

ETHICAL GUIDELINES OF THE FINNISH SOCIETY OF TOXICOLOGY

Introduction

The Finnish Society of Toxicology has launched a professional title, the registered toxicologist. Both theoretical knowledge and working experience are required of holders of this title. Toxicologists as a group represent a wide variety of basic educations in biomedical sciences, and work in a wide variety of fields. A common denominator for toxicologists is that through their work they enhance the health and safety of humans, other living organisms and the ecosystem as a whole.

The ethical guidelines of the Finnish Society of Toxicology have been formulated as set of practical instructions to support, clarify and guide the work of the toxicologist. These guidelines are based on laws, regulations and other rules governing research and the field of toxicology.

1. Principles of scientific research

1.1. Scientific research

All research work must follow good research practice, which more specifically means that

- the study is well designed and run according to relevant laws, regulations and good scientific practice
- methods applied and test organisms used are reliable and suitable for the experiment
- the study is planned beforehand in sufficient detail (written study protocol)
- study personnel has sufficient training
- study is documented in detail and the documentation archived for a proper period of time
- research results, when published, are discussed with scientific critique, from different points of view, and by referring to the literature. All conclusions are to be based on facts. Conscious biased interpretation and presentation of research results is not to be allowed.

1.2. Scientific publications

- Original research results shall be published only once in an international journal. In this context a conference abstract is not considered an article.

- All authors shall be responsible for published material
- To assure validity, an article based on an original study must contain a detailed enough description of methods and results
- The correctness of references used in an article must be checked, and efforts should be made to refer to original findings
- Literature should be cited comprehensively to represent different points of view
- Acknowledgements may not contain names of persons who have contributed to the scientific content of the article without proper authorization

Literature:

- *Research fraud and methods to deal with it, a Finnish language recommendation published by the advisory committee on research ethics of the Ministry of Education, 1994.*
- *GLP guidelines (OECD Guidelines for the Testing of Chemicals, 1993; Annex 2, 21 CFR 50, April 1, 1994 (FDA)).*
- *International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals. BMJ, 302, 338-341, 1991.*

2. Research involving laboratory animals

Research involving laboratory animals comprises both studies on tissue or primary cell isolates from laboratory animals and studies in which laboratory animals are exposed to test compounds in vivo. This definition includes also field studies performed on non-captive wild animals.

- according to current legislation, the intended use of animals and the experimental set-up must be subjected to the appropriate laboratory animal committee for approval, and the responsible person must be qualified to perform animal studies
- the experimental set-up must be planned so that unnecessary use of laboratory animals will be avoided
- study personnel must be sufficiently trained in the handling of laboratory animals
- proper care of laboratory animals must be arranged with respect to food, drink, cages and other environmental factors
- laboratory animals must be free from such infections that may affect the course of the study

- handling of laboratory animals and studies on laboratory animals may not cause undue pain or suffering to the animals

Literature:

- *Law on animal protection 91/71, amendments 777/85, 1267/88 and 36/91.*
- *Regulation on animal protection 333/71, amendments 729/79, 1075/86 and 1136/87.*
- *Regulation on activities involving laboratory animals 1076/85.*
- *Classification of scientific animal experiments; resolution 477/86 by the veterinary medicine section of the Ministry of Agriculture and Forestry .*
- *European general agreement on the protection of vertebrate animals used for experimental and other scientific purposes. Appendices A and B, Ministry of Agriculture and Forestry , 1991 (in Finnish). The tabular part of Appendix B has been amended later, circular 413/712/93 of the veterinary medicine section of the Ministry of Agriculture and Forestry .*
- *Euthanasia of Experimental Animals, Commission of the European Union, 1993.*

3. **Research involving human subjects**

Research involving human subjects comprises both clinical (studies on diagnosis, treatment and prevention of disease) and non-clinical biomedical research. Included in this definition is also research on human embryos and germ cells.

- the study protocol must be subjected for approval to the appropriate ethics committee(s)
- the health and safety of subjects is foremost in all research
- research subjects shall give informed consent to participate in the study
- research must follow generally approved scientific principles
- before commencing studies on human subjects, sufficient knowledge, by experience and/or from the literature, must exist of experimental set-ups and of animal studies
- before commencing a study, the benefits and risks to the subjects or to others and also general benefits must be evaluated
- the person in charge of the study and other researchers must have sufficient training and expertise

- research results shall not be given to a third party without the permission of the subject (after death from the appropriate authority)
- the identity of subjects who have given study samples that are kept in a tissue bank must remain confidential when the samples are used later, or a permission to divulge the identity must be obtained from the subject (for deceased subjects from the appropriate authority)

Literature:

- *Declaration of Helsinki: Recommendations guiding physicians in biomedical research involving human subjects, Helsinki 1964, as amended in Hong Kong 1989.*
- *Ethics for the Physician, a Finnish language book published by the Finnish Medical Association, 1994.*
- *Draft Convention for the protection of Human Rights and dignity of the Human being with regard to the application of biology and medicine: Bioethics Convention, and explanatory report. Council of Europe, July 1994.*

4. Research on genetic material

Research on genetic material comprises research on humans, animals, plants and microbes. This definition includes both studying and manipulating of genetic material and the studying of acquired genetic alterations.

4.1. Research on human genes

- development and use of tests on genetic diseases or genetic susceptibility to certain diseases shall be the subject of particular concern
- interpretation of the results of the above tests, and the later use of the results, shall also be subject of particular concern
- before commencing a study the benefits and risks to the subjects or to others must be weighed
- research subjects shall give informed consent to participate in the study
- the person in charge of the study and other researchers must have sufficient training and expertise
- research results shall not be given to a third party without the permission of the subject

4.2. Other research on genetic material

In addition to the concerns laid out in chapter 4.1.,

- special attention must be paid to the hazards involved with genetic manipulation of organisms aimed at new combinations/alterations of genetic material, and to avoiding the spread of genetically manipulated organisms to the environment

Literature:

- *Ethics and Human Genetics, Council of Europe, October 5, 1993.*
- *Bioetisk debatt i Norden 1993, TemaNord, 1994:550 (Nordisk Ministerråd, Copenhagen, 1994). "Bioethical debate in the Nordic countries", a publication of the Nordic Council of Ministers.*
- *Patenting genetic engineering from the point of view of environmental protection, a Finnish language memorandum published by the Ministry of the Environment, 1994.*
- *Law on gene technology (377/95).*
- *Regulation on gene technology (821/95).*

5. The environment

Toxicologists shall always respect both the working environment and the surrounding nature. Toxicologists shall avoid harming or changing nature. Good laboratory practice, occupational health and safety standards shall be borne in mind for the benefit of oneself and for ones coworkers.

Literature:

- *Law on occupational safety 299/1958, amendment 1987/27.*
- *Law on gene technology (377/95).*
- *Prevention of VNP-work-induced cancer risk, no. 1182/92.*
- *Regulation on gene technology (821/95).*

6. Professional activities and communication

6.1. Serving as expert

The toxicologist may give statements and serve as an expert. While serving as an expert the toxicologist shall interpret existing information objectively. The person responsible for an expert opinion/statement/report is the toxicologist him/herself, not the contracting party.

6.2. Public announcements and communication

In offering, for example, his/her services to the public, the toxicologist shall keep objectively to existing facts in presenting benefits or health effects from his/her research, and shall clearly indicate possible hypotheses that have not been generally accepted in science. Public communication, such as public lectures, newspaper articles and announcements, shall be limited to presenting factual information objectively and from different points of view.

7. The general responsibility of the toxicologist

The toxicologist represents the highest level of expertise and professional skill in appraising the health effects and safe use of chemicals and other environmental factors. In all research the toxicologist shall actively enhance the health and safety of humans and minimize negative effects on the environment.

The Finnish Society of Toxicology requires that its members follow these ethical guidelines. If conflicts arise between the actions of a member and these ethical guidelines, the board shall take up the issue and may remind the member of these guidelines. If the reminder has no positive effect, the association may bring up the matter in an annual meeting for discussion and re-evaluation of membership.

The ethical guidelines are in force as of January 1, 1995.