



# A Survey Concerning the Work of Ethics Committees and Licensing Authorities for Animal Experiments in Germany

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## Summary

*In 2006, the German Animal Welfare Federation started its 3rd survey since the establishment of ethics committees for animal experiments according to the German Animal Welfare Act in Germany in 1987. As animal welfare has been included as a "state goal" in the German constitution in 2002, the present survey aimed at an analysis of specific changes within the licensing process. A series of other aspects of the work of ethics committees and licensing authorities was also examined.*

*The survey was based on questionnaires that had been addressed to licensing authorities and members of ethics committees. One of the main results is that the importance of animal welfare within the licensing process, after inclusion of animal welfare into the German constitution, has not changed or changed only to a small extent. It also becomes clear that ethical parameters are still of minor importance when animal experiments are licensed. The findings underline the importance to reform the German authorisation system for animal experiments. The pending revision of EU-Directive 86/609 is an opportunity which should not be missed in this context.*

**Zusammenfassung:** Eine Umfrage zur Tätigkeit der beratenden Kommissionen und Genehmigungsbehörden für Tierversuche in Deutschland

*2006 führte der Deutsche Tierschutzbund seine dritte Umfrage seit der im Jahre 1987 erfolgten Einführung der beratenden Kommissionen gemäß Tierschutzgesetz durch. Nach der Aufnahme des Staatsziels Tierschutz in die Deutsche Verfassung 2002 zielte die vorliegende Umfrage auf eine Analyse möglicher Veränderungen im Genehmigungsverfahren für Tierversuche ab. Eine Reihe anderer Gesichtspunkte der Tätigkeit von Genehmigungsbehörden und beratenden Kommissionen wurde ebenfalls untersucht.*

*Die Umfrage basierte auf Fragebögen, welche an Genehmigungsbehörden und Mitglieder von beratenden Kommissionen gerichtet waren. Eines der wesentlichen Ergebnisse besteht darin, dass sich die Bedeutung des Tierschutzes nach Aufnahme des Staatsziels Tierschutz nicht oder nur unwesentlich verändert hat. Ebenso deutlich wurde, dass ethische Gesichtspunkte weiterhin nur bedingt bei der Genehmigung von Tierversuchen Berücksichtigung finden. Die Ergebnisse unterstreichen die Notwendigkeit, das Genehmigungsverfahren für Tierversuche in Deutschland einer Reform zu unterziehen. Die anstehende Revision der EU-Richtlinie 86/609 ist eine Gelegenheit hierfür, die nicht versäumt werden darf.*

**Keywords:** animal welfare legislation, animal experiments, ethical evaluation, ethics committee, Directive 86/609/EEC

## 1 Introduction

### 1.1 Legal background for the authorisation of animal experiments in Germany

In Germany, since an amendment of the Animal Welfare Act in 1986, experiments on vertebrate animals require prior authorisation by regional licensing authorities. However, experiments carried out to fulfill legal requirements in Germany or the European Union are not included – they must merely be announced to the authority (Bundestag, 1998).

The licensing authorities' task is to examine the applications for permission

they receive particularly with regard to indispensability and ethical justifiability of the experiments. They must also check whether the institution in which the experiments are to be carried out or the qualification of those performing the experiments meet the legal requirements as laid down in the Animal Welfare Act.

According to § 15 of the Animal Welfare Act the licensing authorities appoint one or more advisory committees<sup>1</sup> to support them in their decision-finding process. These committees normally

consist of six members, and there is a deputy for each of them. With regard to their qualification, the law demands that the majority of the members, i.e. normally four persons, must possess a university degree in veterinary medicine, medicine or natural sciences. One third of the members, i.e. normally two persons, must be chosen from a list of candidates that has been compiled by defined animal welfare organisations.<sup>2</sup>

All tasks and duties of these ethics committees are precisely defined in a

<sup>1</sup> For easier reading, in the following these advisory committees are called "ethics committees" even though this is not the correct official term.

<sup>2</sup> Further, in this article these two different factions within ethics committees are simplified by the terms "animal welfare representatives" and "researchers".

regulation (Bundesministerium der Justiz, 2000). The committees must respond to an application within four weeks, and specifically have to declare whether the proposed experiment is indispensable according to the state-of-the-art, whether it is ethically justifiable, and whether it is of utmost importance if it involves significant suffering and distress.

It is, however, solely in the authorities' competence to decide whether the conditions for licensing an animal experiment are met or not. The opinion/recommendation of its ethics committee is not binding.

## 1.2 Legal situation before and after the inclusion of animal welfare into the German Constitution in August 2002

The legal basis for the licensing of animal experiments as laid down in the German Animal Welfare Act was counteracted by the fact that – contrary to animal protection – freedom of research was a constitutional right, such as arts, religion, or education (Caspar and Schroeter, 2003.) According to court decisions that freedom could not be constricted by animal welfare legislation, in its decision of 1994, the German Federal Constitutional Court laid down that a licensing authority was not entitled to make its own conclusions about the ethical justifiability of applications for animal experiments. Instead it had to accept the applicant's reasoning, as long as this was coherent, and as long as no formal reasons stood against it (Kolar, 2005).

This decision had concrete consequences for the practice of licensing of animal experimentation in Germany. For instance, after that decision, the local competent authority of Berlin was officially advised to restrict its examination of applications for animal experiments to formal criteria.

This practice contradicted basic provisions of the German Animal Welfare Act, and of Council Directive 86/609/EEC for the Protection of Animals Used for Experimental and other Scientific Purposes (Anon 1986), that Germany had to imple-

ment and enforce, being a Member of the European Union. In its Article 12, the Directive explicitly states that "the authority shall take appropriate judicial or administrative action if it is not satisfied that the experiment is of sufficient importance for meeting the essential needs of man or animal". This provision clearly implies that the authority is expected to make its own assessment of the ethical justifiability of a proposed animal experiment.

After a long and vivid public debate, the German Constitution was amended in 2002 to give more weight to animal welfare. The amendment concerned its Article 20a, which before 2002 read: "The state takes responsibility for protecting the natural foundations of life in the interests of future generations." The legal interpretation of this article had been that "life" was to mean "human life"; therefore animals were not addressed within this article before 2002. The amendment of Article 20a basically consisted in adding the words "and animals" to the clause, which now reads:

*"Mindful also of its responsibility toward future generations, the state shall protect the natural bases of life and animals by legislation and, in accordance with law and justice, by executive and judicial action, all within the framework of the constitutional order."*

The legal interpretations of this amendment generally concluded that it provides a legal basis for weighing animal protection measures against human interests in matters such as research and teaching (see for example Caspar and Schroeter, 2003).

This was reflected in the legal practice: In 2003 the University of Marburg filed a lawsuit against the local competent authority's decision not to grant licenses for experiments on rats in the context of drug-induced pathophysiology of weight regulation. The Administrative Court of the City of Giessen rejected the University's lawsuit, and reasoned that after a reference to animal welfare had been inserted into the Constitution, the local authorities had the right and the duty to perform their own ethical evaluation. The

court also made clear that the authorities had the duty to reject applications if provisions of the Animal Welfare Act (they referred to indispensability and ethical justification) were not met.

## 1.3 Previous surveys of the German Animal Welfare Federation on the practice of licensing animal experiments in Germany

The German Animal Welfare Federation's interest in the process of licensing of animal experiments has a long history. As early as 1988, when, after an amendment of the Animal Welfare Act, ethics committees had been established for the first time, it undertook a survey among members of these committees that focussed on general parameters within the licensing process. In 1995, 17 years after establishment of the present licensing system and 5 years after the German unification, the second survey was carried out. The aim was to update the information gathered in 1988, and to investigate specific developments after the reunification (Rusche, 1997; Gruber and Kolar, 1997).

## 1.4 Set-up of the survey of 2006

The present survey was the most comprehensive to date. Contrary to the previous surveys, licensing authorities were also addressed. The main questions behind this survey were:

- Has the work of the authorities and the committees changed since the last survey?
- Has the increased legal value of animal welfare penetrated the work of ethics committees and licensing authorities?
- What are the main issues and problems with regard to the task to deliver an ethical evaluation of proposed animal experiments?
- Which suggestions for improvement are given by those individuals that are personally involved in the licensing process?

Two questionnaires were developed<sup>3</sup> – one of them aiming at the licensing authorities and the other aiming at ethics

<sup>3</sup> Questionnaires were developed in co-operation with Norbert Alzmann as part of his Ph.D. thesis within the postgraduate programme "Bioethics" at the Interdepartmental Centre for Ethics in the Sciences and Humanities (IZEW) at the University of Tübingen.



committee members. To reduce the workload for responding, answers to questions were given in a multiple-choice format. However, for any question a possibility was also given to provide different answers and/or comments. For many questions multiple answers were permitted.

The timeframe investigated ranged from 2003 to 2005. All questions underwent prior judicial examination to ensure that no confidential information was requested and that confidentiality agreements of both authorities and ethics committee members were not infringed upon.

#### 1.4.1 Survey among licensing authorities

As mentioned before, previous surveys had not included licensing authorities. This time they were included in order to receive hard data on the – possibly altered – number/ratio of refused applications after inclusion of animal welfare into the German constitution, and in order to receive first-hand information on potential changes in the authorities' work.

In Germany, 29 licensing authorities exist over the 16 federal states. All were sent questionnaires, and follow-up calls were made in those cases where answers were not received in the specified timeframes.

#### 1.4.2 Survey among ethics committee members

Each authority is assisted by one or more ethical committees. The number of ethics committee members in Germany is therefore 174 at minimum, and there is the same number of deputies. Most authorities keep the names of ethics committee members confidential<sup>4</sup>, so that most of these individuals could not be addressed directly within this survey. Therefore all licensing authorities were sent questionnaires and asked to forward these to their ethics committee members and their deputies. However, the names of 34 members of ethics committees that had been proposed by animal welfare organisations (see 1.1), were known to the German Animal Welfare Federation and these individuals were addressed directly.

## 2 Results of the survey<sup>2</sup>

### 2.1 Feed-back by licensing authorities

In total, 16 completed questionnaires were returned. Both the Bavarian State Ministry for the Environment, Health and Consumer Protection and the Hessian Ministry for the Environment, Agriculture and Consumer Protection filled in questionnaires on behalf of the four respectively three licensing authorities under their control<sup>6</sup>. Thus, for 21 of all 29 licensing authorities information was received. Seven authorities did not respond to the survey despite repeated enquiries. The Federal State of Thüringen (where the only licensing authority in this state is located) answered by sending an animal welfare report; however, only few questions could be answered by analysing it.

### 2.2 Feed-back by ethics committee members

In total 52 ethics committee members returned a completed questionnaire. Out of these, 37 were regular members, and 14 were deputies. 35 replies (70%) came

from animal welfare representatives, 15 (30%) from researchers.

### 2.3. Information on the general licensing procedure

#### 2.3.1 Number of applications to deal with

The licensing authorities were asked how many applications for licensing they received.

Between 2003 and 2005 in 17 licensing authorities 3.792 applications were processed, and the number of applications grew from year to year within this period (Fig. 1).

#### 2.3.2 Rejection of applications

The licensing authorities were asked how many applications for licensing were approved, and how many were rejected or later withdrawn by the applicant.

It is rare that a license for an animal experiment is not granted in Germany: 95.8 of all submitted applications were directly approved by the authorities, 1.3% were rejected. The remaining 2.9% of applications were withdrawn by the applicants after further enquiries by the authorities<sup>7</sup> (Fig. 2).

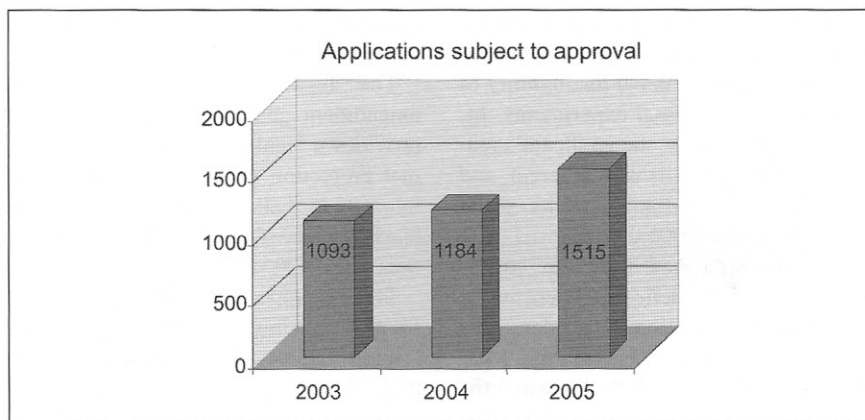


Fig. 1: Number of applications subject to approval between 2003 and 2005 (data from 17 licensing authorities)

<sup>4</sup> There is no legal obligation for the authorities to keep the names of ethics committee members confidential. In fact, in the past some authorities have even published these names in the press.

<sup>5</sup> When interpreting the following results one should bear in mind that multiple answers were possible for many questions, and that some questions were not answered by the respondents.

<sup>6</sup> Therefore, it cannot be excluded that some overall answers were given by the ministries that do not reveal peculiarities in individual licensing authorities under their control.

<sup>7</sup> In 32% of all applications the authority made further enquiries that in most cases concerned the degree of suffering and distress (8 out of 15 answers), the indispensability of the procedure (6 out of 15 answers), and ethical justifiability (5 out of 15 answers). In fewer cases questions concerned the study design (4 out of 15 answers), animal numbers and statistical concept (4 out of 15 answers) or use of analgesics (3 out of 15 answers).

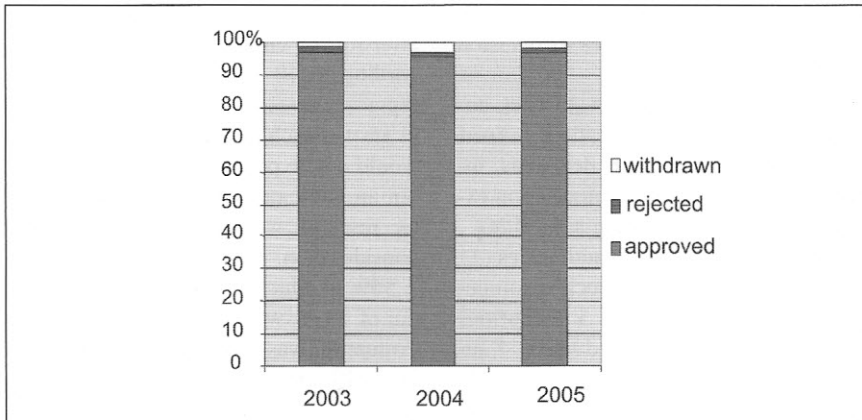


Fig. 2: Percentage of approved/rejected applications between 2003 and 2005

The authorities gave the following reasons why applications were rejected:

- lacking ethical justifiability of experiments (9 out of 14 answers)
- insufficient scientific concept (8 out of 14 answers)
- severe suffering of animals to be expected (6 out of 14 answers)
- study design incomprehensible (4 out of 14 answers)

In single cases (1 answer received for each), the following reasons were mentioned:

- availability of alternative methods not taken into account
- lacking literature references
- statistics incomprehensible

### 2.3.3 Workload of ethics committees

The licensing authorities were asked how often their ethics committees meet, and how many applications they have to deal with per meeting.

Meeting intervals differ significantly: More than two thirds of ethics committees met regularly every 2 to 4 weeks (9 out of 19 answers) or 5 to 8 weeks (6 out of 19 answers). Only 3 committees met less often than once every 8 weeks. One committee only meets 2 to 4 times per year. (Fig. 3)

The number of applications to be examined in a meeting of an ethics com-

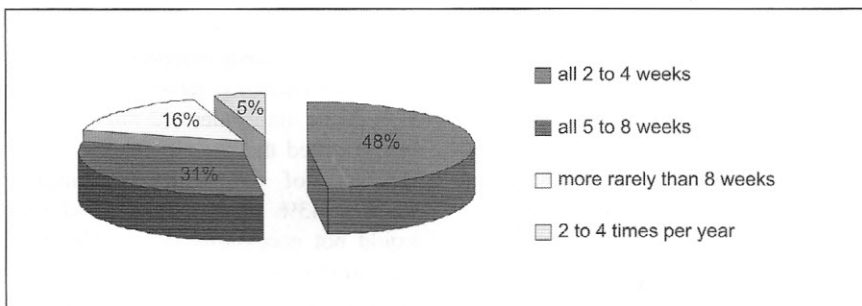


Fig. 3: Meeting intervals of ethics committees

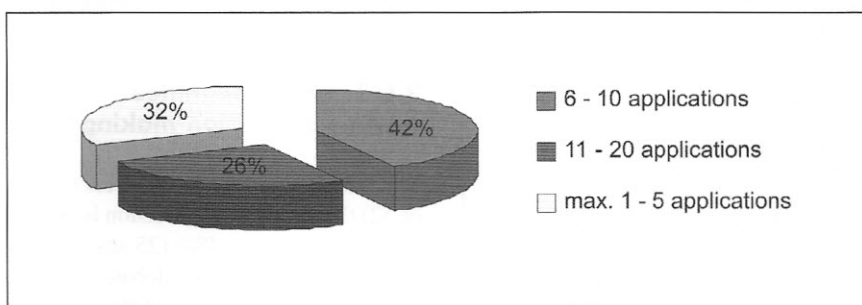


Fig. 4: Number of applications per meeting of ethics committees

mittee also varies significantly. Per meeting, in 8 committees (of a total of 19 answers) 6 to 10 applications were examined, and in 5 committees 11 to 20 applications. In 6 committees 1 to 5 applications were examined per meeting. (Fig. 4)

## 2.4 The significance of having included animal welfare into the German Constitution

Authorities and ethics committees were asked whether the inclusion of animal welfare into the German Constitution has resulted in changes in their work.

### 2.4.1 The significance of having included animal welfare into the German Constitution from the point of view of licensing authorities

Half of the authorities (10 out of 20 answers) stated that the inclusion of animal welfare into the German Constitution had not resulted in any changes in their work. The same number of answers was received for each of the two contrary explanations of this, one being that no change could be expected because neither the German Animal Welfare Act nor the respective ordinance had been amended, the other being that even before the constitutional change a high standard for the ethical evaluation had existed.

However, 4 authorities stated that their work in fact had changed because the state goal "animal welfare" affected the ethical evaluation that would have to be taken into account even without a change of the Animal Welfare Act or the respective ordinance.

In one authority the changed legal situation had resulted in a change of the way the indispensability of an experiment was evaluated. In another authority ethicists were more involved. Another authority stated it tried to perform a "more rigid" evaluation process that, however, would require specific court decisions because law experts had different opinions on the implications of having animal welfare in the Constitution. 6 authorities had no clear position on this matter.



### 2.4.2 The significance of having included animal welfare into the German Constitution from the point of view of ethics committee members

32 ethics committee members (61%) stated that their work had not changed after the inclusion of animal welfare into the Constitution. The reason given most often (17 answers) was that already before, the ethical evaluation had been carried out seriously. 13 answers indicated that the ethical evaluation and the examination of the indispensability were still not satisfactory. In contrast, 13 answers (25%) indicated that the work had changed in particular regarding the ethical evaluation (11 out of 13 answers) and the examination of the indispensability (8 out of 13 answers). (Fig. 5)

## 2.5. Ethical evaluation

Authorities and ethics committees were asked how they reached their decision about the ethical justifiability of a proposed experiment and which specific competence in ethics they resorted to (e.g. whether colleagues had a degree in bioethics, philosophy or theology or other types of education in ethics such as interdisciplinary seminars).

### 2.5.1 Licensing authorities' approaches to ethical evaluation

19 out of 20 authorities reported that they would always stick to the ethical evaluation of their ethics committee. More than half (11 answers) stated they would also

perform their own ethical evaluation. One authority stated it bases its decision on its own evaluation only.

To perform the ethical evaluation, authorities resorted to publications, expert reports, pain scales, court decisions, internet searches as well as information exchange with other licensing authorities.

About two thirds of the authorities (11 out of 17 answers) had specific competence in ethics available. 5 authorities used external ethicists as advisers. 4 authorities resorted to the competence in ethics of members of their ethics committees. 2 authorities stated that they had one co-worker who had further education in bioethics or philosophy. 6 authorities could not draw on any specific competence in ethics. 1 authority did not provide information on this aspect.

### 2.5.2 Ethics committees' members approaches to ethical evaluation

According to 81% of answers received (42 out of 52), ethics committee members performed their own ethical evaluation and did not rely on the statements given by the applicant. Asked how they do this, most answers (10) referred to intuition and personal moral judgement. Publications (6 answers), case studies (5 answers), self-made catalogues (3 answers) and/or external expert reports were also named in this context. 3 answers named discussions within the ethics committee as a means for ethical evaluation. Ethics committee members relied on the evaluation of the applicant

as it was or when it was comprehensible after further enquiry of the applicant according to 10 answers. Animal welfare representatives on the committees stated (1 answer each) that an ethical evaluation would not be performed, that ethics were not an issue, or that any reference to basic research would outweigh any other consideration.

54% of ethics committee members (28 out of 52 answers) stated that the ethical evaluation was provided for sufficiently. 36% (19 out of 52 answers) did not take this view. They mostly referred to insufficient education in ethics and insufficient criteria for the evaluation (14 answers each). According to 11 answers, problems existed within the decision-making process because the advice to the authority was based on a majority vote within the committee (see also 2.6.2), and therefore ethical concerns could be overruled. In 5 answers lack of time was mentioned as a reason for an insufficient ethical discourse.

## 2.6. Decision-making process

Licensing authorities were asked about the basis for their decision to grant a license or not. Ethics committee members were asked how the committees arrive at their decision.

### 2.6.1 Licensing authorities' decision-making process

57% of the authorities (12 out of 21 answers) stated they would follow the advice/vote of their ethics committee whereas 43% (9 answers) stated they would not necessarily do so. However, even in the latter cases the authority arrived at a different opinion only in 25% of applications.

One authority explicitly stated that it had to rely on the competence of its ethics committee.

### 2.6.2 Ethics committee members' decision-making process

According to 75% of the answers (39 out of 52) the committee's decision is arrived at by majority vote. 48% (25 answers) referred to consensus after debate, 23% (12 answers) stated that the different opinions including all arguments were com-

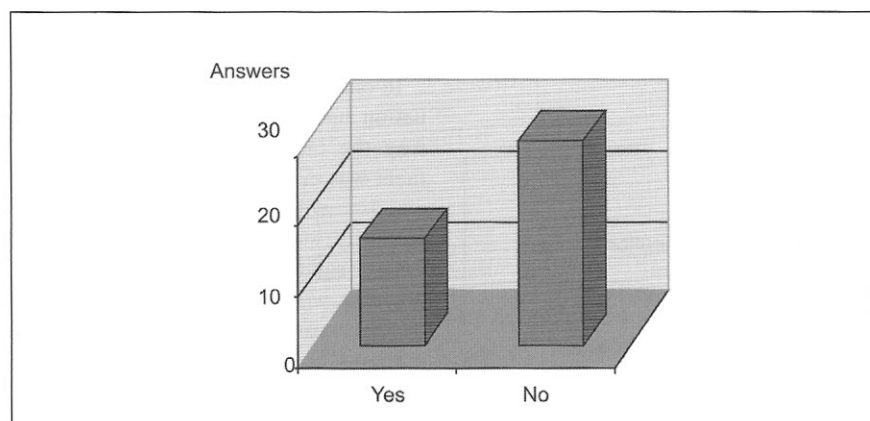


Fig. 5: Changes after inclusion of animal welfare into the German Constitution from the point of view of ethics committees' members?

municated to the authority. 11% (6 answers) named other options such as communicating the opinion of the animal welfare representatives as a minority vote to the authority. In single cases options were mentioned, such as voting after questioning the applicant, or presence of the authority and its assistance at decision-making.

Remarkably, according to 5 answers, ethics committee members vote on their own applications (Fig. 6), and according to 30 answers they vote on applications that come from the institute they work for (Fig. 7).

## 2.7 Suggestions for improvement

Authorities and ethics committees were asked for concrete suggestions to improve/support their work.

### 2.7.1 Suggestions for improvement by licensing authorities

16 licensing authorities delivered the following 24 proposals:

- Use of standard pain and distress scales (5 answers)
- Establish criteria for evaluation of ethical justifiability (4)
- Better co-operation with animal welfare officers (4)
- Regular meetings of authorities (3)
- Additional personnel (3)
- Education/Training (3)
- Strengthening of ZEBET (the German Centre for Documentation and Evalua-

tion of Alternatives to Animal Experiments) (1)

- More willingness to co-operate of animal welfare representatives (1)

### 2.7.2 Suggestions for improvement by ethics committee members

In total, 74 proposals were chosen/provided. 14 suggestions concerned changes in the legal framework:

- Equal numbers of animal welfare representatives and scientists in the committees (5 answers)
- Introduction of reports on approved animal experiments (4)
- Establishment of a list of animal experiments involving severe suffering that should not be approved (1)
- Independent animal welfare officers (1)
- Restriction of basic research (1)
- Introduction of pilot phases for new experimental setups (1)
- All animal experiments must be subject to approval (only notification is not acceptable) (1)

More general suggestions (total 60) concerned the following issues:

- Support for evaluation of ethical justifiability (11 answers)
- Making relevant literature (11 answers) available
- Education/training (11)
- Making pain and distress scales (9) available
- Making data base searches or access to data bases (8) available

- Making experts' reports (7) available
- Increased information exchange between authorities (1)
- Examination of specific aspects of applications by others (1)
- Independent chairmen (1)
- Less applications per meeting (1)

## 3 Discussion

### 3.1. Quality of the authorisation process

#### 3.1.1 Workload

Our results clearly demonstrate that the workload in many ethics committees and licensing authorities is too high. To deal with 10 or even 20 voluminous applications within one meeting, which is normally held within 2-3 hours on one evening, makes it impossible to thoroughly analyse, evaluate, and discuss these applications. A satisfactory examination of all applications is not ensured under these circumstances. It is disappointing that this grievance has been reported several times for more than a decade (Rusche, 1995; Gruber and Kolar, 1997; Kolar, 2000; Kolar, 2005) and has remained unchanged.

#### 3.1.2 Approval rate

Clearly, the background for the introduction of a system to scrutinise proposed animal experiments almost 20 years ago was to separate legitimate animal experiments from illegitimate ones (and prevent the latter). In light of the fact that

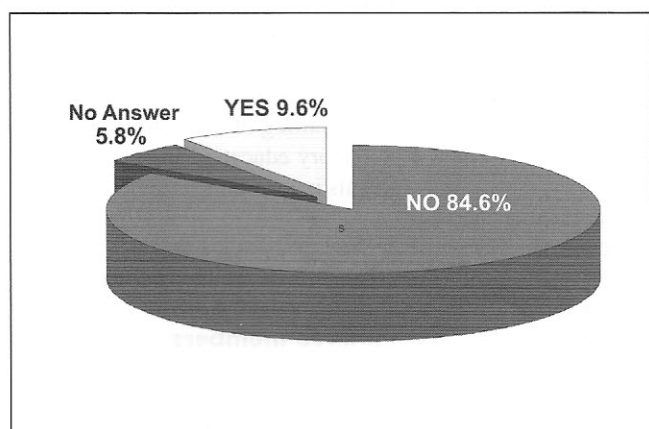


Fig. 6: Ethics committee members voting on their own applications

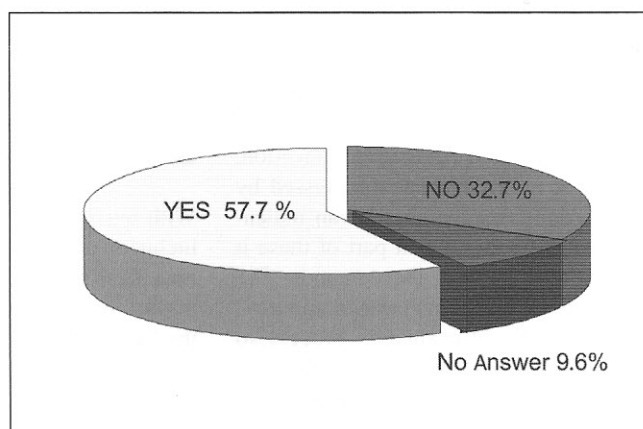


Fig. 7: Ethics committee members voting on applications from their own institute



nowadays only a negligible proportion of applications is not granted, this approach needs to be reconsidered. Even if one takes into account that possibly applicants are more aware of the conditions their applications have to meet, and that before granting a license authorities require further information by the applicant, the present system must rather be seen a formality than an ethical crossroad. Particularly when taking into account the oftentimes heard statements by politicians and other decision-makers, that a rigid system is in place that would only allow those animal experiments to be carried out that are absolutely indispensable and unavoidable, the practice of licensing animal experiments in Germany cannot meet the expectations such statements raise. Obviously, the ethical justifiability of an application is oftentimes not substantially questioned under the current authorisation process. This is also indicated by the growing number of animal experiments in Germany over the last years. Personal experiences of ethics committee members (including the ones of the author of this article), reporting approval of experiments that are highly questionable, support this finding. Further profound analysis of such cases, which seems highly desirable, is presently obstructed by the rigid confidentiality issues surrounding the approval process (see below). Nevertheless, a recent study on the outcome of a large number of approved animal experiments (Lindl et al., 2005) suggests that applicants tend to highly overestimate the importance of their research, which, however, is one of the crucial criteria to grant a licence or not.

### 3.1.3 Competence and interests of ethics committee members

The high demand for advice, education, supply of information etc. expressed by ethics committee members is an indication that for a significant part of these it is hard to cope with the demands. The main type of advice mentioned concerns the actual ethical evaluation process so that it can be concluded that more competence in ethics is needed within that process.

The fact that it is at all possible that ethics committee members evaluate their

own applications must be regarded as a scandal that probably would not be possible in any other type of official committee that has a controlling function. Moreover, if almost 60% of answers indicate that ethics committee members evaluate the applications of colleagues from their own institute, it is without doubt that a clear conflict of interest exists for many members, and the functioning of the whole system is severely jeopardised. One must ask why this is still tolerated, particularly after a previous survey in 1995 (Rusche; Gruber and Kolar, 1997) delivered similar results regarding this issue.

### 3.1.4 Ethical evaluation

In this survey, most licensing authorities acknowledged the importance of having ethics committees in place for the ethical evaluation of applications for animal experiments. This indicates that on principle ethics committees can be regarded a valuable instrument within the evaluation process. However, a number of problems were revealed in this survey. For instance, it is hard to understand and accept that some licensing authorities cannot draw on any type of professional ethical competence. And the high number of replies from ethics committee members pointing at serious deficiencies in the ethical evaluation and in the examination of the indispensability of animal experiments indicates the need to improve the system. In this context, the typical composition of ethics committees – two animal welfare representatives on the one side and four researchers on the other side, is to be critically appraised.

### 3.2 The significance of having included animal welfare into the German Constitution

With regard to the question whether the inclusion of animal welfare into the German Constitution has had a significant impact on the authorisation procedure, the feedback received was highly heterogeneous. Any conclusions therefore have to be drawn very carefully. On the one hand, there is an indication that in a number of cases an enhanced consideration of ethical justifiability and indis-

pensability now takes place. On the other hand, a significant number of ethics committee members report that the ethical evaluation continues to be unsatisfactory.

In this context it is disturbing that at least some authorities are of the opinion that no change in the authorisation procedure can be expected because the Animal Welfare Act has not changed. One has to recall that one of the main goals for the inclusion of animal welfare into the German constitution was to allow for an enforcement of the Animal Welfare Act, including a proper authorisation process (giving the authorities the competence to question contents of applications), that had been prevented by the constitutional right of freedom of research (see above).

The conclusion that in fact can be drawn from these results is that too much depends on an individual authority's or ethics committee's performance. This problem already existed before 2002 and has not changed since then. Obviously more concrete advice is needed for both licensing authorities and ethics committees to fully implement the changed legal situation.

According to Caspar and Schröter (2003), other measures to come to a more satisfactory implementation of the changed legal situation include *inter alia*:

- binding criteria for the assessment of pain and suffering, of (medical) benefit and ethical justifiability
- equal numbers of animal welfare representatives and researchers on committees
- binding advice of committees towards the authorities
- controlling function of ethics committees for experiments
- better staffing of licensing authorities
- obligatory education in ethics of individuals involved

### 3.3 Suggestions for improvement by licensing authorities and ethics committee members

Remarkably, there is a significant overlap in many suggestions made by authorities and ethics committees. These refer particularly to the need for assistance in the

difficult task of weighing animal suffering against potential benefits. This underlines the demand that has been spelled out many times long ago that Germany should introduce official standardised pain scales as they exist in many other countries. It also supports the call for more competence in ethics in ethics committees, be it by involvement of competent individuals or education and training of existing persons involved. The same is true for knowledge about/competence in alternative methods.

The fact that there is little information exchange between the 29 licensing authorities in Germany may also deliver an approach for concrete action. A system for exchange of information, be it computer-based, by meetings/conferences etc. or both would be helpful in this context.

### 3.4 Further demands by the German Animal Welfare Federation

In addition to the above, the German Animal Welfare Federation has named various measures that are needed to improve the effectiveness and acceptance of the authorisation procedure for animal experiments in Germany (Kolar, 2000; Kolar, 2005). Some of the most relevant in the context of this article include the following:

#### *Obligatory retrospective evaluation of projects that involve animal experimentation*

A retrospective ethical evaluation of licensed animal experiments is needed. This should consist of a review of the success of experiments with specific consideration of the prognosticated significance of their results. Any evaluation of follow-up applications should then be based on an analysis and discussion of the concrete results of the preceding experiments. Such type of quality control would also be helpful to identify further aspects of the licensing process that require improvement.

#### *Legal basis for objections of animal welfare organisations*

The present legal situation allows researchers (or institutions) to go to court

to question rejections of applications by the licensing authority. On the other hand, there is no legal provision in place to allow questioning the approval of an animal experiment by the authority - for ethics committees, animal welfare organisations or others. This is a problem in itself, however, with the inclusion of animal welfare into the Constitution, a balance in terms of equal legal means for both sides seems overdue (see also Caspar and Schröter, 2003).

#### *Licensing and ethical evaluation of all animal experiments*

In Germany, as well as in many other countries, not all animal experiments undergo an ethical evaluation process. For example, regulatory demanded tests, which make up about 30% of all animal experiments, do not have to be justified or evaluated by an ethics committee. The idea behind this is obviously that such experiments are regarded ethical *per se*. However, even if one regards animal tests as necessary, e.g. for the safety testing of cosmetics products or ingredients, when the marketing of these substances requires the suffering of thousands of laboratory animals, it should be indispensable to assess the justification for this suffering. No concept yet exists for an ethical scheme to address this issue in practice, but it seems clear that whenever animal testing is involved, the assessment of its justifiability would require addressing the society's need for the substance or product in question, as long as the law requires animal tests for the marketing or use of that substance or product (Kolar, 2006).

#### *A limit to the „cost“*

There is no limit to the suffering in animal experiments. No procedure is painful or unbearable enough to be excluded by legislation. There are voluntary restrictive policies, such as in Switzerland, where the Swiss Academy of Sciences has set up guidelines that include a renunciation of extremely painful animal experiments, independent of the importance of the gain of knowledge they would promise (1995). However, from an animal welfare point of view, there is the need for legal provision in this context.

#### *Transparency*

One major issue concerns the transparency of this process. Animal experiments are largely supported by public money, and in a democracy the whole ethical framework for such experiments is also set by the public and/or its representatives (Kolar, 2004). It is therefore unacceptable that information about the reality of animal experimentation is hard, if not impossible, to get for the public, and that persons involved in the licensing process have to face the threat of severe legal sanctions in case they do not keep their knowledge about the experiments they evaluate strictly confidential. This atmosphere of concealment also fosters "irrational" views on animal experiments and prevents proper information exchange that could be beneficial for both financial/scientific aspects and the application of the 3Rs (from the scale of a single research project to the national scale).

A public discourse on specific projects should become possible. This would also shift responsibility of few people (often personally involved in some aspects of this issue) to a broader audience and could lead to more democracy-based and accepted decisions. It would also lead to more equality in the conditions for animal research throughout the country.

## 4 Conclusions and outlook

Even when interpreting the results of the present survey carefully, one must conclude that the German system for authorisation of animal experiments needs to be reformed urgently. This urgency is underlined by the fact that many of the problems observed have been reported before. Another reason is that the inclusion of animal welfare into the German Constitution in 2002 has still had only a limited impact on the licensing practice, even though legal experts and court decisions have clearly indicated that since that time point stricter requirements exist for this practice.

Independent of the developments in Germany, the European Commission initiated a revision of Council Directive 86/609/EEC regarding the protection of animals used for experimental and other





scientific purposes in 2003 (Kolar and Achenbach, 2003). One of the issues addressed in this revision concerns standards for the authorisation process of animal experiments, including standards for the ethical review. In the course of its public consultation and negotiations with stakeholders, the Commission received numerous suggestions in this context. Moreover, one of the four Technical Expert Working Groups (TEWG) that the Commission had installed to deliver reports on the various aspects of the revision has produced a series of specific recommendations. At all levels of the revision process, the German Animal Welfare Federation as well as its European umbrella organisations, Eurogroup for Animals and the European Coalition to End Animal Experiments, and their other national members have pointed out the necessary steps to be taken. Hopefully the Commission will take existing problems like those in its Member States into account and the revised Directive will address them in a way that will lead to a significant change. However, it is also the responsibility of the German government to draw the right consequences when negotiating the revision on EU-level, and when it comes to the implementation of the revised Directive on national level in the future.

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