Proposal for the Composition of Animal Experiments Committees in the Netherlands

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Summary
The Dutch Act on Animal Experimentation (1996) requires that local animal experiments committees (AEC's) review animal experiments and balance the scientific and societal benefits of the experiments against the suffering caused to the animals used. Each AEC is composed of at least seven members who provide a balance of expertise in animal experiments, alternatives to laboratory animal experiments, ethics, and animal welfare and protection.
This study proposes selection criteria for individuals possessing each of the four AEC required areas of expertise. Criteria were established minding that, on the one hand, sufficient knowledge and expertise can be demonstrated whilst, on the other hand, a sufficient number of people would qualify to participate in the AEC's.
The results of this study may serve as a starting point for further discussion of selection criteria for members of AEC's both in the Netherlands and in other countries where ethical review processes have been or are being implemented.

Zusammenfassung: Vorschlag für die Zusammensetzung von Ethikkommissionen für Tierversuche in den Niederlanden
Das holländische Tierversuchsgesetz (1996) fordert, dass regionale Ethikkommissionen Tierversuchsanträge beurteilen und den wissenschaftlichen und gesellschaftlichen Nutzen der Experimente gegen das Leiden der Tiere aufwiegen. Jede Kommission besteht aus mindestens sieben Mitgliedern, die eine ausgewogene Expertise auf den Gebieten Tierversuche, Alternativen zu Tierversuchen, Ethik und Tierschutz einbringen.
Die vorliegende Studie schlägt Auswahlkriterien vor für Personen, die eine der vier geforderten Kenntnisse besitzen. Die Kriterien wurden dahingehend formuliert, dass sowohl ausreichendes Wissen und Expertise nachgewiesen werden und dass eine ausreichende Anzahl von Personen sich für die Mitgliedschaft in einer Ethikkommission qualifizieren.
Die Ergebnisse dieser Untersuchung können als Ansatzpunkt für weitere Diskussionen über Selektionskriterien für Mitglieder von Ethikkommissionen dienen, sowohl in den Niederlanden als auch in anderen Ländern, in denen Ethikkommissionen eingesetzt werden oder eingesetzt werden sollen.

Keywords: animal experiments, animal welfare, assessment, ethics committees, composition

1 Introduction

Animal experimentation is no longer an integral part of biomedical research per se. Growing public concern about animal welfare has led to regulations on the use of animals for experimental and other scientific purposes. Both the European Union (Anon., 1986) and the Council of Europe (Anon., 1991) have made provision for the regulation of the use of animals.

Under the terms of the European Directive, Member States may require prior authorisation of animal experiments. The Directive is currently being revised. The European Commission has stated that the current Directive lacks provision for, among other things, a mandatory ethical review process or the compulsory advance authorisation of experiments. Technical Expert Working Groups have advised the Commission on aspects of the proposed revision of the Directive. The Technical Expert Working Sub-Group on ethical review (Anon., 2003) concluded that ethical review should be a key component of the humane use of animals for experimental and other scientific purposes. In addition, it advised that some elements of ethical review are best pursued at the local establishment level. Moreover, it was considered important that ethical review should involve individuals with an awareness of the ethical, animal welfare and scientific issues that are part of ethical review. It is expected that an ethical review process will be made mandatory by EU regulations in the near future.

Some countries have already established ethics committees or processes whose permission is required before animal experiments are begun. Since 1997,

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the Dutch Act on Animal Experimentation (Anon., 1997) has required the compulsory evaluation of each research protocol involving animals by an Animal Experiments Committee (AEC). Only when the AEC has given a positive recommendation to the institute's license holder may the researcher proceed with the animal use.

According to the latest statistics (Anon., 2004) 26 AEC's are registered in the Netherlands. Most large institutions have their own AEC. Smaller institutions either share an AEC or make use of the AEC of a larger institution. A national Central Animal Experiments Committee is responsible for considering exemptions to provisions laid down in the Act, it approves the AEC's, and acts as a board of appeals for proposals that receive a negative recommendation at local level.

According to the Dutch law, the AEC should consider the qualifications of the persons that design and perform the experiments and those responsible for the care of animals. Furthermore, the AEC may only recommend in favour of an experiment when no suitable methods are available as alternatives to the animal experiment. Also, when other means of meeting the objectives are available which require fewer animals or entail less suffering than the experiment in question, these must be applied. Importantly, but arguably more difficult to establish, it must be satisfied that the information gained from the experiment justifies the suffering caused to the animals.

At least seven members participate in each Dutch AEC. At least three members, including the chairperson, may not be employed by the organisation which the AEC advises. At least two members may not be directly involved in animal experimentation. The animal welfare officer participates in each meeting as an advisor to the AEC. To facilitate balanced advice by the AEC, the Dutch Act requires that the AEC possesses four areas of expertise: "they comprise in equal numbers experts in the field of animal experiments, experts in the field of alternative methods, experts in the field of animal welfare and protection and experts in the field of ethical assessment". Despite an earlier attempt by the Central Animal Experiments Committee to define criteria for the selection of these four expert competences in the AEC, the selection criteria have not been formalised in the Act or in an Order of Council. In practice, the relevant inspectorate, the Food and Consumer Product Safety Authority (VWA), approves the composition of each AEC but does not judge the qualifications of each of the four experts against published criteria. Some suggest this may imply that some AEC members are not sufficiently qualified.

A study was performed aimed at developing eligibility or selection criteria for each of the experts in an AEC, such that it would require sufficient knowledge and experience and, at the same time, would ensure that enough persons in the Netherlands would be eligible for a position on an AEC. Objective criteria are desirable to assist selecting the right persons with the appropriate expertise and background.

Although the study was performed in the context of the Dutch situation, other countries that may have AEC's with no defined means of selecting experts or that may be preparing to establish AEC's may benefit from it. This paper may serve as guidance in further discussions on the composition of the AEC, whether institutional, local, regional or national.

2 Methods

A literature search on the four expert areas of the AEC's was carried out. Based on the information obtained, questionnaires were devised and sent to persons identified as experts in one or more of the areas (respondents). The questionnaire was meant to establish a first inventory of opinions of the respondents and comprised the following questions: what is the task of the specific expertise, what qualifications (education, experience) should apply for an expert. Based on the results, the respondents were then interviewed in an open way to harmonise the selection criteria for each expertise. The emerging criteria were returned to the experts for evaluation. Adjustments were made to ensure that consensus was reached and a sufficient number of eligible candidates would be available for expert positions on AEC's.

Six persons were contacted for each of the four expert areas. Each of them have previously participated, or currently participate, in an AEC. Each respondent is regarded as an expert in his or her field. Respondents for the ethics expertise were experienced ethicists in biomedical sciences. Respondents for alternatives to animal experimentation were persons related to organisations on alternatives or who develop alternatives. Respondents for experimental animals and their protection were composed of animal welfare officers, biotechnicians and veterinarians. The group of respondents for "animal experiments" was composed of animal welfare officers and scientists performing animal experiments. All had relevant experience as members on one or more animal ethics committees and should therefore be able to develop criteria for their respective expertise.

Tab. 1: Requirements for the field of ethics

Persons have verifiable qualities and experience to make the ethical judgment in a broad societal context possible. Qualified persons:	
A)	- have a university degree with a master in ethics that covered at least bio-ethics and research philosophy; *or:* - have a biomedical university degree and have a demonstrable established interest (e.g. through publications) in bio-ethics;
And:	
B)	have participated in ethical review committees (AEC, medical ethics committee) and/or have actively participated in relevant discussions (public debates).
In certain instances also the following persons could qualify:	
C)	- persons with completed masters degrees in ethics, *and/or:* - philosophers/theologists;

3 Results and discussion

Below, criteria are proposed, based on the answers given by the respondents, for each of the four areas of expertise required for Dutch AEC's. These should provide a sufficiently large pool of experts with sufficient knowledge and experience to complete AECs and to provide a balanced assessment of proposed animal experiments.

3.1 Proposed expert profiles

3.1.1 Ethics

According to the respondents the main task of the ethicist is to assist the AEC to reach consensus in discussions. Thus, the ethicist generally plays a practical role rather than a theoretical role. Crucial qualities for this task are objectivity and the ability to critically weigh all the arguments and concepts used in the AEC discussion in order to address and balance these in the process of reaching consensus.

Therefore, this expert would either have to have completed an ethics course that included practical components, or have practical experience in bio-ethical discussions. Ideally, this expert should possess a university degree in philosophy with a master in ethics and have a minimum of 4 years research experience in ethics with relevant publications or with relevant experience on other ethical committees.

However, it was obvious that only few people would meet these criteria, and therefore more pragmatic criteria were developed for selection of AEC members with this expertise (see Tab. 1).

A) The respondents had a preference for ethicists who have completed a master's course in ethics and have experience in applied ethics. Persons who have completed a course in a biomedical subject and a master's course in ethics would also be well equipped for the position of ethicist in the AEC.

In order not to be too restrictive, persons who have completed a biomedical education and have demonstrable interest (scientific publications) in bio-ethics could also be considered. In cases where two persons provide the ethics expertise in an AEC, at least one of them should hold a master's degree in ethics.

Tab. 2: Requirements for the field of animal experiments

Qualified persons:	
A)	have completed the course on Laboratory Animal Science and are involved in animal experimentation;
And B)	have at least 4 years of experience in designing and performing animal experiments.

B) It is regarded essential that the ethicist has practical experience of discussions in ethical committees and/or has actively participated in discussions regarding the ethical acceptance of animal experiments. Such participation should have been gained on an independent basis, not as stakeholder. Although not many candidate ethicists may meet this requirement, this could be solved by a short introductory course.

Criterion C was added to increase the number of qualified candidates, but only for a second ethicist in the AEC. Persons who only qualify for A will then get the necessary experience to qualify as full ethicist after a certain period.

3.1.2 Animal experiments

It is important to include scientists who are experienced in animal research on the committee. They have experience in designing and performing animal experiments which involves, among other things, insight into the minimal number of animals necessary to reach statistical significance, different experimental designs, and methods to minimise suffering.

It was initially proposed that a person applying for this expertise should ideally have completed the Laboratory Animal Science Course Cat. C (FELASA, 1995; van der Valk and van Zutphen, 2004; Wilson et al., 1995), be an animal welfare officer or have completed the master's course on Laboratory Animal Science (Nevalainen et al., 1999), and have 5 years experience in the design and performance of animal experiments.

Again, only few people would qualify using these stringent criteria. Therefore, more pragmatic criteria were developed (see Tab. 2).

According to the respondents, the main task of the expert on animal experiments is to judge whether the protocol for using experimental animals is well prepared. The experimental design and the selection of the animal model and experimental techniques should be taken into consideration in the deliberations of AEC's.

A) Having completed the course on Laboratory Animal Science according to the FELASA guidelines (FELASA, 1995) and being involved in animal experimentation qualifies for this expertise. These persons should have sufficient knowledge of experimental techniques, animal models, experimental design, statistics and animal physiology.

B) The minimum experience that is required is 4 years in both the design and performance of animal experiments.

Some respondents also indicated that biotechnicians (Nevalainen et al., 2000) could qualify for this position. However since they generally have no experience in the design of animal experiments, they would not meet the criteria.

3.1.3 Alternatives to animal experimentation

There is a significant societal demand to minimise animal experimentation. In addition, implementation of the 3Rs principle generally leads to scientifically improved research models. Therefore, the AEC should have experts as members who are able to evaluate whether 3Rs alternatives have been considered sufficiently in the proposed experiment.

Ideally, experts on alternatives (3Rs models) 1) should have completed the Laboratory Animal Science Course; 2) have at least 5 years of experience with all 3Rs, replacement, reduction and refinement, and be involved in at least one of the 3Rs areas at the time of AEC employment; 3) have been involved in validation and implementation activities; and 4) have experience on 3Rs committees.

The ideal criteria would drastically limit the number of available experts, so

the following list with minimal requirements was developed (see Tab. 3).

The main task of an expert on alternatives is defined as: "assessing for each protocol whether there are possibilities to replace or reduce the animal experiment, and whether the applicants have satisfactorily investigated 3Rs possibilities and have explained adequately why no 3R model could be applied".

Refinement was excluded from this profile, since this particular competence is covered by the experts on "experimental animals and their protection". Therefore, the expert on alternatives should have sufficient knowledge of replacement and reduction models and techniques. Persons qualifying for this expertise should have practical experience in alternatives and be aware of their potentials and limitations. In addition, they should have knowledge of developments outside their field of research that could contribute to replacing or reducing animal experiments. As a result, criterion B was included.

3.1.4 Experimental animals and their protection

This proved the most difficult expertise to assess. It is unclear from the title, given by Dutch legislation, whether the animals themselves or whether their welfare should be protected. From earlier communications with the Dutch Inspectorate, one could conclude that this expertise should focus on the welfare of the animals. Since none of the other experts in the AEC covers housing conditions, husbandry, analgesia, anaesthesia and euthanasia, this expertise should cover all of these items. In general, these experts should safeguard the refinement possibilities of each animal experiment. The most knowledgeable person in this capacity is the animal welfare officer. Therefore, in the most ideal situation, an animal welfare officer, who has at least 5 years of experience in animal experimentation and has verifiable achievements through publications in the area of experimental animal welfare, would be the most suitable person. One of the main tasks of this expert is to assess whether the proposed research protocol applies every possible means to minimise animal suffering. Respondents felt that this expert should have some knowledge of the following topics: animal welfare, animal suffering (stress, pain), biology of the different species, humane endpoints, pathology, pathophysiology, anaesthesiology, ethology, analgesia, legislation and biotechnology.

Only few people in the Netherlands have complete knowledge of all the topics mentioned above. For instance, very few persons have knowledge of humane endpoints for the different experimental animals.

A profile was developed in which the required knowledge and the number of persons available to cover this expertise were balanced (see Tab. 4).

The required knowledge and experience may be gained by several means, thus a university degree is not specifically required.

Animal welfare officers would be the ideal persons for this expertise. Their training (Nevalainen et al., 1999) is specifically aimed at developing knowledge in the areas covered by the "Experimental animals and their protection" profile.

Biotechnicians are the persons that work with the experimental animals on a daily basis and are responsible for their care. They are expected to have sufficient knowledge of humane endpoints, welfare and suffering of experimental animals.

Ethologists have expertise on animal behaviour, but this should not be restricted to only one or few animal species.

Veterinarians may be valuable contributors to the AEC's discussions because of their knowledge of the physiology and health of the animals.

Pathophysiologists with expertise in the area of (patho-)physiology of pain may offer advice on effective and efficient ways to relieve pain in animals, while animal physiologists focus on animal behaviour and stress. Such experts could offer an important contribution to an AEC, however their areas of interest might be too limited to be of value to very specific AEC's.

The respondents concluded that the title "Experimental animals and their protection" for this expertise is misleading and should be changed to "Experimental animals and welfare".

Tab. 3: Requirements for the field of alternatives to animal experimentation

Qualified persons:	
A)	have at least 4 demonstrable years of experience with replacement and/or reduction of animal experiments and are working in this area at the time of appointment, verifiable by: • research in the development, validation and application of 3Rs models; *or* • relevant publications in peer-reviewed journals.
And	
B)	have gained experience and knowledge on alternatives to animal experiments in other ways, for instance by having participated in organisations or commissions in this area (e.g. NCA, Dutch Platform on Alternatives).

Tab. 4: Requirements for the field of experimental animals and their protection

Qualified persons:	
A)	are employed as one of the following - Animal welfare officer - Biotechnician - Ethologist - Veterinarian - Pathophysiologist/ animal physiologist
And	
B)	have been involved in animal experimentation for at least 4 years prior to the AEC assignment;
And	
C)	have demonstrable activities in the area of (the protection of) the welfare of (experimental) animals, e.g. by relevant publications in peer-reviewed journals.

3.2 Laypersons and animal protectionists

AEC's were established as a result of public awareness with respect to animal experimentation. The AEC is one of the main warrants that only such animal experiments are performed that are considered necessary. AEC's are the result of the "No, unless…. principle", accepted by many countries. In Europe, 13 European countries have implemented a legal provision for a national AEC. In 9 countries, legislation provides for local or regional animal ethics committees (van Zutphen, 2004). Since the AEC focuses not only on interests of the animals, but also on those of scientists and the community, the composition of an AEC is extremely important. Several countries in Europe now require by law an approval of an AEC before animal experiments can commence.

It appears that there are several differences between countries regarding the composition of AEC's. In most countries scientists can be members of the committee. With respect to representatives of animal protection organisations or lay members, the situation differs from country to country.

For some countries, input from the community is essential for the decision-making in an AEC, since social values are involved. It is argued that, in addition to lay members, members from the community who are deeply concerned about animal welfare and organised in animal protection organisations should also be part of the AEC (Orlans, 1997). When considering participation of lay members, in particular representatives of animal protection societies, careful consideration should be given to the role these persons could and should play on an AEC. According to Orlans (Orlans, 1993), the last group could stimulate the ethical discussion. In the Dutch situation, where ethicists are members of the AEC, this part is covered by these experts. On the other hand, discussions in the AEC could also be hampered by the lack of knowledge and experience of laypersons with regard to research and its objectives.

The respondents to this study regarded representatives from animal protection organisations inappropriate for participation in an AEC, since they generally have limited or no knowledge of the physiology and behaviour of animals, which is regarded a very important aspect for the expertise. Furthermore, representatives from animal protection organisations generally act based on their ideology rather than on scientific knowledge. Nevertheless, representatives from these organisations can be admitted to the AEC as laypersons. They may have relevant contributions with regard to the protection of animals and may make an important contribution to the ethical discussions. Their input could balance that of the researchers on the AEC. But, also, representatives of animal protection societies in the Netherlands do not wish to participate in committees that may approve animal experimentation.

Some countries' AEC's have veterinarians among their members. In the Netherlands, the animal welfare officers, most of whom are veterinarians, offer advice to the AEC, participate in each AEC meeting and have an important contribution to, in particular, animal welfare aspects.

3.3 General aspects with regard to AEC members

The role of AEC's depends heavily on the research that is performed in the institute(s) they advise. Regulatory-based protocol tests require a different assessment than animal experiments in basic research. Therefore, the respondents suggested that, in addition to the qualifications described above, it is also important to consider the background of each AEC member with respect to the particular type of experiments being performed in the respective institute. This is particularly important for the expertise on "Alternatives to animal experimentation" and "Experimental animals and their protection".

AEC members need to have up-to-date knowledge to ensure that their contributions to the discussions are relevant. Therefore, for each expertise, terms with respect to experience have been included. Each of the participants is responsible for updating their own relevant knowledge even after they have left a particular working area (see also the next part on continued professional development).

During the interviews with the respondents, interesting aspects were brought forward with respect to the general qualities of each individual AEC member. In addition to the specific qualities for each expertise, each AEC member should possess the following qualifications:

- be able to look beyond his or her own field of interest;
- possess good social skills;
- act without personal interest, i.e. be objective and independent;
- have specific interest in animal experimentation;
- be unbiased;
- be dedicated;
- be able to express his or her specific expertise in the discussions.

The professional background is only one important consideration for AEC members. To ensure that a final and balanced decision of the AEC can be reached, it is important to have members that are competent and independent, hold informed discussion, are prepared to listen to each other and respect each other's opinions (De Cock Buning, 1997).

Continued professional development is important, especially in the area of ethics and communication (Johnston and Rusche, 1997). In the current study, both continuing education on each expertise as well as on more general aspects as ethics and discussion techniques are suggested to improve the standards of the AEC. In the Netherlands, annual refresher courses are organised for AEC members. These courses involve topics that are relevant to all AEC members, such as statistics, alternatives, ethics, legislation, discussion techniques, and importance of consensus, etc., and therefore do not only focus on particular topics, but also train the participants in the ethical decision-making.

Unfortunately, participation in these courses is still voluntary. According to the respondents, these courses should be made compulsory. Continuing professional development can be offered as symposia, courses or workshops. It should be focussed on the practical aspects of the AEC and be offered at least once a year. In addition, it is recommended that specific courses for each ex-

pertise be organised in order to update experts on specific developments that could be important for the decision-making process in the AEC.

4 Conclusions

This report proposes criteria for selection of the various experts that are required by law to participate in the Dutch AEC's and should result in AEC's that are well equipped to assess animal experiments proposals according to the societal demands. Although in other countries laypersons or representatives from animal protection societies can or should participate in any AEC, it is regarded as not essential for the Dutch situation. In addition to the knowledge and expertise required of each expert on appointment to an AEC, continuing education is regarded essential for continued balanced, consensus-driven discussions in the AEC's. A compulsory course is proposed on topics relevant to all experts in an AEC, as well as another focused on each specific expertise.

This report is primarily focussed on the Dutch situation where local AEC's are established. In many countries the establishment of some form of assessment of animal experiments is considered. This report may stimulate discussions on the composition of AEC's in those situations. It may help to select suitable persons for vacancies and could be the basis for further discussion on the composition of the AEC in relation to the decision-making process.

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