point of debate. Out of all the countries we surveyed, 13 respondents replied that a scientific review is part of the activity of AWCs. However, in view of the vital role of scientific standards, the assessment of the scientific aspects is also a matter for institutions, persons and/or mechanisms other than an AWC. A number of aspects regarding scientific quality are often considered to be within the competence of the researcher and/or the institute, the financing body, etc. Questions concerning the experimental design, such as the choice of species, the microbiological status, and the number of animals are generally considered part of the review of an AWC. However, there is a grey area between the laboratory-animal science aspects and the general scientific aspects of research.

Questions concerning the necessity of an experiment can be of either a scientific or an ethical nature. Whether an experiment is necessary to reach a certain objective is a scientific or methodological question. The question whether the objective justifies the experiment is an ethical question. The fact that this last question is a matter of review for AWCs was mentioned by 16 out of 21 respondents.

Whether animal models are reliable sources for information on the human condition is a renowned question. Abolitionists often claim that using animals for research for human diseases has no scientific validity. This is a difficult aspect for an AWC to review because it needs specific scientific expertise. The researcher is often the specialist and therefore it is difficult for non-specialist members of an AWC to discuss this matter on an equal basis. Nevertheless, 13 out of 21 respondents replied that the scientific validity of models is considered.

## Analysis and evaluation

The procedures for scientific review and the relationship between AWCs and other authorities and bodies are often unclear (see also point 3.3). There are general and specific questions about the effectivity of the use of animals, the answers to which remain contentious. More information about how AWCs deal with these matters is needed, taking into account the diversity that is introduced by the differences between areas of research and the different elements of scientific review. The assessment of a single procedure may be just a matter of monitoring competencies and applying best practices. However, the assessment of the scientific value and the impact of projects and programmes involve difficult questions of a normative nature and probability. Whether local or institutional AWCs are equipped and/or mandated for this task may be questioned. Nevertheless, they may play a role in, and profit from, broader frameworks of assessment of scientific research projects. Reviewing the scientific validity of projects and assessing their value and significance is an important part of the balancing process, which determines whether animal suffering in experiments is justified, especially in fundamental research. More attention should be given by AWCs to the possibilities of linking this aspect of the review to the assessment of funding procedures, the reports on scientific performance of organisations, and other general mechanisms of monitoring scientific performance.

### 4.3 Reviewing the Three Rs: opportunities for Replacement, Reduction of numbers, Refinement of experimental procedures

The Three Rs concept was introduced as an appeal to perform animal experiments in as humane and responsible a way as possible, and are now widely accepted in laboratory animal science. The concept of the Three Rs is a more detailed interpretation of the term 'alternatives'.

#### Results (Appendix B, table 16)

Controlling opportunities to apply the Three Rs in a scientific procedure is, to a large extent, a scientific issue. It requires detailed information concerning the procedure to which the animals are subjected. The information needed includes data about the number and species of the animals, housing, surgery, anaesthesia, restraint, fluid collection, humane end points, type of discomfort, etc. The discussions are of a technical nature and cover the fields of veterinarian science, statistics, housing, use of analgesics, in vitro toxicology, etc. The scientific and technical character enables a professional and objective discussion.

Reviewing the Three Rs is, according to many respondents, the backbone of the review processes of AWCs in the countries studied. Eighteen out of 21 respondents confirmed doing reviews according to the Three Rs concept.

#### Analysis and evaluation

Local or institutional AWCs seem well equipped and suited to review the application of the Three Rs, given the kinds of expertise that are present, and the fact that they have the relevant detailed information available. The field of knowledge concerning the Three Rs, however, is in steady development, scientifically as well as legally. So it is important that efficient and readily accessible sources of information and regulation on 'alternatives' are available, and that members of AWCs are regularly trained to keep informed about the latest developments.

The review of the Three Rs is not an ethical review in the strict sense, as it includes many laboratory science aspects. It is a review that is motivated by moral considerations of optimising animal experiments by considering what the animals will experience. Sometimes applying the Three Rs may lead to moral dilemmas, for example, when an experiment may be conducted with fewer animals that suffer more – a conflict between Reduction (less animals) and Refinement (less suffering).

### 4.4 Ethical review: harms and benefits of experiments

The ethical review concentrates on the balancing of the interests of animals and human beings (or animals and animals in the case of veterinary research). The central dilemma is the conflict between the moral *principle of non-harming* (of sentient beings) and the *principle of beneficence* (promoting well-being). Harming the interests of animals and making them suffer, sometimes severely, requires moral justification. Justifying reasons involve the substantial benefits that may result from doing animal experiments, for instance the production of a new,

improved drug or the acquisition of insight in the etiology of human diseases. This ethical evaluation should take into account the significance of interests (vital, serious and trivial) as well as the many and sometimes complex aspects of probability and uncertainty that mark scientific and applied research.

## Results

In 14 countries, a harm-benefit analysis and ethical evaluation is officially expected as part of the AWCs' brief (see Appendix B, table 17). In order to conduct a harm-benefit analysis and an ethical review and evaluation, the AWC needs to be informed of the degree of animal suffering involved and the objectives and purport of the research. This information is made available by the researcher by means of a standard application form. Ten countries indicated that they use such a form (Appendix B, table 15). AWCs may also use other sources of information. However, not many resources were mentioned. The resources listed were guidelines by the Laboratory Animal Science Associations like the FELASA and AVMA. In addition, websites were included (e.g. for IACUC, ILAR, ECVAM, EUCOPA), books (e.g. *Animal Alternatives, Welfare and Ethics* (van Zutphen et al., eds., 1993) and journals (e.g. *Laboratory Animals*). However, significantly, no mention was made of sources for the ethical evaluation.

## Analysis and evaluation

The results show that the ethical review and evaluation are less prominent than the scientific and Three Rs review, which lend them to more objective and technical assessment and are closer to the competencies of most members of AWCs. Ethical reviews and evaluations are often experienced as difficult, involving vague and subjective judgments. Balancing the interests of animals and human beings is a complex issue on both sides of the dilemma. That animals have the capacity to suffer is rarely questioned, but it is difficult to measure the degree of suffering and to attach a degree of moral significance to these effects. When severe suffering is involved – and there seems to be consensus on this in most cases – this is an incentive to stimulate the search for Refinement of the experiment.

The difficulties involved in assessing and valuing the benefits derived from animal experiments go much deeper. The difficulties vary for fundamental research, applied research and standard testing of substances. The difficulties can emerge by demanding a detailed description and valuation of the objective of the animal experiment. This objective can, in most cases, be described as the acquisition of some amount of information, for instance about the toxicity of a substance. However, the meaning and significance of this objective comes into its own only by taking into account the wider purpose, strategy and constraints of research or application. This wider context can be described in different ways, and the interests that come to the fore in the description may well be valued differently. A toxicity test may be part of the development and marketing of a new (innovative) food colorant that is in the interest of a company. Is getting the information on the toxicity a matter of protecting 'public health', a generally recognised fundamental interest, or a matter of serving the economic interest of the company? Both descriptions differ considerably and presumably will be valued differently in the ethical balancing. We have found no information from our respondents as to how AWCs deal with these matters.

The valuation and balancing of interests is also bound up with moral pluralism, which is the basis of the liberal-democratic order in western nation states, and involves the sensitive relation between moral considerations and the market mechanism. The moral positions, with

regard to animal experiments in society, may be less a matter of engaging in balancing interests on a case-by-case basis, than a matter of setting moral priorities with respect to the value of animals or the rights and interests of human beings. It is doubtful whether AWCs, especially local AWCs, can claim the authority to break new ground in these political and ethical issues. Though perhaps they should have the right and duty to signal to society the moral problems, objections and tensions that they encounter, leaving the decision about ethical matters to the formal legal and political institutions that shape public morality.

Sometimes the activity of AWCs is criticised for being confined to an 'inner circle' of those who have a stake in animal experimentation. A suggestion is that it might be better if experiments were brought to the courts to see how judges and juries balance the interests of animals and human beings.

These summary remarks on these sensitive issues show how deeply the activity of AWCs with their relatively open and wide brief might touch on fundamental problems of a legal and political nature. Politicians and policy-makers should be aware of these implications and should broach and/or support initiatives, which will enable them to discuss and decide on the issues in an informed way.

#### **4.5 Review of legal requirements and of facilitary conditions: additional tasks of AWCs**

Besides the review and recommendations regarding protocols or projects, AWCs may have a number of additional tasks with regard to the local conditions (institutional AWCs) or, in the case of national AWCs, with regard to the general climate, discussion and requirements concerning animal experimentation. They may also set standards of a more general nature concerning the moral acceptability of animal experiments. However, we know of no examples in which this has led to something that seriously amounts to 'moral jurisprudence'. We will concentrate in this section on the tasks of institutional AWCs.

##### **Results**

The review of institutional AWCs may include housing conditions and the competence of the animal care staff. It also monitors whether protocols conform to legal and professional requirements. In some countries, this is the responsibility of the inspectorate, whereas AWCs are responsible for protocol review. In the UK, it is emphasised that the responsibility of the local AWCs is not restricted to reviewing protocols and includes "creating a culture of care". In the Netherlands, housing and competence requirements are the responsibility of the inspectorate and the institutional welfare officer, but the AWCs have a "background or supportive" role. In Sweden and Switzerland, housing conditions are part of the review. In the Netherlands and Switzerland, the review process includes the source of supply of the animals. Training of staff is included in the review in France, Ireland, Italy, the Netherlands, Norway, Spain, Sweden, Switzerland and the UK. Belgium, Spain and the UK indicate that management systems, technical and administrative facilities and procedures are also reviewed by the AWC.

## **Analysis and evaluation**

The tasks of AWCs here described are often part of a broader chain of responsibilities and powers of other authorities, formal frameworks and standards, both within the institution and within the broader legal regulations concerning animal experiments. It is important to be clear about the tasks, boundaries and responsibilities of AWCs, to avoid confusion. It is especially important that AWCs are not seen as policing institutions, an image which might compromise the opportunities of gaining moral authority, and of expanding the opportunities for discussion and education about ethical standards within the institution.

The relation between the various elements of the remit of the AWCs (formal, scientific, alternatives and ethical) should be carefully thought over, in view of the limited capacities and resources of AWCs and its members, but also in view of the possible tensions and conflicts between different tasks and elements of the remit.



# Conclusions and Recommendations

## Conclusions

1. In all 25 EU Member States, except Greece, Animal Welfare Committees (AWCs) exist for the review of scientific procedures involving vertebrate animals.
2. The most common system found consists of local or institutional AWCs, combined with a national AWC for general issues concerning animal experiments and purposes of appeal.
3. A review of opportunities for implementing the Three Rs principle (Replacement, Reduction and Refinement) is the backbone of the work of institutional AWCs, in many cases including a scientific review and some kind of harm-benefit evaluation.
4. There is a general belief that *particular* procedures should be reviewed and advised on, and that the review should not be limited to the aggregate level of programmes and policies.
5. AWCs generally consist of experts in four areas: (a) general scientific methodology and the use of animals in science (animal laboratory science); (b) quality and value of research; (c) animal welfare, and (d) alternatives to animal experiments. Often members qualified in legal and ethical matters, representatives of authorities and laymen are present.
6. Independence of judgement is safeguarded in a variety of ways, some of which rely on the characteristics of people (unpaid layperson), others on procedures (diversity of background, public character of procedure, appointment by government).
7. Protection and confidentiality are important concerns in view of the intimidating opposition against animal experiments, and in view of the economic and scientific interests involved.
8. Meetings of AWCs are not public. Overall, annual reports are made public. Minutes and specific, motivated recommendations on protocols are either not available or not made public.
9. Institutional AWCs are well equipped and suited to review the opportunities for Replacing, Reducing and Refining scientific procedures with animals.
10. A harm-benefit assessment and ethical evaluation is officially part of an AWC's remit in many countries, but is often difficult to achieve because it involves a complex and time-consuming combination of scientific, probabilistic, evaluative and moral judgments.

## Recommendations

### Concerning legal aspects

1. AWCs should have a legal basis and a clear remit, both at national and European level.
2. Review and recommendations by AWCs on scientific procedures with vertebrates, regarding the opportunities for applying the Three Rs principle and regarding ethical matters, should be made mandatory.
3. AWCs should at least consist of experts in (a) scientific research; (b) scientific design and methods with regard to the use of animals in research; (c) animal welfare, and (d) 'alternatives' (Replacement, Refinement and Reduction). To safeguard a plurality of points of view, a membership of lawyers, ethicists, civil servants and 'laymen' is important.
4. It is essential that the experts, as well as other members, have no interests in a proposal under consideration, or do not take part in the decision-making if they have an interest in it. It is important that members are appointed according to a clear and transparent procedure. Institutional AWCs should have a minimal number of members with an independent position.
5. Institutional or local AWCs should be held accountable, and considered authoritative, for a thorough and scientifically sound implementation of the Three Rs principle.
6. In view of requirements of logistics, expertise, independence and moral authority, and in view of the availability of a procedure of appeal, it is desirable to develop a system that divides assignments and powers between institutional (or regional) AWCs and a national AWC. The division should be based on:
  - a) on relevant aspects of review (scientific, Three Rs and ethical evaluation)
  - b) on relative aggregate levels and objects of review (protocols, programmes and policies).

### Concerning conditions and constraints

7. In view of the rights and interests of stakeholders, it is important to do the following:
  - a) be as clear as possible about the formal and legal requirements and powers of AWCs
  - b) guarantee conditions for a professional and independent judgment, such as adequate administrative and financial conditions
  - c) consider carefully the grounds and implications of different aspects of the review – scientific, Three Rs and ethical.
8. In order to safeguard conditions of equality under which market parties and scientific institutions operate and to foreclose 'shopping around' to get approvals, it is important to prevent large differences of constitution and procedure between AWCs in organisations and/or countries.

9. A clear procedure of public accountability and transparency with respect to procedures, recommendations and motivations of AWCs is essential to ensure trust and to make sure that decisions are based on standards and values that are broadly supported in society.
10. It is important to ensure that measures to protect privacy of members and confidentiality of information are balanced, and do not undermine the credibility of AWCs as trustworthy and independent bodies for judging the quality and acceptability of scientific procedures.
11. The principled as well as practical difficulties of the ethical review should be recognised. Instead of formal and binding ethical recommendations, the development of an 'ethical warning system' could be considered. This should enable AWCs to voice moral concerns and considerations that, in their view, ought to become subject of a public debate and political decision-making.

### Concerning research

12. Knowledge, comparison and evaluation of the procedures, aspects and responsibilities regarding the *scientific* review and evaluation of proposals and projects by AWCs, relative to the assessment of other bodies, are important.
13. Research into the procedures of AWCs, especially with regard to the issue of *independence* and *impartiality* of judgment, is needed.
14. A European network should be developed that promotes the exchange of expertise, experiences and information about 'best practices' for AWCs.
15. Research into the ethical assumptions and frameworks of AWCs in European Research Area countries is needed.



## Appendix A

# Directory of Contact Persons and Addresses of Animal Welfare Committees in Countries of the European Research Area

Updated on 1 October 2004

### Austria

#### *National contacts*

Federal Ministry for Education,  
Science and Culture  
Unit for Genetic Engineering and  
Animal Experimentation Matters  
Rosengasse 2-6  
AT-1010 Vienna  
alois.haslinger@bmbwk.bv.at  
Tel +43 1 53120 7114  
Fax +43 1 53120 6205  
[www.bmbwk.gv.at/gentechnik](http://www.bmbwk.gv.at/gentechnik)  
[www.bmbwk.gv.at/tierversuch](http://www.bmbwk.gv.at/tierversuch)

University of Veterinary Medicine Vienna  
Institut für Tierhaltung und Tierschutz  
josef.Troxler@vu-wien.ac.at  
Tel +43 1 25077  
Fax +43 1 24900

#### *Local contacts*

University of Vienna  
Faculty of Medicine  
Department of Biomedical Research  
Vienna General Hospital  
Währinger Gürtel 18-20  
AT-1090 Vienna  
Udo.losert@univie.ac.at  
Tel +43 1 40400 5220  
Fax +43 1 40400 5229

University of Innsbruck  
Christoph-Probst-Platz  
Innrain 52  
AT-6020 Innsbruck  
hermann.dietrich@uibk.ac.at  
Tel +43 512/507  
Fax 2061  
[www.uibk.ac.at](http://www.uibk.ac.at)

## Belgium

### *National contact*

Federal Public Service Public Health,  
Food Security Chain and Environment  
Department of Animal Welfare and CITES  
Building ARCADES 6th floor  
Pacheco Bld 19  
BE-1010 Brussels  
jean.belot@healthfgov.be  
Tel +32 2 210 5132  
Fax +32 2 210 5061

### *Local contacts*

Johnson & Johnson Pharmaceutical R&D  
Division of Janssen Pharmaceutica  
Turnhousweg 30  
BE-2340 Beerse  
gdvroey@prdbe.jnj.com  
Tel +32 14 60 34 91  
Fax +32 14 60 61 38

Faculty of Agricultural Sciences  
Animal and Microbial Biology Unit  
Av. Marechal Juin 6  
BE-5030 Gembloux  
portetelle.d@fsagx.ac.be  
Tel +32 81 62 23 54  
Fax +32 81 61 15 55  
www.fsagx.ac.be/mi/

Endoscopic Training Centre Antwerp (ACZA)  
Campus Stuivenberg,  
Lange Beeldekenstraat 267  
BE-2060 Antwerp  
bruno.vanherendael@planetinternet.be  
Tel +32 3 213 3750  
Fax +32 3 213 3730  
www.ua.ac.be

University of Antwerp  
Lange Nieuwstraat 55  
BE-2000 Antwerp  
peter.dedeyn@ua.ac.be  
Tel +32 3 212 1670  
Fax +32 3 212 1671  
www.ua.ac.be

### *AWCs:*

- Centre d'Etude et de Recherches Vétérinaires et Agrochimiques (CERVA)
- Institut Pasteur de Bruxelles (IPB)
- Institut Scientifique de la Santé Publique (ISSP)

### *Secretariat:*

Service of Biosafety and Biotechnology  
Scientific Institute of Public Health  
SPF Santé Publique  
Sécurité de la Chaîne Alimentaire et Environnement  
Rue Juliette Wytsmanstraat 14  
BE-1050 Brussels  
eth.com@iph.fgov.be  
Tel +32 2 642 5293  
Fax +32 2 642 5292

## Bulgaria

### *National contacts*

National Veterinary Service  
Directorate European Integration  
15A Pencho Slaveikov Blvd  
Sofia 1606  
Tel +359 2 952 1345  
Fax +359 2 954 9593

IWNS  
P.O. Box 134  
Sofia 1592  
ina\_ah@yahoo.com

## Cyprus

### *National contact*

Ministry of Agriculture,  
Natural Resources and Environment  
Animal Welfare Department of Veterinary Services  
CY-1417 Nicosia  
director@vs.moa.gov.cy

## Czech Republic

### *National contact*

Municipal Veterinary Administration  
Na Kozacce 3  
CZ-12000 Prague  
sovjakrichard@hotmail.com

### *Local contact*

Municipal Veterinary Administration  
Pellicova 48  
CZ-602 00 Brno  
pipalova@med.muni.cz

## Denmark

### *National contacts*

Danish Animal Experiments Inspectorate  
Dyreforsogstilsynet Ostre Landsret.  
Bredgade 59  
DK-1260 Copenhagen  
dyreforsogstilsynet@jm.dk

Danish Ministry of Justice  
Animal Experiments Inspectorate  
Slotsholmsgade 10  
DK-1216 Copenhagen  
dyreforsogstilsynet@jm.dk

### *Local contacts*

DVM, LEO Pharma A/S  
Animal Facility LEO Internal  
Animal Care and Use Committee  
Industriparken 55  
DK-2750 Ballerup  
tbe@leo-pharma.com  
Tel +45 5 7226 3539

SCANTOX A/S  
Animal Welfare Committee  
Hestehavevej 36A Ejby  
DK-4623 Lille Skensved  
info@scantox.com  
Tel +45 5686 1500  
Fax +45 5682 1202  
www.scantox.com

H. Lundbeck A/S  
Animal Welfare Committee  
Ottiliavej 7  
DK-2500 Valby  
anim@lundbeck.com

## Finland

### *National contact*

Ministry of Agriculture and Forestry  
Food and Health Department  
P.O. Box 30 (Mariankatu 23)  
FIN-00023 Government  
kai.pelkonen@mmm.fi  
Tel +358 9 1605 2896  
Fax +358 9 1605 3338  
www.mmm.fi

### *Local contact*

University of Oulu  
Laboratory Animal Centre  
P.O. Box 5000  
FIN-90014  
Hanna-Marja.Voipio@oulu.fi  
Tel +358 8 537 5087  
+358 40 742 1085

## France

### *Local contacts*

Comité Régional Rhône Alpes  
d'Éthique Animale  
ethique@dr7.cnrs.fr

Institut de Pharmacologie  
Cellulaire et Moléculaire  
CNRS-UNSA UMR6097  
660 Route des Lucioles  
Sophia Antipolis  
FR-06560 Valbonnen  
guy@ipmc.cnrs.fr  
Tel +33 4 93 95 77 77/41  
Fax +33 4 93 95 77 08

Groupe de Réflexion interprofessionnel  
sur les comités d'éthique (GRICE)  
grice@gircor.net  
autiss@netgrs.com

Comité Régional d'éthique  
en matière d'expérimentation animale  
de Strasbourg (CREMEAS)  
cremeas@medecine.u-strasbg.fr  
www-ulpmed.u-strasbg.fr/cremeas/

CNRS  
Département des Sciences de la Vie  
3 Rue Michel-Ange  
FR-75794 Paris Cedex 16  
Tel +33 1 44 96 40 00  
Fax +33 1 44 96 53 90

Université Blaise Pascal  
de Clermont-Ferrand  
Laboratoire de Physiologie Animale  
Comité Ethique d'Auvergne  
pour l'expérimentation animale  
FR-63177 Aubiere Cedex  
michel.dalle@univ-bpclermont.fr

Ecole Nationale Vétérinaire de Lyon  
ENVL  
s.vidal@vet-lyon.fr  
Tel +33 4 78 87 27 11

Gircor  
bruno.verschuere@sanofi-synthelabo.com  
www.gircor.org/gri/recom/grice.PDF

## Germany

### *National contact*

Federal Ministry of Consumer Protection,  
Food and Agriculture  
Referat 321 'Animal Welfare'  
PO Box 14 02 70  
DE-53107 Bonn  
321@bmvvel.bund.de

## Greece

### *National contact*

Academy of Athens  
Veterinarian Foundation of Biomedical Research  
7, Kerkiras Street  
GR-111 46 Athens  
nkostom@hol.gr  
Tel +30 21 065 973 66

## Hungary

### *National contact*

Ministry of Agriculture and Rural Development  
Animal Health and Food Control Station  
Lehel ut 43  
1389 Budapest  
www.fvm.hu

### *Local contact*

University of Oulu  
Hungarian Academy of Sciences  
Institute of Experimental Medicine  
Szigony u. 43  
1083 Budapest  
madarasz@koki.hu  
Tel +36 1 210 9966

## Iceland

### *National contact*

Animal Welfare Committee  
Surdurlandsbraut 24  
108 Reykjavik  
arnor@vst.is

## Ireland

### *National contacts*

Department of Health and Children  
Department of Environment and Local  
Government (transgenic animals)  
Hawkins House Hawkins Street  
IE-Dublin 2  
Tel +353 1 635 4000  
Fax +353 1 677 1695  
[www.doh.ie](http://www.doh.ie)

Department of Environment and  
Local Government (transgenic animals)  
Custom House  
IE-Dublin 1  
Tel +353 1 888 2000  
[www.environ.ie](http://www.environ.ie)

## Italy

### *National contacts*

Ministry of Health  
Direttore Generale Dipartimento degli Alimenti  
Piazza Marconi 25  
IT-00144 Rome  
[www.ministerosalute.it](http://www.ministerosalute.it)

National Institute of Health  
(National) Commission for Animal  
Experimentation  
Viale Regina Elena 299  
IT-00161 Rome  
Tel +39 06 4990 621  
Fax +39 06 4957 621  
<http://www.gsf.de/UNEP/itnat.html>

National Commission for Bioethics  
Via Veneto 56  
IT-00187 Rome  
[cnbioetica@palazzochigi.it](mailto:cnbioetica@palazzochigi.it)  
Tel +39 06 4816 1490  
Fax +39 06 4816 1493  
[www.palazzochigi.it/bioetica/eng/index.html](http://www.palazzochigi.it/bioetica/eng/index.html)

Commission of the National Research  
Council (CNR) for Bioethics  
Piazzale Aldo Moro 7  
IT-00185 Rome  
[urp@urp.cnr.it](mailto:urp@urp.cnr.it)  
Tel +39 06 499 31  
Fax +39 06 446 1954  
[www.cnr.it](http://www.cnr.it)

### *Local contacts*

ENEA C.R. Casaccia  
Sezione Tossicologia e Scienze Biomediche  
Via Anguillarese 301  
IT-00060 Rome  
Tel +39 06 3048 6351  
Fax +39 06 3048 4062  
[www.cas.casaccia.enea.it/centro](http://www.cas.casaccia.enea.it/centro)

National Cancer Research Institute  
Largo Rosanna Benzi 10  
IT-16132 Genova  
Tel +39 010 352 776  
Fax +39 010 355 573  
[www.istge.it](http://www.istge.it)

DIBIT San Raffaele Hospital  
Via Olgettina 58  
IT-20132 Milan  
Tel +39 02 2643 4897  
Fax +39 02 2643 3012

Institute for Pharmacological Research  
Mario Negri  
Animal Care Unit  
Via Eritrea 62  
IT-20157 Milan  
[usg@marionegri.it](mailto:usg@marionegri.it)  
Tel +39 02 3901 4565  
Fax +39 02 354 6277  
[www.marionegri.it](http://www.marionegri.it)

## Latvia

### *Local contact*

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Faculty of Medicine  
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## Lithuania

### *Local contact*

Vilnius University  
Faculty of Natural Sciences  
Department of Biochemistry and Biophysics  
Ciurlionio 21  
LT-2009 Vilnius  
osvaldas.ruksenas@gf.vu.lt  
Tel +370 5 2398 222  
Fax +370 5 2398 216  
www.gf.vu.lt/bbk

## Netherlands

### *National contact*

Ministry of Public Health, Welfare and Sport  
Food and Consumer Safety Authority  
Directorate of Inspection  
Dept. of Veterinary Public Health,  
Animal Diseases, Animal Welfare and Animal Food  
PO Box 19506  
NL-2511 VX The Hague  
wim.de.leeuw@vwa.nl

### *Local contact*

Animal Research Institute AMC  
NV-DEC  
Meibergdreef 67  
NL-1105 BK Amsterdam  
NV-DEC@amc.uva.nl  
Tel +31 20 566 5560  
+31 20 566 9310

## Norway

### *National contact*

National Animal Welfare Committee (forsoksdyrutvalget)  
Ministry of Agriculture  
P.O. Box 8147, dep 0033 Oslo  
fdu@dyrehelsetilsynet.no  
Tel +47 23 21 6584  
Fax +47 23 21 6501

## Portugal

### *National contact*

Ministry of Agriculture  
Direcção geral de Veterinaria Medica  
Veterinaria Principal  
PT-1294 Lisbon Codex  
Cristina\_briosa@dgv.min-agricultura.pt  
Tel +351 1 323 9702  
Fax +351 1 323 9565

### *Local contacts*

Institute for Molecular and Cell Biology  
Animal Behaviour and Welfare - Bioethics  
Rua do Campo Alegre 823,  
PT-4150-80 Porto  
olsson@ibmc.up.pt

Instituto Gulbenkian da Ciencia  
Rua da Quinta Grande 6, Apartado 14, 70  
PT-2781-901 Oeiras Codex  
jocelyne@igc.gulbenkian.pt  
Tel +351 21 440 7908  
Fax +351 21 440 79 79  
www.igc.gulbenkian.pt

## Romania

### *National contact*

NCP for Genomics and Biotechnology for Health (FP6)  
Ministry of European Integration  
Ministry of Education and Research  
Mendeleev Street 21-25  
Bucharest  
iispas@mct.ro  
Tel +40 21 210 9275

## Slovakia

### *National contact*

State Veterinary and Food Administration  
of the Slovak Republic  
Botanicka 17  
SK-84213 Bratislava  
welfare@svssr.sk  
Tel +421 2 60 257 227  
Fax +421 65 411 159

## Spain

### *Local contacts*

Universitat Autònoma de Barcelona  
Area d'Investigació i de Desenvolupament  
Rectorat  
Bellaterra  
(Cerdanyola del Valles) ES-08193  
ivan.martinez@uab.es  
Tel +34 93 581 2854  
php?i=cat&p=ceea&c=st  
Fax +34 93 581 2023

CIFA, Universidad de Navarra  
Animal Services Unit  
C/Irunlarrea 1  
ES-31008 Pamplona  
jguillen@unav.es  
Tel +34 94 842 5653

Cancer Research Institute (IRO)  
c/Gran Via s/n km 2.7  
ES-08907 Campus Universitari UAB  
L'Hospitalet de Llobregat Barcelona  
epr@iro.es  
Tel +34 93 260 7415  
www.iro.es/index.

Spanish National Cancer Centre (CNIO)  
Laboratory Animal Unit  
Melchor Fedz. Almagro 3  
ES-28029 Madrid  
jmcaballero@cnio.es  
Tel +34 91 224 6902  
Fax +34 91 224 6921

## Sweden

### *National contacts*

The National Board for  
Laboratory Animals (CFN)  
Box 22015  
SE-104 22 Stockholm  
Tommy.stagh@cfn.se  
Tel +46 8 651 1990  
Fax +46 8 610 9339  
www.cfn.se

Ministry of Agriculture, Food and Fisheries  
Fredsgatan 8  
SE-103 33 Stockholm  
lena.odland@agriculture.ministry.se  
Tel +46 8 405 1000  
Fax +46 8 4 20 6496

## Switzerland

### *National contact*

Swiss Veterinary Office  
Federal Committee for Animal Experimentation  
Schwarzenburgstrasse 161  
CH-3003 Bern  
Ursula.moser@bvet.admin.ch

### *Local contacts*

Kantonales Veterinaramt Zurich  
Aufsichtskommission fur Tierversuche  
Culmanstrasse 1  
CH-8090 Zurich  
Kantonales Veterinaramt Luzern  
Kommission fur Tierversuche  
Meyerstrasse 20  
CH-6003 Luzern

Veterinardienst Bern,  
Amt fur Landwirtschaft  
Herrengasse 1  
CH-3011 Bern  
Land- und Forstwirtschafts-  
direktion des Kantons Uri  
Kantonale Kommission fur Tierversuche  
Klausenstrasse 2  
CH-6460 Altdorf

Veterinardienst des Kantons Zug  
Kommission fur Tierversuche  
Postfach 455  
CH-6301 Zug

Office vétérinaire cantonal de Fribourg  
Commission de surveillance  
des expériences sur les animaux  
Chemin de la Madeleine 1  
CH-1763 Granges-Paccot

Kantonales Veterinaramt Basel-Stadt  
Tierversuchskommission der Kantone Basel-Stadt,  
Basel-Land und Aargau  
Postfach 264  
CH-4025 Basel

Kantonales Veterinaramt St. Gallen  
Tierversuchskommission  
des Kantons St. Gallen  
Davidstrasse 35  
CH-9001 St. Gallen

Kantonales Veterinaramt Chur  
Aufsichtskommission fur Tierversuche  
Hofgraben 11  
CH-7001 Chur

Kantonales Veterinaramt Thurgau  
Aufsichtskommission fur Tierversuche  
Spannerstrasse 22  
CH-8510 Frauenfeld

Ufficio del Farmacista cantonale del Ticino  
Commissione sorveglianza sugli esperimenti  
su animali  
Via Ag. Maspoli  
CH-6850 Mendrisio

Service vétérinaire cantonal de Vaud  
Commission de surveillance  
des expériences sur les animaux  
Rue du Dr Cesar-Roux 37  
CH-1014 Lausanne

Service vétérinaire cantonal  
Commission de surveillance  
des expériences sur les animaux  
Rue Pré d'Amédée 2  
CH-1950 Sion

Service vétérinaire cantonal de Neuchâtel  
Commission consultative et  
de surveillance des expériences  
sur les Animaux  
Rue Jehanne-de-Hochberg 5  
CH-2001 Neuchâtel

Office vétérinaire cantonal de Genève  
Sous-commission de surveillance  
des expériences sur animaux vivants  
Ch. Du Pont-du-Centenaire 109  
CH-1228 Plan-les-Ouates

## Turkey

### *Local contacts*

Kirikkale Universitesi  
Faculty of Veterinary Medicine  
71450 Kampus Kirikkale  
siyamikarahan@yahoo.com  
Tel +90 318 357 3301

GATA Medical School  
Centre for Research and Development  
Gulhane Military Medical School  
Dept. Lab. Animal Health  
06018 Etlik  
Ankara  
tide@gata.edu.tr

## United Kingdom

### *National contact*

Home Office  
ASPI  
Room 513  
Allington Towers  
19 Allington Street  
SW1E 5EB London  
jon.richmond@homeoffice.gsi.gov.uk  
Tel +44 207 035 5551  
[www.homeoffice.gov.uk/animact/apchome.htm](http://www.homeoffice.gov.uk/animact/apchome.htm)

### *Local contact*

Charles River UK Limited  
Manston Road  
CT9 4LT Margate  
c.sear@criver.co.uk  
Tel +44 1843 82 4214/82 3388  
Fax +44 1843 82 4297



## Appendix B

# Tables with Result of the Questionnaire

**Table 1: Data Acquisition**

Questionnaire		E-mail	Internet	Animal Welfare Act	Other	
	Utrecht University and FELASA:	Other (ESF)				
Austria	2	2	Yes	Yes		
Belgium	5	1			Yes	
Bulgaria			Yes		Yes	
Cyprus	1	1		Yes	Yes	
Czech Republic	1	1	Yes		Yes	
Denmark	2	2	Yes	Yes		
Estonia	1	1	Yes	Yes		
Finland	2	1	Yes	Yes		
France	1	2	Yes	Yes		
Germany	3	1	Yes	Yes	Yes	
Greece	1					
Hungary	1	1	Yes	Yes		
Iceland			Yes			
Ireland	2	1	Yes	Yes		
Israel				Yes	Yes	
Italy	2		Yes		Yes	
Latvia	2				Yes	
Lithuania	2			Yes		
Netherlands	1	2			Yes	
Norway				Yes	Yes	
Poland		2			Yes	
Portugal	2	1	Yes			
Slovakia	1	1	Yes			
Slovenia		2				
Spain	8	1		Yes		
Sweden	1	1	Yes	Yes	Yes	
Switzerland	3	1		Yes	Yes	
Turkey	2	1	Yes		Yes	
United Kingdom	5	4	Yes	Yes	Yes	
<b>TOTAL</b>	<b>51</b>	<b>30</b>	<b>17</b>	<b>16</b>	<b>8</b>	<b>9</b>

**Table 2: Countries with Established Animal Welfare Committees and their Legal Status**

<b>COUNTRY</b>	<b>MANDATORY?</b>
Austria	National committee mandatory
Belgium	Yes
Bulgaria	Not yet institutionalised (2005)
Cyprus	Yes
Czech Republic	Yes
Denmark	Yes (national)
Estonia	No (not yet)
Finland	Yes
France	No
Germany	Yes
Greece*	No AWC
Hungary	Yes
Iceland	No
Ireland	No
Italy	National committee mandatory
Latvia	Yes
Lithuania	Yes
Netherlands	Yes
Norway	Yes
Poland	Yes
Portugal	National committee mandatory
Slovakia	Yes
Slovenia	National committee mandatory
Spain	Yes (dependent on regional law)
Sweden	Yes
Switzerland	Yes
Turkey	No
United Kingdom	National committee mandatory Local ethical review mandatory

\* Greece has no AWCs. The local Veterinary Service issues the licence and performs the ethical evaluation.

## Table 3: Aspects of Remit

### 3.1 Care and Accommodation

Belgium	Humane end points
Finland	Humane end points
France	Humane end points, euthanasia, housing, husbandry, breeding, transportation
Germany	Humane end points, group housing also during experiments
Israel	Treatment of the animals, fate of the animals after the experiment
Lithuania	Euthanasia
Netherlands	Origin of the animals used and destination after experiment, housing and care conditions before, during and after the experiment, humane end points
Norway	Euthanasia
Spain	Euthanasia, humane end points
Sweden	Care and accommodation before, during and after the experiment
Switzerland	Housing facilities, source of animals
United Kingdom	Assessing care and accommodation standards applied to all animals in the establishment

### 3.2 Management

Belgium	Administration
Spain	Centre's facilities
United Kingdom	Review of the establishment's management systems, procedures and protocols

### 3.3 Training of Staff

France	Training
Ireland	Background and education of researcher
Italy	Persons involved and their experience, veterinarian in charge
Netherlands	Competence and experience of the researcher and the animal care staff
Norway	The local competent person is responsible to ensure that all personnel have the necessary training.
Spain	Training of staff
Sweden	The National Board for Laboratory Animals is responsible for the regulation of education and training requirements for researchers and technicians.
Switzerland	Competence of researchers
United Kingdom	Advice on the appropriate training of all staff, deciding on how employees can be kept up to date with ethical recommendations, best practice and legislation. Local AWCs aim to permeate and influence the whole establishment in which animals are used, creating an appropriate 'culture of care', and providing recommendations and resources to ensure proper consideration of ethical aspects and application of the Three Rs in all scientific work involving animals.

**Table 4: Appeal Procedures**

Austria	The applicant is given the opportunity to comment on the recommendation of the committee and/or to amend the proposed animal procedure, which is then either corrected or withdrawn.
Belgium	The licence is either not granted or withdrawn after the AWC has given a warning. The director in the lab is ultimately responsible for the transgression. Each member of the local ethics committee may ask the national committee for recommendations.
Cyprus	An appeal is made to the director of Veterinary Services.
Czech Republic	Legal prosecution, which may lead to the ban of the research or breeding activities.
Denmark	At national level, a dialogue where the national committee sets terms and conditions to be followed if the licence is to be issued.
Finland	Firstly, a discussion takes place with the researcher to see if he cannot change the protocol. If the discussion is not fruitful, the local committee may send the application to the provincial government, in which case the provincial veterinarian acts as a presenter of the case. If this authority does not accept the application either, the researcher has the option of appealing to the provincial Court of Justice.
France	The AWC reviews are advisory. Researchers are free to either take the recommendation into account or not. However, AWCs are strongly supported by the directors of the institutions.
Hungary	In the case of minor alterations, non-formal local actions are taken by the AWC. A formal procedure is conducted in the case of major alterations, but local provisions still are made, such as restricting the conditions of approval or withdrawal, thereby suspending the execution of the given animal procedure. In the case of violations of the law, or when the former provisions have no effect, the AWC communicates to the authority, which can revoke the permission for the whole experiment, even for the institute. The authority can also impose a fine.
Latvia	The applicant is invited to rewrite the proposal according to good scientific practice requirements.
Lithuania	The applicant receives an explanation of what is wrong and what has to be changed in the application and, after making these changes, the application can be resubmitted.
Netherlands	An appeal, via the director of the institute, is made to the national committee.
Slovakia	If the user establishment is of the opinion that the recommendation of the AWC is not correct, it may submit the project for approval to the State Veterinary and Food Administration. If the SVFA is in doubt as to whether the project considers the animal welfare sufficiently, it asks for a recommendation from an independent advisory body to assess the project, which has been cleaned of any data concerning the applying institution, thus ensuring maximum objectivity.

Spain	An appeal takes place before the academic or administrative authority (government of autonomous community).
Switzerland	The competent government body will give a justification to the AWC. In one canton, the AWC may appeal against the governmental decision.
Turkey	The researcher may object to the recommendation. The decision of the AWC at an institute is usually final, but the individual researcher may appeal.
United Kingdom	The Home Office inspector may be consulted.

**Table 5: National, Regional and Local AWCs**

**5.1 National, Regional and Local AWCs**

Austria	Local and national: the committee advises the federal Ministry for Education, Science and Culture on each application. When making its formal decision, the Ministry considers the recommendation.
Belgium	Local and national: the national ethics committee (National Deontological Committee) does not address individual researchers; local AWCs do. When an ethical problem is identified by a local AWC and no solution can be found, the local AWC addresses its position to or requests advice from the national committee.
Cyprus	The National Veterinary Service advises the individual researcher, the research group, the institute and the competent governmental body. When the applicant does not accept the recommendation of the AWC, he can turn to the director of the Veterinary Services.
Czech Republic	The local AWC addresses the institute and the Ministry of Agriculture.
Denmark	Local and national: formal legal approval is required by the Animal Experimentation Inspectorate (AEI). The AEI performs the ethical review as well as the issuing of licences. Review/recommendation is addressed to the applicant. The local AWC do not carry out pre-reviews. The local AWC performs reviews of licences with protocols/experiments in progress. A recommendation is given to the applicant, the research group or all researchers, dependent on the nature of the animal welfare subject. If the recommendation is not accepted, the national AEI sets terms and conditions to be followed if the licence is to be issued.
Estonia	Local and national: approval is required by Ministry of Agriculture.
Finland	Local: formal legal approval is required by the local AWC, the provincial State Office or the Ministry of Agriculture and Forestry, depending on the pain and distress classification of the project. If the AWC recommendation is not accepted, the applicant can turn to the provincial government, and finally to the provincial Court of Justice.
France	Local
Germany	Local and regional/federal: regionally based advisory committees advise the local government about the approval of proposed animal experiments.

Hungary	Local and national: the AWC gives a recommendation to the individual researcher, the research group, the institute and the competent governmental body. The Animal Experimentation Scientific Ethical Council is a national advisory body of the State Food and Veterinary Service, which gives expert opinion to the authorities on the process of authorising animal experiments. The State Food and Veterinary Service issues the licence. If the recommendation is not accepted, local action can be taken. In the case of violation of the law, the AWC communicates with the authority. No experiments are allowed without the approval by the AWC.
Ireland	Local
Italy	Local and national: certain projects are reviewed by a special committee at the National Institute of Health, which is responsible for reviewing experimentation with cats, dogs, primates, purposes of projects, experimental protocols and procedures.
Latvia	Local and national: after the evaluation of an opinion by the Animal Protection Ethics Council, the State Veterinary Service will issue a permit. The Ethics Committee on Laboratory Animal Use in Biomedical Experiments (CLAUBR) at the Latvian Council of Science (LCS) deals only with scientific projects submitted for funding by the LCS. Ethical committees inform the LCS about its activities.
Lithuania	Local: a review is addressed to the Lithuanian State Food and Veterinary Service, who, based on the results of the review, issue a licence.
Netherlands	Local and national: the local committees advise the institute. If the recommendation is not accepted, the national ethics committee will advise. A special committee advises on the research involving the making of genetically modified animals, and advises the Ministry of Agriculture, which considers this recommendation.
Norway	National
Poland	Local and national
Portugal	Local and national: research projects involving animals must be approved by the Veterinary General Direction, the Portuguese governmental body. The review/recommendation is also addressed to the individual researcher.
Slovakia	Local and national: the review/recommendation is addressed to the institute and the competent governmental body. The State Veterinary and Food Administration of Slovakia are responsible for the approval and can be approached if the recommendation is not accepted.
Spain	Local and regional: the review/recommendation is addressed to the individual researcher, the research group, the institute and the competent governmental body. The Animal Experimental Ethical Commission advises on regulatory tests.
Sweden	Regional and national
Switzerland	Regional/federal and national: the review/recommendation is addressed to the individual researcher, the research group and the competent governmental body. If the recommendation is not accepted, the authority requires a justification, and, in the worst case, will stop the experimentation, annul the authorisation and initiate legal proceedings.

Turkey	Local: the review/recommendation is addressed to the individual researcher and the research group.
United Kingdom	Local and national: operational on both a local committee-based system of assessment and a central government-based system of assessment for animal research projects. The review is addressed to the individual researcher, the research group, the institute and the competent governmental body. If the recommendation is not accepted, the Home Office may be consulted.

## 5.2 Elements Reviewed by National AWCs

Belgium	When deontological or ethical problems occur during the fulfilment of the AWC's duties, the AWC should present the problem to the national Deontological Committee.
Cyprus	There is only one national committee.
Finland	If the experiment is a class 1 type (severe pain, distress, suffering or a serious illness), the application is sent to the provincial State Office. If the provincial State Office is in doubt as to whether to grant a licence, the application is forwarded to the Ministry of Agriculture and Forestry.
Greece*	All scientific work using animals.
Hungary	After approval by the local AWC, the licence application is forwarded to the National Ethical Council.
Italy	Experiments with cats, dogs, non-human primates and other special exemptions are reviewed by the commission for animal experimentation at the National Institute of Health. The National Commission for Bioethics and the Commission of the National Research Council (CNR) for Bioethics have an advisory function. Both have sub-committees of experts on genetic manipulation and biomedical research involving animals.
Latvia	The Ethical Committee of the Latvian Council of Science reviews applications for the possible financing by the Latvian Council of Science.
Lithuania	There is only a national Ethics Committee.
Netherlands	The national Ethics Committee acts as a 'Court of Appeal' when a local committee has rejected a proposal.
Norway	The National Animal Research Authority (NARA) appoints a competent person at each institute/unit to whom responsibility for approving research protocols can be delegated. Should the competent person of an institute have any doubt, the application will be forwarded to the NARA for approval. The NARA handles applications for field research (a large amount of research in Norway is field research), applications where painkillers are deliberately withheld and proposals involving prolonged or significant pain. The NARA may issue a general approval to an institute for routine work (for example, immunisation and diagnostic services).
Poland	The National Ethics Committee on Animal Experimentation works as an appeal authority.

Portugal	After the proposal has been reviewed by the local AWC, a national advisory board of the Veterinary General Direction reviews the proposal and makes a decision.
Slovakia	If the institute is of the opinion that the recommendation of the institutional AWC is not correct, it can submit the proposal for approval to the State Veterinary and Food Administration (SVFA). The SVFA may seek the opinion of an independent advisor.
Slovenia	There is only a national Ethics Committee.
Spain	Spain has several autonomous regions. Some procedures require special authorisation from the regional Animal Experimental Ethical Commission.
United Kingdom	<p>A national independent advisory committee, the Animal Procedures Committee (APC), advises the government about matters concerning the Act. There is a local committee-based system of assessment and a central government-based system of assessment for animal research projects. All project licences are first assessed and approved by a local committee. The Home Office inspectors review all project licence applications and advise the Secretary of State. The APC advises the Home Office on certain classes of project licence applications, as well as on more general issues, such as alternatives and the welfare operation of the Act. When there is doubt about whether to license a particular piece of work, the Home Secretary may seek advice from the APC. The APC may also consider topics of its own choosing. By convention, the following classes of application are/have been automatically referred to the APC:</p> <ul style="list-style-type: none"> <li>• those involving the use of tobacco and tobacco products on conscious animals</li> <li>• microsurgical training</li> <li>• the use of non-human primates in procedures of substantial severity</li> <li>• the use of wild-caught, non-human primates</li> <li>• the testing of cosmetics (which is now no longer authorised in the UK).</li> </ul>
* Greece has no AWCs. The local Veterinary Service issues the licence and performs the ethical evaluation.	

**Table 6: AWC members - Expertises and Qualifications**

### 6.1 Expertise in the Field of Experimental Design, Including Statistics

Belgium	Biotechnician
Denmark	Laboratory technician
Germany	Statistician
United Kingdom	Statistician
Ireland	Statistician
Italy	Statistician
Netherlands	Statistician
Spain	Statistician
Turkey	Statistician

## 6.2 Expertise in the Field of Veterinary Science

Belgium	Veterinarian in charge of animal welfare (or expert responsible for the animal care and welfare), veterinary inspector (representative of the Ministry of Agriculture).
Bulgaria	1 veterinarian from the National Veterinary Service, 1 representative of veterinary faculty. (An AWC is to be established.)
Cyprus	Veterinary officer
Estonia	Veterinarian
Finland	Veterinarian
France	Veterinarian
Germany	Veterinarian
Hungary	Veterinarian
Ireland	Veterinarian
Italy	Veterinarian
Latvia	Veterinarian
Lithuania	Veterinarian
Netherlands	Veterinarian
Norway	Veterinarian
Slovenia	Veterinarian
Spain	Veterinarian
Switzerland	Veterinarian
Turkey	Veterinarian
United Kingdom	Named veterinarian

## 6.3 Expertise in the Field of Animal Husbandry

Belgium	Expert responsible for animal care and welfare (or veterinarian)
Finland	Animal care staff
Ireland	Animal care staff
Latvia	Animal care staff
Netherlands	Animal care staff
Slovakia	Animal care staff
Sweden	Animal care staff
United Kingdom	Named animal care and welfare officer

## 6.4 Expertise in Areas of Scientific Use of Animals

Austria	Professor, researchers and students
Belgium	Principal researcher
Bulgaria (AWC to be established)	2 medical doctors (1 representative of Ministry of Health, 1 representative of medical university), 1 researcher (representative of Bulgarian Academy of Science), 1 ecologist (representative of Ministry of Environment), 1 zoologist (representative of faculty of biology)
Cyprus	Physician, biological science
Czech Republic	Representative of research institutes and the Academy of Science
Denmark	Researcher

Estonia	Laboratory animal science, medicine, biology
Finland	Scientists, animal welfare specialist, chairman in charge of experimentation within institute
Germany	Medicine or other discipline of natural science, animal welfare specialist
Hungary	Scientists from different fields of neuroscience or physiology
Ireland	Scientists who use animals, animal welfare specialists
Italy	Laboratory animal specialist, pre-clinical or clinical researcher
Latvia	Animal welfare specialist, scientists who use animals, laboratory animal breeders
Lithuania	Scientist who uses animals, animal welfare specialist
Netherlands	Scientists who use animals, animal welfare specialist
Norway	Laboratory animal specialist, doctor, biologist, specialist in transgenic animals
Poland	Scientists
Portugal	Scientists
Slovakia	Scientists
Slovenia	Scientists in the field of humane medicine, biology, zoo technician
Spain	Scientists who use animals, animal welfare specialist, laboratory animal science specialist
Sweden	Scientists, laboratory or animal technicians
Switzerland	Scientists from university or industry who use animals, animal welfare specialist
Turkey	Scientists (e.g. biomedical research), animal welfare officer
United Kingdom	Project and personal licensees

### 6.5 Expertise in Other Fields

Austria	NGO e.g. animal welfare organisation, head of faculty
Belgium	External expert (e.g. layperson, alternatives expert or representative of animal welfare organisation), director of laboratory, representatives of specific institutes (Pharmaceutical Industry, Fund for Scientific Research, Belgian Council for Laboratory Animal Science, Royal Academy of Medicine, Council on Animal Welfare, federal Council on Scientific Politics, Ministry of Social Affairs, Public Health and Environment, National Authorities on Animal Welfare)
Bulgaria	Animal welfare organisation, lawyer
Cyprus	NGO, representative of government and local authorities
Czech Republic	Representatives of ministries under which the research is carried out (Health, Agriculture, Environment, Interior)
Denmark	Animal welfare organisation, lay people (HR or communication)
Estonia	Scientists not involved in animal use
Finland	Animal welfare organisation
France	Laymen, external visiting members
Germany	Animal welfare organisation

Sweden	Laymen (animal welfare organisation)
Ireland	Scientists not involved in animal use, laymen
Italy	Laymen, director of institute, ethicists, lawyer, theologist
Latvia	Laymen, animal welfare organisation, scientist not involved in animal use, representative of the Latvian Council of Science, the State Veterinary Department, the Ministry of Welfare, the environment protection organisation, and of the Baltic Laboratory Animal Science Association
Lithuania	Animal welfare organisation, scientists not involved in animal use, representative of State Food and Veterinary Service
Netherlands	Scientists not involved in animal use, alternative experts, ethicists, students, animal welfare organisation
Norway	Legal expert, animal welfare organisation
Poland	Animal welfare organisation
Portugal	Animal welfare organisation, general director of the institute
Sweden	Judge, laymen representing the general public or animal welfare organisations
Switzerland	Animal welfare organisation
Spain	Non-scientist (e.g. lawyer), animal welfare organisation, representative from the quality control/assurance unit, alternatives expert, bio-ethicist, sociologist, biologist not related to any research activity, legal medicine specialist
Turkey	Scientists not involved in animal use
United Kingdom	Laymen (often administrative staff or staff from other faculties within the establishment concerned), alternatives expert, animal protection organisation, external people

**Table 7: Independence**

Belgium	The Minister nominates the members of the National Deontological Committee for a two-year mandate. Independence of local AWCs is somewhat dependent on the culture within the company, but externals and laymen are independent. Name and qualification of an external expert can be reviewed by the Minister.
Cyprus	The members of the committees are appointed directly by the Minister of Agriculture and report to the Minister.
Czech Republic	Members are representatives of various ministries under which research is carried out. They are appointed by the Minister of Agriculture with the approval of the Minister of Environment. The status of the committee is enacted in the Animal Protection Act.

Denmark	In local AWCs, the problem is that there are employees involved who will speak their mind but, as employees, they also have a loyalty to the company. There is not always an external representation.
Finland	Members of local committees know most of the researchers applying for the licences. This is one reason why the legislation needs to be changed. In certain cases, as when a member himself would like to apply for a licence, the member does not take part in reviewing his own application. In practice, there seem to be no problems with this.
Hungary	Presently there is no guarantee by law; the practice and in-house regulations of the institutes determine the independence of the members. The AWC is an advisory board helping the decision-making of the director. Opinions, recommendations and discussions are freely communicated towards the management and the researchers of the institute. The constitution of the committee guarantees a many-sided and balanced evaluation of scientific protocols.
Latvia	The AWCs are independent, working without reward. Members are from different institutions and include lay people.
Lithuania	Committee members are not paid for their work.
Netherlands	The independence is mandatory by law. Three members, including the chairperson, should be independent of the institute.
Slovakia	Membership of the AWC is not a paid function. The members are not involved in the experiments and one third is independent of the institution.
Spain	Not all members from AWCs are independent, for example the external Animal Welfare Assessor and one layperson. The members of the AWC are not related to the procedures to be evaluated.
Switzerland	The cantons appoint a committee of specialists on animal experiments, which should be independent of the authority entitled to authorise the experiments. The committee members are independent from the governmental body and the applicants, and are from university, industry and animal welfare organisations.
Turkey	The members of the committee are usually from different departments and everyone's vote counts as equal. Everyone has a right to express his or her views.

**Table 8: Procedures of Information and Communication**

Austria	The Ministry forwards the written application to the committee, which may consult with the applicant to resolve technical issues (generally in writing) before giving its recommendation to the Ministry. The proposals are in writing and a hearing of the senior investigator and/or co-workers takes place.
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Belgium	The National Deontological Committee can invite researchers as experts when explanations on specific issues about a protocol are required. The principal investigator fills in a specific form for ethical review, with comment by e-mail. Local AWCs may demand additional information from a researcher before approving a protocol.
Cyprus	The recommendation is received in writing.
Czech Republic	All forms of communication take place (including personal contact, written recommendation, attendance of meetings), but the most frequent are personal contacts and training activities according to the Animal Protection Act. Researchers have to attend courses.
Denmark	National: any kind of communication – meetings, by letter, telephone and e-mail. Local: meetings, written recommendations, inspections of experiments, through a named vet.
Finland	The secretary, who also acts as the presenter, often pre-checks the applications. If necessary, the researcher is contacted before and after the meeting for further information. In some cases, the researcher will attend the committee meeting to explain the idea and basis of the experiment further.
France	The applications are written. The researchers are invited to discuss their application at the meeting.
Hungary	By personal contact and attendance at meetings. Personal discussions are allowed regarding applications. Written recommendation in the form of a permit is given to perform the experiment in question.
Latvia	By personal contact and written recommendation.
Lithuania	The researcher either receives a licence to perform experiments or, if the application is rejected, receives written comments.
Portugal	At the institutional level: the committee provides written codes of practice, rules and regulations and sees that they are adhered to. The committee also provides individual training and advises the researchers through personal contact. It meets regularly with the Animal Users Committee.
Slovakia	Usually the communication is direct and personal, but an official written recommendation is obligatory.
Spain	In general, the communication is in writing. After the meeting of the AWC, the researcher receives a written recommendation. Personal contact between the designated member of the AWC and the researcher is established when the AWC considers it necessary to further inquire about the researcher's procedure. In that case, the researcher could be required by the committee to attend the meeting.
Switzerland	The recommendation is normally in writing, but sometimes also by personal contact and attendance at meetings.
Turkey	Communication between researchers and the committees is done by secure mail. The written recommendation is conveyed to the researchers as soon as possible. If the committee thinks that the researcher should be present to clarify certain issues regarding the project, he is invited to the meeting.
United Kingdom	By personal contact.

**Table 9: Deliverables**

Belgium	The decision is taken on a written basis, annual report, lay (non-technical) summary of projects/protocol, sometimes on-going review to evaluate pain by monitoring and registering on observation score sheets.
Cyprus	Written recommendation.
Czech Republic	Annual report.
Denmark	Written recommendation, annual report, lay (non-technical) summary.
Finland	Lay (non-technical) summary.
France	Documents, annual report, internal documents, presentations, training sessions, information briefings.
Germany	Cases of fundamental significance are reported to the federal government and published in the Animal Welfare Report.
Greece	Lay summaries.
Hungary	Published recommendation for members of the institute only.
Ireland	Lay summaries.
Italy	Institutional statistics.
Latvia	Written recommendation.
Lithuania	Researcher receives licence or, if the application is rejected, written comment.
Netherlands	Written recommendation, institutional annual report, national annual report.
Norway	Institutional and national annual report.
Poland	Written recommendation.
Portugal	Annual report, rules and regulations.
Slovakia	Written recommendation.
Spain	Written recommendation.
Sweden	Written minutes, statistical records;
Switzerland	Written recommendation, annual report.
Turkey	Written recommendation.
United Kingdom	Annual report: number and type of animals, purpose for which they are used and the type of establishment using them. Lay summary.

**Table 10: Transparency - Public Information and Guidelines****10.1 Public Information**

Austria	Meetings are not open to the public or to the inspectorate. The recommendation is not available to the public but is to the inspectorate. Issues of animal experimentation: <a href="http://www.bmbwk.gv.at/tierversuch">www.bmbwk.gv.at/tierversuch</a>
Belgium	Meetings are not open to the public but are open to the inspectorate. The recommendation is not available to the public or the inspectorate. The National Deontological Committee provides the authority with recommendations about communication with the public.

Cyprus	Meetings are not open to the public but are open to the inspectorate. The recommendation is available to the public and to the inspectorate.
Czech Republic	Meetings are not open to the public but public meetings are considered at the plenary meetings of the committee. The meetings are open to the inspectorate. The committee may ask for the presence of the inspectorate to solve specific tasks. The recommendation is available to the public and the inspectorate in the form of an annual report. Results of animal welfare violations are reported in the annual report. Statistical data is available.
Denmark	Meetings are not open to the public but are open to the inspectorate. The recommendation is available to the public on the web ( <a href="http://www.dyreforsoegstilsynet.dk">www.dyreforsoegstilsynet.dk</a> ) and to the inspectorate. Public information is in an anonymous format. An annual report is prepared by the Animal Experimentation Inspectorate. <a href="http://www.jm.dk/wimpdoc.asp?page=document&amp;objno=50882">http://www.jm.dk/wimpdoc.asp?page=document&amp;objno=50882</a> <a href="http://www.dyreforsoegstilsynet.dk">www.dyreforsoegstilsynet.dk</a>
Finland	Meetings are not open to the public but are open to the inspectorate. The provincial veterinarian often participates in the meetings and receives all the written information. All decisions are open to the public and are available at the provincial government. Often there is at least one representative of an animal welfare organisation on the committee. Even though the meetings are confidential, the new legislation of publicity, however, demands that some points of the licences are available to the public. In the application, it is possible to announce that the research plan is confidential because the results are applicable for a patent. In the latter case, the research plan can be kept and reviewed confidentially.
France	Meetings are not open to the public but are open to the inspectorate. The annual report and summaries are available to the public. The recommendation is available to the inspectorate.
Germany	Meetings are not open to the public but are open to the inspectorate. The recommendation is available to the inspectorate. Cases of fundamental significance are reported to the federal government and published in the Animal Welfare Report.
Hungary	Meetings are not open to the public but are open to the inspectorate. The recommendation is not available to the public but is to the inspectorate.
Latvia	The meetings are open to the public and the inspectorate. The written recommendation is not available to the public.
Lithuania	Meetings are not open to the public but are open to the inspectorate. The recommendation is not available to the public but is to the inspectorate.
Netherlands	The annual report published by the Ministry of Public Health is public. The meetings are not public but are open to the inspectorate. The institutional annual report is not open to the public but is to the inspectorate. The review process of the National Animal Biotechnology Committee includes a public hearing.
Norway	Several laboratory animal units have their own web pages, for example <a href="http://oslovet.veths.no">http://oslovet.veths.no</a>

Portugal	Meetings are not open to the public but are open to the inspectorate. The recommendation is available to the public and to the inspectorate. An annual report is available to the public.
Slovakia	The recommendation is available to the inspectorate.
Spain	Meetings are not open to the public but are open to the inspectorate. The recommendation is not available to the public but is to the inspectorate.
Sweden	Meetings are not open to the public but are open to the inspectorate. The recommendation is available to the public in the form of an annual report, and to the inspectorate. The documents are available on request, with the exception of a few that are confidential (armed forces and industry).
Switzerland	Meetings are not open to the public but are open to the inspectorate (depending on the canton's legislation). The recommendation is not available to the public but is to the inspectorate (depending on the canton's legislation). There is an annual report.
Turkey	Meetings are not open to the public but are open to the inspectorate. The recommendation is not available to the public but is to the inspectorate.
United Kingdom	Meetings are not open to the public but are open to the inspectorate. The recommendation is not available to the public but is to the inspectorate. A (proposed, anonymous) summary of every new project licence granted for animal research is prepared, setting out the salient features of the approved programmes of work. Jennings, M., Smith, J., Local ethical review processes, <i>RSPCA</i> January 2003.

## 10.2 Guidelines

Belgium	The ethical review involves approval of the procedures, statistics on animal use, local visits to the animal facilities, holding and procedure rooms, policies and ethical aspects on animal use (recommendations to the lab director and scientists), discussions on new trends, knowledge and legislation. Info and guidelines from Johnson & Johnson Pharmaceutical R&D, for example on legislation, good practice, documents (administration of substances, blood collection etc.), euthanasia guidelines, info on lab animal suppliers and lab animal equipment, who to contact for animal welfare questions, links, etc., available on J&J intranet web page: Aanv_000_ENG.DOC
Cyprus	Law on Animals (Scientific Experiments) 1995 art. 20/21
Czech Republic	Animal Protection Act 246/1992 Co. (§ 17) Decree 311/1997 Col.
Denmark	Animal Testing Act <a href="http://www.retsinfo.dk">www.retsinfo.dk</a> There are guidelines from the Animal Experimentation Inspectorate on blood sampling, size of tumours and production of polyclonal/monoclonal antibodies. The national committee, in some cases, performs inspection of a pilot experiment. Also post-licensing inspection. There is on-going review after initial permission has been granted through inspections and interviews with researchers.

Finland	<a href="http://www.uku.fi/~kaliste/ketohje.htm">www.uku.fi/~kaliste/ketohje.htm</a>
France	Ethics Committee's recommendations for laboratory animals in private research in France, Verschuere B., et al, <i>Laboratory Animals</i> (2000) 34, 236-243.
Germany	Animal Welfare Act 1998 <a href="http://www.tiho-hannover.de/einricht/tsb/gesetz.htm">www.tiho-hannover.de/einricht/tsb/gesetz.htm</a>
Hungary	Ethical Codex
Italy	Institutional guidelines developed by the Mario Negri Institute for Pharmacological Research (IRFMN) in Milan.
Latvia	Good Scientific Practice. Regulations of the Ethical Committee on the Investigations using Laboratory Animals (Latvian Council of Science).
Lithuania	Guidelines of the Ethics Committee of the State Food and Veterinary Service. The Kaunas Medical University has adopted its own regulations, apart from the licence by the State Veterinary Service
Netherlands	There are several committees with guidelines. For example: <a href="http://www.cpv.unimaas.nl/E_informatie_dec.htm">www.cpv.unimaas.nl/E_informatie_dec.htm</a>
Norway	Procedures considered unethical include blood sampling through retro-orbital puncture and the routine use of ether for anaesthesia. Some procedures have special mention: exsanguinations and blood sampling from injections into the heart only under total anaesthesia.
Sweden	Approval of proposals is based on scientific significance, public interest, whether the experiments can be achieved without the use of laboratory animals, whether the experiment can be performed in a more humane manner, and whether the experiment unnecessarily duplicates previous experiments. The National Board for Laboratory Animals has drawn up guidelines for immunisation, production of monoclonal antibodies and acute toxicity testing.
Switzerland	<a href="http://www.bvet.admin.ch/tierschultz/d/berichte_publicationen/tierversuche/1_index.html">www.bvet.admin.ch/tierschultz/d/berichte_publicationen/tierversuche/1_index.html</a>
United Kingdom	There are no mandatory guidelines, though there is some Home Office documentation on the factors considered. The APC is currently finalising a report that gives advice in more detail. <a href="http://www.apc.gov.uk/reference/reports.htm">www.apc.gov.uk/reference/reports.htm</a> and <a href="http://www.homeoffice.gov.uk/animalsinsp/index.htm">www.homeoffice.gov.uk/animalsinsp/index.htm</a> <a href="http://www.homeoffice.gov.uk/animalsinsp/reference/erp/erp/chief.htm">www.homeoffice.gov.uk/animalsinsp/reference/erp/erp/chief.htm</a>

**Table 11: Scientific Procedures Involving Animals Subject to Review by AWCs**

Belgium	All scientific work involving animals. Euthanasia of animals for <i>in vitro</i> scientific work is not considered an animal experiment and review is therefore not legally required.
Czech Republic	Production and experiments with vertebrates.

Denmark	All experiments with vertebrate animals. Some scientific work involving animals does not require ethical review, e.g. field studies and some dietary studies.
Estonia	All scientific work involving vertebrate animals
Finland	All scientific work involving vertebrate animals
Germany	All scientific work involving vertebrate animals. Euthanasia of animals for <i>in vitro</i> scientific work is not considered an animal experiment and application is therefore not legally required. Furthermore, no authorisation and ethical argumentation is required for experiments. <ol style="list-style-type: none"> <li>1. Expressly required by an act, or the Pharmacopoeia, by general provisions issued by the federal government, by order of a judge or an authority.</li> <li>2. Taking the form of a vaccination, withdrawal of blood samples and other diagnostic measures serving to detect human diseases, defects or serving to test serum, etc.</li> </ol>
Sweden	All animal studies (vertebrate and invertebrate) including feeding studies, experiments under terminal anaesthesia and the killing of animals to remove tissues for <i>in vitro</i> research.
Italy	Experiments involving cats, dogs, non-human primates, experiments without the use of anaesthesia.
Lithuania	All scientific projects involving vertebrate animals.
Netherlands	All scientific projects involving vertebrate animals or the octopus, which serve a purpose as laid out in the Dutch Experiments on Animals Act. Also when distress is to be expected. Experiments that do not cause pain or distress in the animals are not considered an animal experiment.
Norway	All scientific projects with living mammals, including embryonic forms and foetal stages, birds, fish, reptiles, amphibians, with their free-living immature stages, and decapods. Fertilised eggs are exempted. Further exemption: clinical veterinary procedures, marking, withdrawal of blood samples, collection of national secretion, breeding, rearing, feeding and environmental procedures.
Spain	All scientific projects involving vertebrate animals, including the developing autonomous larval forms capable of reproduction, excluding foetal and embryonic forms.
Sweden	All scientific projects involving all animals, not just vertebrates, including feeding studies, experiments under terminal anaesthesia and the killing of animals to remove tissues for <i>in vitro</i> research.
Switzerland	All scientific projects involving vertebrate animals, decapods, cephalopods.
United Kingdom	All scientific work involving vertebrate animals and the octopus, breeding animals that have harmful genetic defects, which may have the effect of causing the animal pain, suffering, distress or lasting harm. Euthanasia of animals for <i>in vitro</i> scientific work is not considered an animal experiment and application is therefore not legally required.

**Table 12: Specific Guidance in Special Cases**

Ireland	All procedures involving severe classification
Italy	Experiments with cats, dogs, non-human primates and other special exemptions are reviewed by the commission for animal experimentation at the National Institute of Health.
Netherlands	There is a special committee for the ethical review of the making of genetically modified animals.
Norway	Some research projects, including the use of transgenic animals, may require prior approval from other Ministries in addition to that obtained from the National Animal Research Authority. The creation for new genetically modified lines requires approval by the Ministry of Health and Social Affairs. A committee at the National Institute of Public Health conducts the approval.
Spain	Not in most institutes. In one institute there are procedures subjected to special review (Procedures of Express Authorisation). Each of these procedures needs special supervision protocols and end point parameters.
Sweden	In principle, the process is the same for all projects, but projects using primates and pet species receive the most interest and stimulate discussions.
Turkey	Canine studies are reviewed very carefully to see if any other animal species can be used.
United Kingdom	Use of non-human primates, cats, dogs and equidae require special justification under the Animals (Scientific Procedures) Act. Special questions relating specifically to ethical aspects of the use of non-human primates are included on the Home Office application form.

**Table 13: Level of Ethical Review**

Belgium	<p>Industry: at the 'procedure' level, a description is made of the procedure, explaining what the animal must undergo (chronology of different steps: surgery, anaesthesia, restraint, fluid collection, administration, duration, discomfort, observation, end point) (e.g. open field, hot plate, single dose toxicology). The same 'procedure', having been reviewed once, may be carried out many times (different test compounds for pharmacological purposes) and this will appear in the yearly statistics. If, within a particular project, a single animal must undergo different procedures, a new ethical review is done with an explanation that the animal will pass through those different procedures as described in other reviews.</p> <p>Academic institutes: At the 'project' level, using the reviews they need to present for getting funds. This may include different kind of experiments.</p>
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Denmark	Mandatory national licensing procedure: 1) submission of application (purpose, detailed description of the experiment, use of analgesics/ anaesthesia, species to be used, number of each species); 2) ethical review process; 3) granting, modification or rejection of application. A licence may only be granted for procedures with a specific purpose, such as prevention, diagnosis and treatment of diseases in human beings and animals, or protection of the natural environment.
Estonia	Project and study protocol: In order to conduct an animal experiment, a person must hold a permit for the conduct of the animal experiment. This permit sets out the conditions for the conduct of the experiment, such as the name and address of the person conducting it, the species and number of experimental animals, the time and place, and the procedures applied during the animal experiment.
Finland	Study protocol level
Greece	The ethical review is carried out as study protocol.
Ireland	Project level
Turkey	Ethical review is carried out at the project as well as the protocol level.
United Kingdom	Generally at the project (five-year programme of work) level, but individual protocols are also scrutinised to determine whether there is scope for further application of the Three Rs.

**Table 14: Prospective/Retrospective Review**

Belgium	Visits to the animal facilities, holding and procedure rooms. No official ongoing review, but most of the institutions ask for a review every number of years. No retrospective review, but the number of times a procedure has been performed and the number of animals used is discussed during the review of the yearly statistics. Some initiatives have been taken to evaluate pain in some experiments during the duration of the experiment (monitoring and registering on observation score sheets).
Denmark	There is an on-going review. These take place nationally by the Animal Experimentation Inspectorate and locally by interviews with researchers, and/or inspections by the local AWC or the laboratory animal veterinarian.
France	Inspections take place.
Ireland	Visits to the facility. Sometimes on-going review. Applicants must submit results of pilot study before being allowed to continue work.
Latvia	On-going review with recommendations to improve the project. Retrospective review in the form of revised review after improvements have been introduced according to the requirements of good scientific practice.
Lithuania	On-going review. In the case of long-lasting projects, the licence has to be renewed every year. Inspections take place.

Netherlands	On-going review. Since most committees review single experiments, rather than entire (PhD) projects, there is an on-going review of projects when sequential experiments are reviewed. On a regular basis, committees will ask what the connection is between separate protocols. Only very few committees are informed about the outcome of a project. There is a code of practice to inform the committee about the observed degree of discomfort, with the purpose to enhance the review process for future procedures. Inspections take place by the inspectorate.
Norway	Inspections of facilities and specific experiments take place.
Spain	In some institutes, there is an on-going review. The animal welfare officer reviews the procedures. In case of modifications, the local AWC must be notified.
Sweden	Inspections take place and there is an on-going review. Each licence has a limited validity of three years and each year a report has to be sent to the cantonal Veterinary Officer. There is a retrospective review because the reported data influence future judgement of similar projects.
Turkey	Inspections take place. Major changes in the protocol require approval by the AWC.
United Kingdom	Ongoing review via Home Office inspector visits, the work of the veterinary surgeons and interim reviews by local AWCs. Also retrospective review by local ethical review processes. The Home Office also requires copies of publications arising from the work. The Home Office guidance says that an ethical review "is not a single event exercised only at the beginning of a programme of work, but a continuous process throughout the life of a licence. Every effort must be made to maximise benefit and minimise severity when work is being planned and when it is in progress. The emerging and actual costs must be evaluated and reviewed, to ensure that the original assumptions and assessment remain sound. Efforts must be made to refine existing protocols where possible."

**Table 15: Elements of Review**

Belgium	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis. Description of procedure, explaining what the animal must undergo (surgery, anaesthesia, restraint, fluid collection, administration, duration, discomfort, observation, end points, open field, hot plate, single dose toxicology, etc.). When a single animal must undergo several procedures, a new ethical review is done. An example can be found on the Johnson & Johnson intranet web page: Aanv_000_ENG.DOC.
Czech Republic	Scientific review, Three Rs, an ethical evaluation to balance the aim of the research and the degree of animal discomfort.

Denmark	<p>Aim and necessity of study, experimental design, scientific validity of using animals, species to be used, number of each species, use of analgesics/anaesthesia, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis.</p> <p>Go to <a href="http://www.jm.dk/wimpdoc.asp?page=document&amp;objno=50882">http://www.jm.dk/wimpdoc.asp?page=document&amp;objno=50882</a> and choose 'ansogningskema + vejledning'.</p>
Estonia	<p>Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, and severity of the harm caused to the animals. Name and address of researcher to conduct the animal experiment, species and number of animals, time and place of experiment, procedures applied in the experiment.</p>
Finland	<p>Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis, humane end points</p> <p><a href="http://www.oulu.fi/keks/koelupa.dot">www.oulu.fi/keks/koelupa.dot</a> (Oulu University)  <a href="http://www.uku.fi/~kaliste/ketoimik.doc">www.uku.fi/~kaliste/ketoimik.doc</a> (Kuopio University)</p>
France	<p>The rationale and purpose of the protocol, animal species, number of animals justified by scientific, regulatory or statistical references, pain assessment, anaesthetics, analgesics, humane end points, stress, discomfort, surgery, euthanasia, housing, training, breeding, transportation (suppliers and shipping).</p>
Germany	<p>Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis. Use of humane end points, use of anaesthesia (also post-operative), group housing also during experiments.</p>
Greece	<p>Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs.</p>
Ireland	<p>Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis, and statistical justification of animal numbers. Species used, background and education of researcher, peer review.</p>
Israel	<p>Details on animals (source, duration, number of animals, sex, age, strain, species, purpose of experiment, abstract research programme, procedure, treatment of the animals, fate of the animals after the experiment, anaesthesia, procedure to reduce pain and suffering.</p>
Italy	<p>Scientific background of the project, objectives, experimental procedures, number of animals, species used, persons involved and their experience, veterinarian in charge, procedures to minimise pain, suffering and distress, anaesthesia, alternatives.</p>

Lithuania	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis, anaesthesia, euthanasia, number of animals.
Netherlands	Aim and relevance of the experiment, competence and experience of the researcher and the animal care staff, argumentation as to why alternatives are not used, animal model, origin of the animals used and destination after experiment, housing and care conditions before, during and after the experiment, experimental conditions (nature, frequency, duration), anticipated degree of discomfort, anaesthesia, analgesia or other methods used to reduce pain or discomfort, re-use, humane end points, scientific, medical and societal benefit.
Norway	Possible alternatives, aim, type and extent of the experiment, species, number of animals, duration of the study, re-use, methods of euthanasia.
Portugal	Scientific aspects, Three Rs, harm-benefit.
Slovenia	Possible alternatives, no duplication.
Spain	Analgesia, anaesthesia, euthanasia, doses, humane end points, Three Rs, scientific project objectives, scientific benefit, justification use, provider and number of animals (statistics), experimental design details, anticipated degree of discomfort, training of staff, species, centre's facilities, harm-benefit.
Sweden	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis, public interest, care and accommodation before, during and after the experiment. Duplication check.
Switzerland	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis, species, number of animals, housing facilities, source of animals, competent researchers.
Turkey	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them.
United Kingdom	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis. Number and type of animals used, steps taken to reduce the number of animals and any distress, suffering or harm involved.

**Table 16: Three Rs Review**

Belgium	Application of the Three Rs and the priority given to them. The National Deontological Committee has a specific working group on alternatives to animal experimentation, which promotes the Three Rs through information meetings for laboratories, redaction of a royal decree to make alternative methods compulsory.
Denmark	Application of the Three Rs and the priority given to them.
Czech Republic	Three Rs.
Finland	Application of the Three Rs and the priority given to them.
Germany	Application of the Three Rs and the priority given to them.
Greece	Application of the Three Rs.
Ireland	Application of the Three Rs and the priority given to them.
Italy	Possible alternatives.
Lithuania	Application of the Three Rs and the priority given to them.
Netherlands	Argumentation as to why alternatives are not used.
Norway	Possible alternatives.
Portugal	Three Rs.
Slovenia	Possible alternatives.
Spain	Three Rs.
Sweden	Application of the Three Rs and the priority given to them.
Switzerland	Application of the Three Rs and the priority given to them.
Turkey	Application of the Three Rs and the priority given to them.
United Kingdom	Application of the Three Rs and the priority given to them.

**Table 17: Harm-benefit analysis**

Belgium	Harm-benefit analysis.
Denmark	Harm-benefit analysis.
Czech Republic	Harm-benefit analysis.
Finland	Harm-benefit analysis.
Germany	Harm-benefit analysis.
Ireland	Harm-benefit analysis.
Lithuania	Harm-benefit analysis.
Netherlands	Harm-benefit analysis.
Portugal	Harm-benefit analysis.
Spain	Harm-benefit analysis.
Sweden	Harm-benefit analysis.
Switzerland	Harm-benefit analysis.
Turkey	Harm-benefit analysis.
United Kingdom	Harm-benefit analysis.





# Opinions of Respondents on AWCs

The respondents were invited, via open questions, to give their personal views concerning the positive and negative aspects of the functioning of the AWCs in their country. Due to the open character of the questions many different answers were given. In addition, it concerns personal views and the answers can only serve as indicative of the positive and negative aspects. Details per country on this topic are not given for reasons of privacy.

### Positive aspects

In countries with mandatory AWCs, this legal status is valued positively. Furthermore, the mere fact that protocols are reviewed by a committee with independent and competent members from different scientific disciplines was broadly deemed positive. On a more detailed level, many different viewpoints were put forward.

### Positive aspects concerning formal status

Different positive points were mentioned concerning the formal status of the committees, such as the fact that the AWCs are functioning at a satisfactory level in countries where a review of protocols is not mandatory by law. Furthermore, the independence of AWCs was put forward, in the sense that committees may be affiliated to an independent scientific or governmental body, but in contrast are also affiliated to the institute and, as a result, are accepted and respected by the members of the institute. The fact that a local committee can be flexible without being hampered by bureaucracy was mentioned once. Finally, the fact that an AWC had its own budget was seen as a positive point.

### Positive aspects concerning the remit

Many respondents mentioned the actual review of the protocols as a positive point. It was considered a disadvantage that the costs involved to submit a protocol are low but it was expected to increase in the near future. The fact that representatives from different institutes evaluate all protocols was a positive point. Furthermore, the work of the committee is in line with the ethical sense of scientists and most laymen, which was also deemed positive.

### Positive aspects concerning operating procedures

A whole range of positive points was given:

- Collaboration and the desire to solve problems for the benefit of animals.
- Positive communication between AWCs – committees may act quite independently about the positive and negative aspects involved.
- Establishment specific close contact and communication with the researchers.
- Methodology (guidelines, good scientific practice) is easily available.

- Applications are analysed and evaluated by a different specialist member of an AWC and decisions are made by open voting.
- It is a relatively fast process.
- Animal welfare specialists play an important role and are responsible for co-operation with researchers.
- Reviews are thorough and every procedure is scrutinised to assess whether an alternative is available.
- Projects are first evaluated by a scientific committee.

### **Positive aspect concerning composition**

Almost all points refer to the many-sidedness of the committee, such as expertise in different fields (scientists, lawyer, lab animal scientists, etc.) and different backgrounds (NGO, government, etc.). This many-sidedness results in a wider perspective and independence. The representation of animal protection organisations was considered a positive point. On the other hand, though, the scientific community is quite receptive to a committee composed mostly of scientists.

### **Positive aspects concerning institutional affiliation**

The affiliation of the committee to an independent governmental or scientific institution was considered positive. On one occasion, it was mentioned that in a country where local AWCs are not required, the companies that have established an AWC can develop it to their liking, according to needs, traditions, etc.

### **Other positive aspects:**

- Satisfaction with constant improvement and close co-operation with local authorities.
- AWC carries through the Council of Europe's Convention concerning vertebrates used for scientific purposes with amendments for their ratification by parliament.
- General willingness to discuss animal welfare matters in an open atmosphere
- The work of the AWCs is improving all the time and there are trails to harmonise – many variations, but they work excellently.
- One country has not signed the Convention yet, but the EC Directive has been operative from 1999.
- After an initial period where AWCs were met with certain scepticism, it seems that there is a much better acceptance nowadays.

### **Bottlenecks**

In countries where the AWC does not have a formal status, this was taken as a serious drawback. Another important negative point was the fact that the process is time-consuming with much paperwork, which may slow down research. It also appeared that several countries had difficulty getting enough competent members for the AWCs.

### **Negative aspects and bottlenecks concerning the functioning of AWCs**

The main bottleneck mentioned is the fact that the review process takes up too much time and is not supported by a legal status. For example:

- In a national committee, there may be very extensive procedures between working groups and plenary meetings to issue positions and recommendations.
- The analysis of protocols is often a very extensive procedure in local committees.
- In local committees, it is rather time-consuming for the members to review all new and renewed experiments.
- The relatively small number of responsible officers slows down the evaluation procedure.
- Difficulties are met in reaching a unanimous decision.
- As it is not always required to establish a local AWC, the companies that have established a committee have the freedom to develop it according to need, tradition, etc.
- It may not be well understood that a review by an AWC is an obligatory legal system.
- The advisory board has a poor formal status. It is not widely known that submitting proposals to the AWC is obligatory.
- There is no legal basis for AWCs yet.
- Members work on an honorary basis and it is difficult to find new members.
- AWC usually have a mere advisory function.

### **Negative aspects and bottlenecks concerning the remit of AWCs**

A variety of answers was given to this question:

- Personal interest;
- No relation between funding institutes and AWCs;
- Low coverage of all the relevant research protocols;
- Protocol is extensive and in a rather fixed format, making it complicated to fill in; yet the structure and the type of questions in the protocol do not guarantee that the appropriate information is provided;
- Main problem is that, so far, inspections are not carried out;
- No time for further training;
- Wide range of responsibility;
- Comprehensive duties/specification;
- Members are usually from within the institutes.

### **Negative aspects and bottlenecks concerning the procedures/methodologies of the AWCs**

The negative aspect mentioned most frequently was the fact that the process is time-consuming and involves much paperwork. Other remarks were:

- The procedure/methodology has not been published.
- There are no published guidelines on the use and care of animals in research or teaching, which are approved of by the institute or the government, to support the AWCs decisions and to contribute to the harmonisation of the operating procedures.

## **Negative aspects and bottlenecks concerning the composition of the AWCs**

Most remarks concentrated on the fact that it is not easy to find qualified, motivated and independent members. Other remarks were:

- From a local point of view, it is rather difficult for all representatives from every field to attend all the meetings. The composition, however, is usually acceptable.
- It used to be a problem to include animal welfare people.
- Setting up a local AWC can be a problem in small institutes.
- The composition of the committee as it is stated in legislative text, in terms of representatives of the different ministries, does not seem to guarantee that the members have the experience and expertise in scientific animal-based research, animal health and welfare and ethics that seem crucial for a functioning committee. It is possible, however, that the different ministries consider such qualifications when appointing members of the committee.
- It is necessary for the autonomous government to contact one of the members of the AWC.

## **Other negative aspects and bottlenecks concerning AWCs**

Some of the remarks made were:

- The optimum would be an independent body affiliated to the government directly, for example a custom administration.
- Trying to bring various conflicting interests together.
- There is insufficient budget.
- Having many individual committees means different kinds of decisions are made. In some cases, there is no common standard; however, this will be improved.
- Speed with which the procedures are handled needs increasing.
- Ethical reviews are a difficult process. The balance between scientific profit and discomfort of the animals is often difficult to measure.

## **Views on the present position and influence of AWCs**

Many respondents were very satisfied (10 out of 17). Some were positive but emphasised that improvements should be made (5 out of 17). Some indicated that the position of an AWC is weak (2 out of 17). Nearly all respondents declared that functional AWCs contribute to the implementation of the Three Rs. Personal views were given about the essentials for an optimal functioning of AWCs in their country and at a European level. Standardisation and harmonisation was a prominent point. In addition, it was felt that there is a need for clear (national and European) guidelines. Education (of staff but also of the researcher), training and funding were mentioned several times. Some countries, in which AWCs do not have a legal status at present, emphasised the need for proper legislation. An important point was the need for a good and positive atmosphere in which to discuss animal welfare issues and for a balanced composition of the committee: good scientists with different backgrounds, all the relevant persons present, including laymen and members of the animal protection movement. Networking within the country but also at a European level was mentioned more than once. The committee should not just be a supportive body to researchers, but should take up a prominent position on animal welfare issues, resulting in a genuine ethical evaluation, a harm-benefit analysis and attention for animal welfare and good science.

Other suggestions were:

- Closer relations between funding institutions, publishers and AWCs.
- Set up a register of experimental results and a list of experiments that have received a negative recommendation.
- Find better public acceptance.
- More financial support.
- Make the recommendations of the AWCs available to the public.



## Appendix D

# Characteristics per Country

L = local, R = regional, N = national, x = a number of, > more than  
*The numbers in brackets refer to the relevant literature*

### Austria (10)

Legal status	At least 2 L (Vienna and Innsbruck) 1N mandatory
Number of committees	> 3
Remit	Review of all applications for scientific and ethical reasons.
Elements of the review	Scientific review; Three Rs; ethics review; educational component; other review conditions. There are sometimes, but rarely, public debates.
Methodology	The Ministry (Federal Ministry of Education, Science and Culture) forwards the written application to the committee, which may consult with the applicant to resolve technical issues (as a general rule in writing) before giving a recommendation to the Ministry. There are no public meetings. Members are bound to confidentiality and written documents are treated as confidential. The review procedure consists of a written proposal and a personal hearing of the senior investigator. The committee is authorised to refuse permission. The protocol is either corrected or withdrawn. The Ministry is advised on each application for animal experimentation. The formal decision of the Ministry takes the recommendation into consideration. The Ministry is formally responsible for all animal studies performed at the universities. The national committee of the Ministry responds to the competent authorities. All animal studies performed outside the universities and academic organisations (e.g. pharmaceutical industry, county hospitals) reside under the Austrian county authorities. Separate procedure for regulatory tests.
Composition	Local: professor, (medical) researchers, students, non-academic staff, co-opted scientific members. National: member of the Austrian Academy of Sciences, representative of academia (medical, veterinary or biology department) and an animal welfare organisation.
Relevant Act	Austrian Animal Experiments Act TVG (national committee) 1974 EC directive transposed into Tierversuchsgesetz 1988 (Animal Testing Act).
Deliverables	—
Relevant Ministry	Ministry of Education, Science and Culture; Ministry of Social Security and Generations (transgenics); Ministry of Economics and Labour; Ministry of Agriculture, Forestry, Environment and Water Management.

## Belgium (10, 11)

Legal status	Approx. 25 L mandatory. (Each institute has an AWC, sometimes AWCs are shared.) 1 N National Deontological Committee mandatory
Number of committees	Approx. 26
Remit	Evaluation and control of the experiments (ethical, procedural, and scientific – statistical – review), local visits, discussions on new trends, knowledge and legislation, public debates in the national ethics committee, the Council of Animal Wellbeing, and television and radio debates. Assess planned and executed animal experiments, determine ethical criteria for animal experiments, inform the principal research project leaders and others regarding ethical aspects of animal use in experiments, give recommendation to the authorities regarding ethical aspects on animal use in experiments. The King may prescribe additional requirements concerning the destination of animals after experiment. No separate review for regulatory tests.
Elements of the review	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis. Description of procedure, explaining what animal must undergo (surgery, anaesthesia, restraint, fluid collection, administration, duration, discomfort, observation, end points, open field, hot plate, single dose toxicology, etc. When a single animal must undergo several procedures, a new ethical review is done. Monitoring and actions are to be taken when pain is beyond ethical end points.
Methodology	The AWCs at the institutional and national level are established by a royal decree from the King. The governmental inspector participates in several AWCs, so has the possibility to compare the way AWCs function and can advise about functional changes. Meetings and information are confidential and members must meet at least once a year. Protection of privacy is laid out in the law and a specific decree. Most AWCs make their decision on a written basis. Reviews usually take a few weeks. There are meetings with the researcher when additional info is required or when there is concern about animal welfare. The ethical review is advisory, but if a researcher does not follow the recommendation of the AWC, the laboratory director is responsible for eventual consequences. Protocols are evaluated by all members. Example procedure of the AWC of a pharmaceutical company: a description is required of the procedure, explaining what the animal will undergo. The same procedure may be carried out many times. This will appear in the yearly statistics. If in one protocol an animal must undergo different procedures, a new ethical review is required. Sometimes monitoring and registration of pain is carried out on score sheets.

	If individual members have ethical problems, which cannot be solved by the local committee, the concern may be expressed and advice obtained from the National Deontological Committee (NDC). The NDC does not usually address individual researchers, but will when some explanation of specific issues about a protocol is requested. After consultation with the NDC, the Ministry may give additional requirements for the composition and functioning of the AWCs, as well as for the nomination and background of external members.
Composition	Minimum is 6 members (4 internal, 2 external). 4 members laboratory/university staff (director, researchers who use animals, biotechnicians, animal welfare specialist, veterinarian), 1 or more members independent of laboratory/university (alternatives expert, layperson, animal protection organisation, scientist not involved in animal use), 1 governmental veterinary inspector from the Ministry of Agriculture (national authority). The National Deontological Committee consists of representatives of the pharmaceutical industry, Fund for Scientific Research, BCLAS, Royal Academy of Medicine, Council on Animal Welfare, Federal Council on Scientific Politics, Ministry of Social Affairs, Public Health and Environment, National Authorities on Animal Welfare.
Relevant Act	Royal Decree 1993 (revised 1998, 2001) on protection of experimental animals. Law of 1986 (revised 1998) on Animal Protection and Animal Welfare.
Deliverables	Written recommendation. An annual report of activities and statistics at least once a year for its members. Official annual publication of the statistics on the use of animals in experiments by the Ministry. Non-technical (lay) summaries. Sometimes pain evaluation on observation score sheets. Guidelines by Johnson & Johnson.
Relevant Ministry	Directive 90/219 under the competence of regional governments. Directive 90/220 Federal competence (Ministry of Agriculture: administration and control, and Ministry of Public Health: animal welfare). Royal Decree 1998 concerning genetically modified animals.

## Bulgaria

Legal status	Not institutionalised yet. 1 N to be established with the enforcement of Ordinance in 2005.
Number of committees	—
Remit	—
Elements of the review	—
Methodology	The ethics committee will meet several times a year.

Composition	An ethics committee will be set up following the enforcement of the Ordinance and will consist of 9 members: 2 vets (1 from National Veterinary Service, 1 representative of Veterinary Faculties), 2 medical doctors (1 from Ministry of Health and 1 from Faculty of Medicine), 1 researcher representing the Bulgarian Academy of Sciences, 1 ecologist representing the Ministry of the Environment, 1 zoologist representing the Faculty of Biology of the University of Sofia, 1 lawyer representing the Ministry of Agriculture and Forestry, 1 representative of an animal welfare organisation.
Relevant Act	European welfare legislation is already adopted in the national 'Law on Veterinary Activities' 1999 (Chapter VII: Rules for the protection of animals and animal welfare), the 'Rules for the Application of the Law on Veterinary Activities' and in related legislative acts, which lay out the detailed requirements for particular issues. The Ordinance for Protection and Welfare of Laboratory Animals adopted in June 2003 will be enforced in 2005 (harmonised with EC directive 86/609).
Deliverables	—
Relevant Ministry	European Directive was transposed into the Bulgarian legislation as a National Regulation of the Ministry of Agriculture and Forestry on 1 July 2003. This regulation is to be implemented in 2005.

## Cyprus (10)

Legal status	1N mandatory
Number of committees	1
Remit	The committee balances the requirements of science and industry and the protection of animals against avoidable suffering and unnecessary use. The members of the AWC (the Experiments Advisory Committee) are appointed directly by the Minister of Agriculture, Natural Resources and Environment. It is the duty of the AWC to advise the director on matters relevant to this law and his functions and powers under it as the committee may determine, or as may be referred to the committee by the director of Veterinary Services. The committee may institute subcommittees, and may promote relevant research to its functions or obtain opinion or advice from experts.
Elements of the review	Scientific review; Three Rs; ethics review. Separate review is required for regulatory tests.
Methodology	If the recommendation is not accepted, the applicant can appeal to the director of Veterinary Services. The committee is appointed for a 5-year term directly by the Minister of Agriculture.
Composition	The AWC consists of 5 members including a veterinarian, a physician, a person qualified in biological science and a member of an animal protection organisation. The chairman may be of any discipline.
Relevant Act	—

Deliverables	Written recommendation, annual report to the Minister.
Relevant Ministry	Ministry of Agriculture, Natural Resources and Environment (Veterinary Services)

## Czech Republic (10, 11)

Legal status	50 L mandatory and 1N of Ministry of Agriculture as an inter-ministries body.
Number of committees	51
Remit	Appointed by Animal Welfare Act 1992, 1993, 1994 no 162 Coll. of Laws of the Ministry of Agriculture (art. 21). Review conditions required by EU legislation. The central committee keeps the main statistics about the number of laboratory animals used for tests, safety warranty, projects of basic research, testing research and education; states conditions for issuing licences for users' establishments and for breeding and supplying establishments; ascertains the level and extent of knowledge needed for the work with laboratory animals; makes decisions in allocating licences; discusses reports about activities of state authorities; agrees regulations for breeding and tests on animals. The Central Committee nominates working councils for the protection of laboratory animals.
Elements of the review	Scientific review; review of Three Rs; harm-benefit analysis.
Methodology	The AWC may direct objections connected with the research conditions in co-operation with the District Administrations, or directly by means of accreditation of research/laboratory animal production establishments. It is not possible to appeal against the decision of the Central Committee. Members require special training.
Composition	The AWC has a minimum of 4 members. Formal status, competence and designation are in accordance with the Animal Protection Act. Members are representatives of various ministries (Health, Agriculture, Environment and Interior) which approve the research carried out, and representatives of research institutes and the Academy of Science. The Minister of Agriculture, with the approval of the Minister of Environment, appoints them.
Relevant Act	Animal Protection Act 246/1992 Co. (para 17) Decree 311/1997 Col. Animal Welfare Act and Decree 311/1997 Col. Genetically Modified Organisms Act under preparation.
Deliverables	Annual report, statistical data. Educational component: public debates in media and campaigns organised by animal protection organisations together with scientists.
Relevant Ministry	Ministry of Agriculture: Animal Welfare Act and the Central Commission for Animal Welfare. The Ministry of Environment for regulations concerning genetically modified animals.

## Denmark (10, 11)

Legal status	4 L and 1 N mandatory. The Board of the Danish Inspectorate for Animal Experiments (Animal Experimentation Inspectorate) is part of the Danish National Authority.
Number of committees	5
Remit	National: ethical review of applications. Some cases receive prior inspection of the pilot experiment; post-licensing mandatory inspection. AWCs sometimes perform an ethical review before submission to the national ethics review. There is no official relationship with national and local AWCs. The Danish Animal Experiment Inspectorate is the national authority in the administration of the legislation on the use of animals for experiments or other scientific purposes.
Elements of the review	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis, use of analgesics/anaesthesia, species to be used, number of each species.
Methodology	National committee: monthly meetings. Appointed for 4 years. The Animal Experimentation Inspectorate conducts mandatory national licensing procedures. With the submission of the application, information about the purpose, description of experiment, use of analgesics/anaesthesia, species and number of animals has to be given for the ethical review process. Application may then be granted, modified or rejected. An application is only granted for a specific purpose. The Act includes rules on anaesthesia and palliative treatment. Animals must not experience severe pain, suffering or fear. The review is directed to the applicant only. A copy of the issued licence is always sent to the named vet at the institute. There is a post-licensing inspection. Mandatory inspections by Animal Experimentation Inspectorate. There are large variations between AWCs of companies in terms of inspection. Local AWCs consult the vet for advice and perform reviews of licences with protocols/experiments in progress, and perform ethical reviews before submission of application to the national ethics review. The recommendation is given to the applicant, the research group or all researchers depending on the nature of the animal welfare subject. If the recommendation is not accepted, there is usually a dialogue where the national committee sets terms and conditions to be followed for the licence to be issued. Local AWCs have meetings, give written recommendations, inspect the experiment and have a consultation with the vet. The names of the members are only available on the intranet to selected employees.
Composition	National: Chairperson is a high court judge. 10 members, who should have a biological academic education, are appointed by the Ministry of Justice. 4 members are from animal welfare organisations, 3 members from academia, 1 member from industry and 2 members from governmental bodies. Local AWC: from 5 to 10 members including a laboratory technician, researcher, member of animal welfare organisation, layperson (HR or communication).

Relevant Act	Animal Testing Act consolidation Act no. 726 1993 amended by Act 1081 1995, and subordinate Executive Orders no 739, 332, 333 (amended by 245), 715, 716.
Deliverables	Written recommendation, annual report by the Animal Experimentation Inspectorate. Lay (non-technical) summary. Public information in an anonymous format. Guidelines.
Relevant Ministry	Ministry of Justice

## Estonia (10, 21)

Legal status	x L and 1 N. There is no special regulation yet, but Estonia is going through a reorganisation of its legislation (Estonian Animal Protection Act). Currently, there is 1 national ethics committee and several local committees, such as the AWC at the Medical Faculty of the Tartu University and the Faculty of Veterinary Science of the Estonian Agricultural University. In 2003, a new committee will be established under the supervision of the Ministry of Agriculture.
Number of committees	1 + x
Remit	Ethical evaluation is required more by the funding bodies (Estonian Science Foundation, etc.) than by governmental institutes.
Elements of the review	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, and severity of the harm caused to the animals.
Methodology	The recommendation is supposed to be mandatory, but there is no control system. The review usually takes place within a month. Decisions are made during the meeting.
Composition	Generally 3 members in the Tartu committee; at least 4 members in the field of medicine, biology and society.
Relevant Act	Estonian Animal Protection Act 2001. The chapter about the Protection of Experimental Animals is to be enforced.
Deliverables	—
Relevant Ministry	Ministry of Agriculture

## Finland (10, 11, 23)

Legal status	117 L mandatory 1 N Provincial State Office. New law is being prepared at the Ministry of Agriculture and Forestry, with changes in the ethics committees. In a few years, the legislation will change to have only 1-4 national committees.
Number of committees	118

Remit	The duty is to process and scrutinise the protocols in terms of their necessity and compliance to the animal welfare regulations and to decide on the classification (class 1 or 2.2 = severe pain) according to the Decision no 477/1986 of the Ministry of Agriculture.
Elements of the review	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis, humane end points, species and number of animals, time and place of experiment, procedures applied in the experiment.
Methodology	Local AWCs handle all protocols and decide unanimously on the classification. A representative of the competent authority (provincial Veterinary Officer) has the right to take part in the meeting. The secretary of the AWC pre-checks the application and the researcher is contacted if there are any queries on the application or from the AWC. Communication is personal, by mail, telephone or written notice. Sometimes a researcher is invited to attend a meeting to explain certain aspects of the application. The licence is applied individually and the review is sent to the applier. The decisions are mandatory and the meetings are confidential. First class experiments (severe pain) are sent, after local review, to the provincial State Office for final consideration. If the provincial State Office is unsure whether to grant the licence, the application is forwarded to the Ministry of Agriculture. Both the local AWC and the provincial State Office may add specific conditions to the licence, which must be followed. If the recommendation is not accepted, the application is sent to the provincial State Office, where the provincial veterinarian acts as a presenter of the case. If this authority does not accept the application either, the researcher has the possibility to complain to the provincial Court of Justice.
Composition	Usually 6-12 members. 4 members are mandatory, i.e. scientists (mandatory) and animal care staff (mandatory) and an external member. The chairman is in charge of experimentation within the institute, at least 2 other members should be familiar with animal experimentation, a member responsible for the care of animals in the institute, 1 veterinarian, 1 animal welfare specialist. Often the AWC includes a member of an animal protection organisation.
Relevant Act	Decree on Animal Experimentation 1076/85, European convention and EU directive. Animal Welfare Act and decree. New law under preparation at the Ministry of Agriculture and Forestry, with changes to the ethics committees, resulting in fewer AWCs.
Deliverables	Lay (non-technical) summary of the studies, seminars and discussions. The recommendation is open to the public and available at the provincial government.
Relevant Ministry	Ministry of Agriculture and Forestry (Veterinary and Food Department), and Ministry of Social Affairs and Health (GMOs).

## France (10, 11, 31)

Legal status	Approx. 25 LxR
Number of committees	—
Remit	Its duty is to ascertain that the use of animals takes place under strict ethical and legal conditions, used under best possible conditions and wellbeing, and that protection is assured. The AWCs are institutional. Review includes scientific review, Three Rs, not necessarily an ethical review, legal review, exchange of information, and training of staff in animal protection.
Elements of the review	The rationale and purpose of the protocol, animal species, number of animals justified by scientific, regulatory or statistical references, pain assessment, anaesthetics, analgesics, humane end points, stress, discomfort, surgery, euthanasia, housing, training, breeding, transportation (suppliers and shipping).
Methodology	The activities consist of meetings, inspections and the drafting of documents. The review is addressed to the individual researcher and the researcher is invited to come to the meeting to discuss the protocol. The aim is consensus approval. Meetings are minuted. The recommendation is consultative and researchers are free to consider the recommendation or not. Nevertheless, the AWCs are strongly supported by the director of the institute. Approved protocols are periodically reviewed. Protocol review is a prerequisite for the purchase or allocation of animals. The AWCs give recommendations/opinions in reply to any questions related to the use of laboratory animals. There are meetings for examination of protocols and exchange of information, regular inspections and drafting of documents: internal documents, annual activity report describing the committee's objectives and achievements to be distributed extensively. Furthermore, there is distribution of external documents, training sessions, info briefings for new staff, and assistance for the company in relations with other committees or persons. Public debates are often organised by GIRCOR (Groupe Interprofessionnel de Reflexion et de Communication sur la Recherche).
Composition	Each AWC consists of 3-9 members made up of 1 who is not a scientist (non-biologist), a veterinarian, invited participants and laymen.
Relevant Act	National Animal Protection Act Decree no 87-848 1987 and 3 ministerial orders 1988. Proposed development of a national inter-organisation committee for ethical discussion and control of animal experimentation.
Deliverables	External and internal documents, annual activity report describing the committee's objectives and achievements to be distributed extensively, presentations, training sessions and information briefings. (Verschuere, B., et al, Ethics committees recommendations for laboratory animals in private research in France, <i>Laboratory Animals</i> (2000) 34, 236-243.)
Relevant Ministry	Ministry of Agriculture

## Germany (8, 9, 10, 11, 25)

Legal status	35 R mandatory
Number of committees	35
Remit	The AWCs are advisors to the local governmental competent authority (CA). The CA decides, but usually follows the recommendation of the AWC. There are separate procedures for protocol research. The competent authorities must be notified beforehand but require no permission. Researchers supply an application to the CA. The application is then passed on to the AWC. AWC may ask for additional information.
Elements of the review	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis. Use of humane end points, use of anaesthesia (also post-operative), group housing also during experiments.
Methodology	The AWCs meet about every 4 weeks. The decisions are advisory to the governmental authority. The review usually takes 4 to 8 weeks. Researchers supply an application to the competent authority. The application is then passed on to the AWC. AWC may ask for additional information. There is a separate procedure for protocol research: no permission required by the competent authorities, but they must be notified beforehand.
Composition	Regional AWCs consist of 6 members, plus the animal welfare officer of the institute and the applicant. The majority of the members must possess expertise in the field of veterinary medicine, medicine or another discipline of natural science, animal welfare. Statisticians are included and members from animal welfare organisations make up one third of the committee.
Relevant Act	Animal Welfare Act 25 May 1998. Articles 7 to 9.16 Lander, several regional authorities (Regierungspraesidium).
Deliverables	Cases of fundamental significance are reported to the federal government and published in the Animal Welfare report.
Relevant Ministry	Ministry of Food, Ministry of Agriculture, and Ministry of Forestry and Health

## Greece (11)

Legal status	There are no AWCs in Greece. The local veterinary service issues the licence and performs the ethical evaluation. By the end of 2003, an institutional AWC will be established in a new Biomedical Centre according to the Guide for the Care and Use of Laboratory Animals (NRC 1996) as part of the institutional policy of the Centre.
Number of committees	0
Remit	—

Elements of the review	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs.
Methodology	Regular visits to the facility. The review/licence is issued within a week.
Composition	The ethical review is carried out by official veterinarian from the local veterinary service in each prefecture.
Relevant Act	—
Deliverables	Lay summaries
Relevant Ministry	—

## Hungary (10)

Legal status	47 L mandatory 1 N mandatory. National Ethical Council
Number of committees	48
Remit	All AWCs act according to a code of practice, an ethical codex.
Elements of the review	Ethical review
Methodology	The recommendation is mandatory. In case of minor alterations, local actions are taken by the AWC and no formal procedure is conducted. In case of major alterations, formal but still local provisions are made, such as restricting the conditions of the AWC approval, or its withdrawal thereby suspending the execution of the procedure. In the case of violations of the law, or when the former provisions have no effect, the AWC communicates to the authority, which can revoke the permission for the whole experiment or even for the institute. A fine can also be imposed.
Composition	The national committee consists of 9 members (1 academic, 3 scientists, 3 researchers, 1 geneticist, 1 independent veterinarian).
Relevant Act	National Animal Protection Act XXVIII 1998 and the governmental decrees 243/1998 and 36/1999.
Deliverables	Written recommendation for members of the institute only. National conferences, local and county events of the animal protection groups and associations. Ethical Codex.
Relevant Ministry	Ministry of Health, Ministry of Agriculture and Regional Development.

## Iceland

Legal status	1N
Number of committees	1
Remit	An independent advisory committee on animal welfare gives guidance to the Environment and Food Agency, which is the implementing agency on the Act on Animal Welfare, and to the Ministry.
Elements of the review	—
Methodology	—
Composition	—
Relevant Act	Act on Animal Welfare no 15/1994
Deliverables	—
Relevant Ministry	—

## Ireland (1, 10)

Legal status	x L
Number of committees	x
Remit	Primary task is to review all applications for licence on scientific and ethical grounds, and to ensure that licences are not granted where alternative methods are reasonably and practicably available. Government inspectors and institutional ethics committees carry out an ethical evaluation. Each institute is free to develop its own model. A number of the state-funded agencies, including the Health Research Board, now require an ethical review prior to funding any animal-based research.
Elements of the review	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis, statistical justification of animal numbers, species used, background and education of researcher, peer review.
Methodology	Government inspectors and institutional ethics committees carry out ethical evaluations. Each institute is free to develop its own model. Protocols must be submitted one month before meetings. Decisions are conveyed within a week after the meeting. The recommendation is mandatory. There is a review after a pilot study and visits to facilities are made. The time it takes for review varies from one day to weeks. Anything involving severe classification is subjected to special review.
Composition	Statistician, veterinarian, animal care staff, scientist who uses animals, animal welfare specialist, scientist not involved in animal use, layperson.

Relevant Act	The Cruelty to Animals Act 1876, 1994. Genetically Modified Organisms Regulations 1994
Deliverables	Lay summaries
Relevant Ministry	Ministry of Health and Children, Ministry of the Environment and local government.

## Israel

Legal status	xL 1. National Council for animal experimentation
Number of committees	1 + x
Remit	The local AWCs review whether the requirements stated by the law have been abided with. No approval will be given if alternatives are available.
Elements of the review	—
Methodology	Approval is given to the researcher.
Composition	—
Relevant Act	—
Deliverables	Experiments in animals, instructions and regulations.
Relevant Ministry	Ministry of Health, implementation via council for animal experimentation.

## Italy (10, 11, 12)

Legal status	xL in several research centres 1 N mandatory. No real AWCs have been established yet, though preliminary proposals to establish AWCs are under evaluation. Several institutes (both public and private) established institutional AWCs voluntarily, which are quite consistent in terms of composition (number and competence) and activities (project review, training of personnel, facility inspection, etc.).
Number of committees	1 + x
Remit	Consultation and recommendation on all aspects of proposed research projects, including suggestions for revision, refinement, replacement. All research protocols must be communicated to the Ministry of Health. A central (Health Ministry) technical committee evaluates the compliance of experimental activities with national legislations of animal use and welfare. A special commission for animal experimentation of the National Health Institute (ISS) reviews special cases (experiments with cats, dogs, primates, special purposes, special experimental protocols and procedures). The national Commission for Bioethics and the Commission of the National Research Council (CNR) for Bioethics have advisory functions, with subcommittees of experts on, for example, genetic modification and biomedical research involving animals. The central process for project revision and authorisation could take more than a year.

Elements of the review	Scientific background of the project, objectives, experimental procedures, number of animals, species used, persons involved and their experience, veterinarian in charge, procedures to minimise pain, suffering and distress, anaesthesia, alternatives, Three Rs, other review conditions required by national or international regulations.
Methodology	Meetings are held two or three times each year. The AWCs give consultation and a recommendation before submitting to the competent authorities. The review is addressed to the institute. If the recommendation is not accepted, a new recommendation with a more robust rationale and literature in support of the project has to be presented. In the case of rejection, both the Central Committee and the institutional AWC send written comments and/or additional details to the submitters. There are no specific processes to guarantee protection of privacy and confidentiality.
Composition	Director of the institute, ethicist, lawyer, theologian, pre-clinical or clinical scientists, veterinarian, laymen, statistician and laboratory animal specialist. The composition may differ per committee.
Relevant Act	Law on laboratory animal protection Legislative decree 1992.
Deliverables	Institutional statistics. Institutional guidelines (Mario Negri Institute, Milan)
Relevant Ministry	Ministry of Health

## Latvia (20, 22)

Legal status	xL and 1 N mandatory. National Ethics Committee on Laboratory Animal Use in Biomedical Experiments at the Latvian Council of Science
Number of committees	1 + x
Remit	Scientific review and ethical review according to good scientific practice. Co-operation with breeding facilities and research institutes in any field connected with laboratory animals, to give recommendations to researchers in the field of welfare, to ensure the scientific projects limit (as much as possible) the use of animals and their suffering, and the unnecessary use of animals, promote use of alternatives, participate in development of legislation concerning the protection of laboratory animals, promote the knowledge on welfare and optimise the welfare conditions in co-operation with the State Veterinary Department to develop regulations for inspection. Review is mandatory before funding by the Latvian Council of Science to organise training
Elements of the review	Scientific review, Three Rs, educational component.
Methodology	Methodology as laid out in good scientific practice. Recommendation is on a written basis. Meetings at least once every 3 months. The committee informs the Latvian Council of Science.

Composition	AWC has 13 members: scientists who use animals (5); veterinarian (1); animal care staff (1); animal welfare specialist (1); members of animal protection organisations (2): scientist not involved in animal use, e.g. statistician (1); laymen from environmental protection organisation and State Drug Agency (2). The AWC should include a representative from the Latvian Council of Science, the State Veterinary Department, the Ministry of Welfare and the Baltic Laboratory Animal Science Association.
Relevant Act	Latvian Law on Animal Protection
Deliverables	Written recommendation. Good scientific practice. Regulations of the ethics committee on the investigations using laboratory animals (Latvian Council of Science).
Relevant Ministry	—

## Lithuania (27)

Legal status	xL and 1 N mandatory
Number of committees	1 + x
Remit	Research protocols are only evaluated with respect to animal welfare.
Elements of the review	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis, anaesthesia, euthanasia, number of animals.
Methodology	Meetings are held every three months. The decisions are advisory. The committee gives a recommendation to the State Food and Veterinary Service that issues mandatory licences. The members of the committee have the right to enter any premises where experiments are carried out, to inspect whether the procedures performed are in agreement with licence permissions.
Composition	12 members from 10 state scientific institutions (Lithuanian Laboratory Animal Science) and 2 public institutions (Society for Animal Protection).
Relevant Act	Law on care, keeping and use of Animals 1997; Order no 4-361 concerning "veterinary requirements for the breeding, rearing, care and transportation of laboratory animals" (1998 State Veterinary Service); Order 4-16 "on the use of laboratory animals for scientific experiments" (199 State Veterinary Service); Rules of Good Laboratory Practice (1999 Ministry of Health)
Deliverables	Licence. Guidelines of the ethics committee of the State Food and Veterinary Service. Institutional regulations (Kaunas Medical University)
Relevant Ministry	State Food and Veterinary Service

## Netherlands (10, 11, 14)

Legal status	29 L mandatory 1 N mandatory (Central Committee Animal Experimentation CCD) and 1 special committee, which reviews protocols for the making of genetically modified animals: the Animal Biotechnology Committee (CBD) 1 independent local AWC, which can be consulted by an institute that does not have its own AWC.
Number of committees	32
Remit	Legal requirements require review of goal and relevance, competence and experience of researchers, possible alternatives, animal model, origin and destination, housing and care, experimental conditions, discomfort anticipated, methods to reduce discomfort, re-use, humane end points.
Elements of the review	Aim and relevance of the experiment, competence and experience of the researcher and the animal care staff, argumentation as to why alternatives are not used, animal model, origin of the animals used and destination after experiment, housing and care conditions before, during and after the experiment, experimental conditions (nature, frequency, duration), anticipated degree of discomfort, anaesthesia, analgesia or other methods used to reduce pain or discomfort, re-use, humane end points, scientific, medical and societal benefit.
Methodology	The recommendation to the director of the institute is advisory. There are monthly meetings. The procedure may take 3-6 weeks. The decision is on a written basis. The committee may ask the researcher to visit the committee to give a more detailed explanation. If the recommendation is negative, and the director wants to overrule this, he has to ask advice from the national committee. The national ethics committee thus acts as a 'court of appeal' in case a local AWC has rejected a proposal. There exists a national association for AWCs that organises meetings and training sessions annually.
Composition	There are at least 7 members, 3 of whom (including the chairperson) are not economically affiliated with the institution and 2 are not involved in animal experiments. There are 4 kinds of experts on the committee: those with expertise in animal experiments, ethical evaluation, alternatives and on the protection of animals. The AWC may include a veterinarian, an animal welfare specialist, statistician, scientists not involved in animal use and students.
Relevant Act	The Dutch Experiments on Animals Act 1996 Animal Health and Welfare Act; genetically modified animals.
Deliverables	Written recommendation. Institutional and national annual report. Public hearings concerning protocols involving the making of genetically modified animals. Institutional guidelines. Codes of practice. Institutional welfare scoring system.
Relevant Ministry	Ministry of Public Health, Welfare and Sport and the Ministry of Agriculture, Nature Management and Fisheries.

## Norway (10, 11, 28)

Legal status	1 N mandatory. National Animal Research Authority (NARA)
Number of committees	1
Remit	All animal experimentation has to be approved by the NARA, appointed by the Ministry of Agriculture. The NARA approves and inspects animal units, designates the animal species that may be housed in these units, appoints a competent person at each unit to whom responsibility for approving research applications can be delegated, and handles applications for field research projects. Some research projects (fish, wild species or GMOs) may require prior approval from other ministries in addition to that obtained from the NARA.
Elements of the review	Possible alternatives, aim, type and extent of the experiment, species, number of animals, duration of the study, re-use, methods of euthanasia.
Methodology	The NARA meets 8-9 times a year. The competent person (CP) of an institute sends all application forms to the NARA, which have been approved by the competent person. In this way, local practices and call for reports on specific projects are monitored. The NARA may also be contacted for advice on interpretation of current legislation. It issues an annual report based upon statistics. The day-to-day approval of experiments is delegated to the competent person at each facility. The CP sends an annual report to the NARA and the NARA sends an annual report to the Council of Europe.
Composition	Veterinarian, legal expert, member of an animal welfare organisation, scientist.
Relevant Act	Animal Welfare Act, amendment to chapter VI, which regulates the use of animals in teaching and research, came into force in 2002. The Gene Technology Act regulates the use of genetically modified animals. Regulations concerning requirements for the housing and management of GMOs came into force in 2002. A regulation concerning transport and import of GMOs came into force in 1999.
Deliverables	Institutional and national annual report. Guidelines concerning procedures that are considered unethical.
Relevant Ministry	Ministry of Agriculture, Ministry of Health and Social Affairs (Gene Technology Act).

## Poland (4, 10, 11)

Legal status	18 L mandatory. 1 N mandatory. National Ethics Committee on Animal Experimentation (1999).
Number of committees	19
Remit	The national ethics committee appoints the local AWCs and oversees their work as an appeal authority. The NEC sets up rules for the processing and ethical evaluation of research projects. An important part of the regulatory work issued by the NEC is the scale of invasiveness (harm scale) for animal experiments. All implementation of the Act is delegated to the Veterinary Inspectorate.
Elements of the review	—
Methodology	—
Composition	5 members at a national level and 6 to 15 members at a local level: 2/3 scientists and 1/3 animal welfare organisation.
Relevant Act	Animal Protection Act 1997
Deliverables	Written recommendation
Relevant Ministry	Ministry of Agriculture and the Ministry of Education.

## Portugal (10, 11)

Legal status	6 or more L and 1 N mandatory. National Advisory Board of the Direcção Geral de Veterinária (DGV)
Number of committees	7 or more
Remit	The DGV is the competent authority for animal protection including laboratory animals and coordinates the local AWC. Local review processes are not yet regulated and each local AWC may work differently.
Elements of the review	Scientific aspects, Three Rs, ethical review, harm-benefit.
Methodology	Research protocols must be approved by the DGV. At the institutional level, the AWCs provide written codes of practice, rules and regulations, and sees that these are abided by. The local AWC also advises the researchers and meets regularly with the Animal Users Committee. Meetings are confidential. Local AWCs are self-regulating.
Composition	Local: General director of the institute, scientist, animal welfare organisation. National: 11 representatives from scientific institutes and 1 representative from animal welfare organisation.
Relevant Act	National Animal Protection Act
Deliverables	Written recommendation, annual report, public debate
Relevant Ministry	Ministry of Agriculture

## Slovakia (10)

Legal status	xL and 1 N mandatory
Number of committees	1 + x
Remit	The ethics committee (the advisory body of the scientific institute) and the Chief Veterinary Officer.
Elements of the review	Scientific review, Three Rs, ethical evaluation, stimulating the ethical debate, the level of education and specialisation of the persons involved in the experiments.
Methodology	If the institute does not agree with the recommendation from the AWC, it may consult the State Veterinary and Food Administration. The latter may seek advice from an independent advisory body.
Composition	Scientists, specialists in animal care.
Relevant Act	National Animal Protection Act: Decree 231/98 to be replaced in August 2003 for an act in line with the EC directive.
Deliverables	Written recommendation
Relevant Ministry	Ministry of Agriculture

## Slovenia (10, 11)

Legal status	1 N mandatory
Number of committees	1
Remit	The ethics committee gives a recommendation to the competent administrative office, concerning granting project licences. It reviews whether alternatives are possible, or whether the experiment is an unnecessary duplication.
Elements of the review	Possible alternatives, no duplication.
Methodology	—
Composition	Veterinarian, scientist in the field of human medicine, biology or zoo technicians.
Relevant Act	National Animal Protection Act 1999
Deliverables	—
Relevant Ministry	Ministry of Agriculture, Forestry and Food and the veterinary administration of the Republic of Slovenia.

## Spain (10)

Legal status	xL and xR (mandatory dependent on regional law).
Number of committees	x
Remit	Analgesia, anaesthesia, euthanasia, doses, humane end points, Three Rs, scientific project objectives, scientific benefit, justification use, provider and number of animals (statistics), experimental design details, pain and suffering expected, alternatives, training of staff, species, centre's facilities, harm-benefit, educational component.
Elements of the review	Analgesia, anaesthesia, euthanasia, doses, humane end points, Three Rs, scientific project objectives, scientific benefit, justification use, provider and number of animals (statistics), experimental design details, pain and suffering expected, alternatives, training of staff, species, centre's facilities, harm-benefit, educational component.
Methodology	The review is addressed to the researcher, the research group, the institute and to the competent governmental authority. Confidentiality required by law. Meetings are usually held once a month. The recommendation is either advisory or mandatory. The review usually takes 1 to 4 weeks. Some procedures are subjected to special review, called Procedures of Express Authorisation (e.g. some oncological procedures).
Composition	Veterinarian, statistician, scientist who uses animals, animal welfare specialist, laboratory animal science specialist.
Relevant Act	Royal Decree 223/1988. Under this decree, each regional community has the power to control the implementation of EC Directive 86/609.
Deliverables	Written recommendation
Relevant Ministry	Ministry of Environmental Health and the Ministry of Agriculture, Fisheries and Food.

## Sweden (5, 10, 11, 13, 16, 24, 25)

Legal status	7 R mandatory 1 N. National Board for Laboratory Animals (CFN)
Number of committees	8
Remit	The National Board for Laboratory Animals (CFN, 1979) is responsible for the long term planning of the use of laboratory animals, further co-operation between breeder, scientists, animal care staff, animal protection organisations, and the authorities. It ensures that the resources available for laboratory animals are efficiently used, and is responsible for the AWCs and their assessment of matters relating to the use of laboratory animals. One of its major objectives is to reduce the need for laboratory animals by promoting the development of alternative methods.

	The CFN is responsible for the dissemination of information on other matters regarding the use of laboratory animals, issues recommendations to the AWCs on the treatment of certain matters in relation to ethical reviews, and organises adequate education for AWC members. There are 5 executive committees with expert knowledge on ethical questions, alternative methods, health and quality of the animals, housing and equipment, training of staff and research. The National Board will cease its activities in 2003. In its place, a Board for Animal Welfare will take over its responsibilities and several other important animal issues. The AWCs are appointed by the National Board for Laboratory Animals and are responsible for the ethical evaluation pursuant to section 21 (1) of the Animal Welfare Act. The decision is mandatory by law.
Elements of the review	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis, public interest, care and accommodation before, during and after the experiment.
Methodology	A small representative group first reviews the application then this group collects additional data. This results in a draft of a decision by the AWC. Meetings are once a month. The review usually takes 1-2 months. Decisions are mandatory. The minutes are reported to the National Board and statistical records are kept. The National Board also keeps statistical records.
Composition	AWCs have 12 members with a judge as chairman and including scientists and laboratory technicians. 6 are lay members, representing the general public or animal welfare organizations (2)
Relevant Act	Animal Welfare Act 1988 and the Animal Welfare Ordinance 1988.
Deliverables	Written minutes, annual reports and statistical records. Documents available on request. Guidelines by the National Board for Laboratory Animals (eg. immunisations, production of monoclonal antibodies and acute toxicity testing). The National Board for Laboratory Animals Regulation with Rules and General Recommendations Concerning Ethical Review of the Use of Laboratory Animals for Scientific Purposes (1989).
Relevant Ministry	Ministry of Agriculture (animal welfare) and the Ministry of Justice (GMOs).

## Switzerland (6, 10, 11)

Legal status	15 R mandatory 1 N mandatory. Federal Committee for Animal Experimentation
Number of committees	16

Remit	Animal Welfare is a federal matter and delegated to cantonal (county) authorities (CA). The review is addressed to the CA. If the recommendation is not accepted by the CA, it will give a justification to the AWC. In one canton, the AWC may appeal against the governmental decision.
Elements of the review	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis, species and number of animals, housing facilities, source of animals, competence researchers and educational component.
Methodology	Any use of animals for experiments has to be reported to the CA, usually the cantonal veterinary office. To obtain a licence, a researcher submits an application to the CA, which makes a decision based on recommendations by an AWC. Review takes approximately 4-6 weeks. Appeal is possible. Licences are given for 2-3 years. To obtain a licence may take up to 3 months. The AWCs also inspect the animal experiments and control the housing and care.
Composition	Scientists from the universities or industries that use animals, animal welfare specialist, veterinarian, member from an animal welfare organisation.
Relevant Act	Swiss Animal Protection Ordinance 1981 (1998) and Swiss Federal Act on Animal Protection 1978. A number of guidelines regulate details of licensing, caging requirements, recording, etc.
Deliverables	Written recommendation, annual report to the CA. The Federal Veterinary Office organises courses for AWC members and local authorities. It also publishes information and guidelines.
Relevant Ministry	Federal Department of Public Economy and the Swiss Veterinary Office.

## Turkey (10)

Legal status	15 L
Number of committees	15
Remit	All animal experiments are subjected to review. Decisions are mandatory. Canine studies are reviewed with extra care, due to growing public resistance.
Elements of the review	Aim and necessity of study, experimental design, ethical evaluation, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them.

Methodology	Ethical review usually takes 3 months. Ethics committees usually require a report from the scientific committee. The review is addressed to the individual researcher and the research group. The recommendation is mandatory.
Composition	Surgeon, veterinarian, statistician, scientist not involved in animal use, biomedical researcher, animal welfare officer.
Relevant Act	National Animal Protection Act
Deliverables	Written recommendation
Relevant Ministry	Ministry of Health

## United Kingdom (7, 10, 11, 15)

Legal status	265 L (not required by law, but the Secretary of State requires that all designated establishments have a viable ethical review process). 1 N mandatory (Animal Procedures Committee). There are local ethics committees at each place undertaking animal research (see Home Office UK website).
Number of committees	266
Remit	Advisory. The AWCs consider scientific and ethical aspects of project licence applications and amendments, review work in progress and perform retrospective appraisal, examine wider issues of husbandry and animal care and accommodation standards and use within the establishment (especially Three Rs). The AWCs keep employees up to date with ethical advice, best practise and legislation, review establishment's management systems, procedures and protocols, advise on appropriate training of all staff. The creation of a 'culture of care'. The national Animal Procedures Committee (APC) advises the Home Office on certain classes of project licence applications, as well as general issues.
Elements of the review	Aim and necessity of study, experimental design, scientific validity of using animals, likely benefits of the study, the need for animal experiments, severity of the harm caused to the animals, application of the Three Rs and the priority given to them, harm-benefit analysis. Number and type of animals used, steps taken to reduce the number of animals and any distress, suffering or harm involved.
Methodology	AWCs meet to discuss applications and other issues, often with the researchers present. The Home Office visits establishments and meets with researchers and other staff. The AWCs' decisions are advisory. Ethical review processes in each establishment review new project licence applications, amendments and consider all other ethical issues arising in the work of the establishment. They advise researchers on ethical and other aspects in the design of the projects and, ultimately, recommend to the establishment's certificate holder whether or not to sign licence and amendment applications before these are forwarded

	to the Home Office (government department). Home Office inspectors also provide recommendations on the design of the projects and advise the Secretary of State whether to grant licences. Certain categories of application are also reviewed by the APC. Where there is doubt about whether to license a particular piece of work, the Home Secretary may seek advice from the APC or other independent assessors. The Home Secretary may refer other matters to the committee and the APC may also consider topics of its own choosing. The review process operates both a local committee-based system of assessment and a central government-based system of assessment plus government inspectors. The time it takes for review varies considerably.
Composition	Local AWCs: project and personal licensees, veterinary surgeon, animal care people, lay people, physicians, scientists, lawyers (occasionally statisticians, alternatives experts, animal protection organisation, other external members). National: The Animal Procedures Committee has a wide range of perspective including an animal welfare organisation, 2/3 medical doctors or veterinarians, biologist, philosopher, lawyer, 1/2 non-licenced (often administrative staff or staff from other faculties within the establishment concerned).
Relevant Act	ASPA Animals (Scientific Procedures) Act 1986 (revised 1999) Specific regulations for genetically modified animals (also Home Office department of Health), special justification under the ASPA for non-human primates, cats, dogs, equidae.
Deliverables	APC annual report: number and type of animals, purpose for which they are used and the type of establishment using them. Lay summary. (Jennings, M., Smith, J., Local ethical review process, RSPCA, January 2003. Home Office documentation. APC report.)
Relevant Ministry	Home Office (mandatory Home Office ethical review process)

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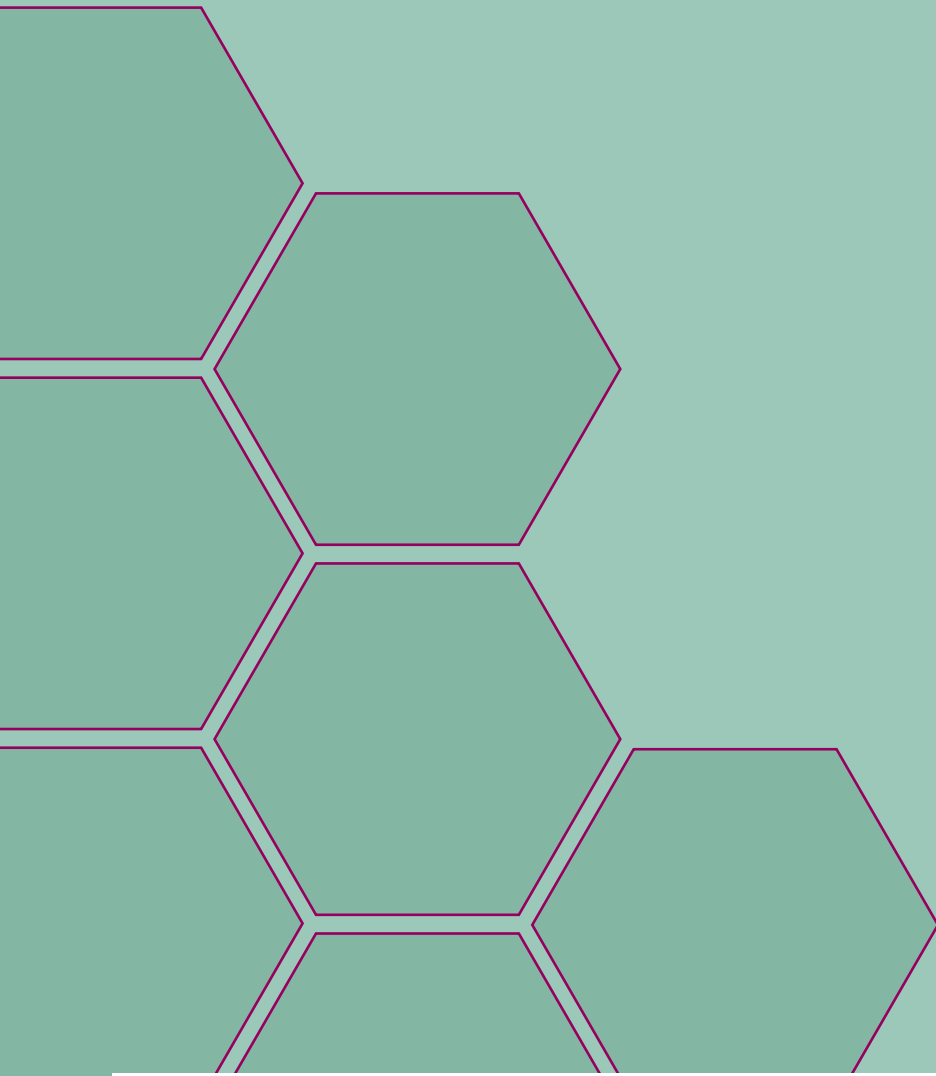
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