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The Hague Our reference
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Subject
Ethical paragraph in dissertations

Dear Mr Lundqvist,

I should like to draw your attention to the following:

In August I received a letter from the new organization TRAIN (Three R's Alternatives Initiating Network, a network of experts who want to reduce the use of laboratory animals) in which they ask me to encourage that promoters issue a standard request to doctoral candidates to include an ethical paragraph in dissertations in which animal experiments are described. To begin with, I would like to state that the rules relating to dissertations are your responsibility, not the government's. Nevertheless I am making an effort, which may help you form your own judgment, to tell you that I sympathize with the idea of doctoral candidates clearly explaining why they have used laboratory animals, which considerations they have made in doing so and whether sufficient attention has been devoted to the three R's (refinement, reduction and replacement).

I should like to hear from you what you think of this idea developed by TRAIN, and whether you intend to flesh out this idea in your rules relating to doctoral presentations. It would show Dutch society that universities are serious about providing clarity about the whys and wherefores of animal experiments.

Enclosed please find the memo of TRAIN in which the idea of the addition of an ethical paragraph to dissertations is elaborated further.

The Minister of Education, Culture and Science,

Maria J.A. van der Hoeven

Appendix to the letter of 17 August 2006 to Mrs Van der Hoeven, Minister of Education, Culture and Science.

ADDITION OF ETHICAL PARAGRAPH TO DISSERTATIONS**Drafted by the working group****TRAIN****Background**

The point of departure in research involving animal experiments in the Netherlands is the principle of 'responsible use of animals'. This means that laboratory animals may only be used if this is strictly necessary, i.e. if there is a demonstrable scientific and/or social interest, if this interest counterbalances the inconvenience for the animals and there are no methods available to replace the use of animals. If these conditions have been met, the number of animals used must not go beyond what is required to answer the scientific question, while the inconvenience for the animals must be restricted as much as possible.

The said principle of responsible use, which has been laid down in existing legislation pertaining to animal experiments (Animal Experiments Act [*Wet op de Dierproeven*], Council Directive 86/609/EEC), forms an important starting point for the course in animal experiments, which is a statutory obligation, and lies at the basis of the activities of the expert conducting animal experiments (art. 14 appropriate education and training) and of the Animal Experiments Committee (DEC).

The above development has contributed to a significant improvement of the wellbeing of laboratory animals and has had a positive effect on the quality of biomedical research.

The individual researcher

The role of the individual researcher is of crucial importance to the responsible use of laboratory animals. It is the researcher who determines the setup and performance of the research involving laboratory animals. By attending the course in animal experiments the aspiring researcher is prepared for the specific responsibilities connected with the setup and performance of animal experiments.

It is essential, however, that the attitude of carefulness, for which the foundation is laid during this period, should be anchored in the next phase. A suitable moment for this is the period in which research is conducted for the benefit of obtaining the PhD, the most critical phase in the researcher's (scientific) development. During this period the researchers learn to draft and test a scientific hypothesis, conduct a literature search, choose research models, plan research and process and report its results. This implies that the doctorate period often yields the blueprint for the scientific schooling of researchers for the rest of their careers. Therefore it is in this phase that the anchoring of an attitude aimed at 'responsible use of laboratory animals' will be the most effective.

Current situation

Within a doctorate research the dissertation is usually the means to account for the research conducted vis-à-vis the outside world. This is often done by placing the research within a wide social and/or scientific context, usually in the introduction or the discussion. If laboratory animals have been used for the research, the discussion of that is mostly limited to the relevant instrumental aspects. Seldom do researchers touch on the ethical aspects. This detracts from the policy claiming a central position for 'responsible use' in biomedical research.

The ethical paragraph

This memo is a plea for the inclusion of an ethical paragraph in dissertations describing research involving laboratory animals. In this ethical paragraph the researcher should discuss the arguments and considerations that have led to the final setup and performance of the research. Matters that should feature in this paragraph should include the social/scientific relevance of the research, the reasons underlying the use of animals, the motivation for and the proven suitability of the animal model or models selected, the considerations regarding the 3 R's (replacement, reduction and refinement of the use of laboratory animals), the possible leads yielded by the research with respect to the 3 R's in follow-up research or a possible 3 R spin-off to other areas of biomedical research, and so on.

The ethical paragraph should be formulated in such a way as to provide leads to exchange ideas with the opposition during the defense of the dissertation, i.e. the paragraph should not contain any clichés and commonplaces.

Proposal for procedure

An ethical paragraph in a dissertation cannot be enforced, but the idea should be supported by the persons involved. This will be possible only if those involved endorse the added value of this paragraph and acknowledge that attention to this may contribute to moral responsibility with respect to the laboratory animal, as well as to the quality of the research.

Parties directly involved are the Executive Boards of universities, promoters and doctoral candidates.

However, it is important that the Minister responsible for Higher Education should take the lead in this respect and call on promoters and doctoral candidates, via the Executive Boards of the universities, to include an ethical paragraph in every dissertation in which research involving laboratory animals is described.
