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issues related to:

	Yes	No
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Human biological samples	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Personal data (whether identified by name or not)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Genetic information	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Animals	<input type="checkbox"/>	<input checked="" type="checkbox"/>

National Regulations on Ethics and Research in

Lithuania

Lietuvoje



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National Regulations
on Ethics and Research in

Lithuania

Lietuvoje

by
Dr. Eugenijus Gefenas
Asta Cekauskaite

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Barbara Rhode, An Baeyens and David Coles
Brussels, 2003

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Foreword

Ethical and legal regulation of biomedical research becomes an inherent part of modern science. Today, it is no longer sufficient for a researcher, who is seeking new methods of treatment and diagnostics, to employ modern equipment to prove even the most promising hypotheses. Protection of the rights and dignity of human subjects involved in research has become an important component of the research. Today in Lithuania and the majority of European states biomedical research involving human subjects can be undertaken only, if permission from a research ethics committee has been received, and where protection of the personal data of human subjects is secured and their informed consent to take part in the investigation has been received. These are only some of the requirements that have been observed by all civilised states of the world over the last few decades, with the view of preventing the practice of irresponsible research that reached its apogee in the Nazi concentration camps.

That is why in the second half of the 20th century guidelines were developed and ethic committees for international biomedical research established. The Nuremberg Code, the Helsinki Declaration, the Council of Europe's Convention on Human Rights and Biomedicine – these are only some of the significant international documents regulating protection of human rights and dignity in the field of biomedicine. It is delightful to note that Lithuania

was one of the first among the Central and East European states to adopt the Law on Biomedical Research in 2000 enforcing the provisions of the above-mentioned international documents in our country. It should be noted that ethic committees for biomedical research are already functioning in our country; their activity is co-ordinated by the Lithuanian Bioethical Committee.

The main provisions of the legal Acts (in force February, 2004) regulating biomedical research involving human subjects, as well as animals, are summarised in this publication. We think that the issue will be helpful to our researchers resolved to participate both in national and international projects and carry out a research activity acceptable from the point of view of ethics. Such activity is a prerequisite to be eligible for a financial support of the institutions of the European Union.

A large, stylized handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

*Mr. Algirdas Mockevicius
Minister of Education and Science*

Introduction

The European Commission is committed to ensuring that research funded under the 6th Framework Programme respects ethical principles. What legal requirements do researchers have to respect in European Commission funded research projects?

The text of the 6th Framework Programmes makes reference to the following international texts:

- The Charter of Fundamental Rights of the European Union
- European Union directives
- Convention of the Council of Europe on Human Rights and Biomedicine (1997) and the additional protocol on the Prohibition of Cloning Human Beings (1998)
- UN Convention on the Rights of the Child (1989)
- Universal Declaration on the human genome and human rights adopted by UNESCO (1997)
- Helsinki Declaration

These regulations and texts are all well known and can be consulted on the website http://europa.eu.int/comm/research/science-society/ethics/legislation_en.html.

Apart from such European legislation and international texts, the Specific Programme for research, technological development and demonstration 'Integrating and strengthening the European Research Area' (2002-2006) requires also that "In compliance with the principle of subsidiarity and the diversity of approaches existing in Europe, participants in research projects must conform to current legislation, regulations and ethical rules in the countries where the research will be carried out. In any case, national provisions apply and no

research forbidden in any given Member State will be supported by Community funding in that Member State.⁽¹⁾"

The specific regulation of ethical issues is a matter of subsidiarity. Rooted in the cultural background of the nation state, there are many ethical rules and guidelines in the national legal system that the scientists have to apply when conducting research in a country.

The guide for proposers of the 6th Framework Programme requires applicants to identify whether workpackages contain one or more of the five following ethical issues, namely whether the research work involves

- humans,
- human tissue,
- personal or private data,
- genetic information,
- or animal experimentation.

Detailed information on how these issues are handled has to be given, including the explanation of the applicable national legal background. Such projects that contain ethical issues may be submitted to an ethical review if they have been shortlisted after the scientific evaluation.

When co-operating in a European research consortium, it is important that researchers from partner countries have easy access to the national regulations on those five areas, where ethical issues

(1) See Annex 1 (COUNCIL DECISION of 30 September 2002 adopting a specific programme for research, technological development and demonstration: 'Integrating and strengthening the European Research Area 2002-2006).

may arise. It is an advantage if researchers not only understand the regulation of their own countries, but also those of potential partners and when they seek to collaborate.

This document is part of a series that aims to make the regulatory situation in the accession and candidate countries more transparent and better accessible to scientists in Europe.

The Lithuanian text has been written by Dr. Eugenijus Gefenas and Mrs. Asta Cekanauskaite and subsequently approved by the Ministry of Education and Science of Lithuania. The Commission has been promoting this project and is now dedicating a bilingual publication (original language and English) to the accession and candidate countries in order to facilitate their participation in the 6th Framework Programme. The project has been co-ordinated for the Commission by Alexandra Bitusikova, An Baeyens and David Coles. The responsibility and credit for the contents rest with the author and the Ministry of Education and Science of Lithuania.



Barbara Rhode
Head of Unit "Ethics and Science"
Research Directorate General

Table of contents

Foreword	3
<input type="checkbox"/> 1. International instruments in Lithuanian law	6
<input type="checkbox"/> 2. National overview	6
<input type="checkbox"/> 3. Research involving persons	9
<input type="checkbox"/> 4. Research involving human biological material	11
<input type="checkbox"/> 5. Research involving human embryos and embryonic stem cells	12
<input type="checkbox"/> 6. Personal data	12
<input type="checkbox"/> 7. Genetic information	14
<input type="checkbox"/> 8. Research involving animals	14

1. International instruments in Lithuanian law

One of the most important international documents in the field of human rights and health care is the Council of Europe's Convention on Human Rights and Biomedicine. Lithuania signed this document in

1997 and ratified it together with its additional protocol on prohibition of human cloning in 2002. Ratified international instruments have a direct binding character in the Republic of Lithuania.

2. National overview

Lithuania is one of the few European countries, which has a special law on regulations of biomedical research. The Law on Ethics of Biomedical Research came into force in 2001. This document deals in detail with the following issues: ethical requirements for biomedical research, vulnerable persons and the protection of their interests, protection of rights of all research subjects, informed consent, protection of privacy and confidentiality, reimbursement of expenses, civil liability of the sponsor and the principal investigator and its insurance, institutions issuing approvals, establishment of the Lithuanian Bioethics Committee and Regional Biomedical Research Ethics Committees and their competence, etc. Supplementary legal documents of the Law came into force during the period of 2000-2001. The following documents set up additional guidelines:

- Health Care Ministry Decree on the Procedure to Issue Approvals to Conduct Biomedical Research
- Health Care Ministry Decree on the Procedure for the Estimation and Covering of Expenses Incurred by Research Subjects
- Lithuanian Bioethics Committee Decree on the List of the Documents to be Presented by the Sponsor of Biomedical Research and (or) by the Principal Investigator in Order to be Authorized to Conduct Biomedical Research

1) Role and remit of research ethics committees or other competent bodies and their power with respect to the law

Following the Law on Ethics of Biomedical Research, there are two kinds of institutions, which have legal responsibility for biomedical research in Lithuania. The Lithuanian Bioethics Committee represents the first type of institution, namely, the national one.

The second type of institution is represented by the Regional Biomedical Research Ethics Committees. Biomedical research in Lithuania may be performed if approval has been received from the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee. Conducting biomedical research without prior approval is unlawful.

The following paragraphs of Art. 13 of the Law on Ethics of Biomedical Research determine the establishment of the Lithuanian Bioethics Committee and its competence:

"1. The Lithuanian Bioethics Committee shall be established and its composition and regulations shall be approved by the Ministry of Health. The Lithuanian Bioethics Committee shall be a legal person. Its activities shall be financed from the state budget.

2. The Lithuanian Bioethics Committee shall deal with the following areas not directly dealing with biomedical research (1-6) as well as those directly related to biomedical research (7-8):

- 1) analyse problems of bioethics and consult central and local authorities, agencies and organisations on these issues, submit conclusions and proposals relating to laws and other legal acts regulating problems of bioethics;
- 2) annually report to the Ministry of Health about its own activities and make proposals on how to address bioethical problems;
- 3) review whether individual and public health care is in conformity with the requirements of medical

- ethics and monitor compliance of legal persons with the requirements of bioethics;
- 4) provide methodological assistance and consult medical ethics committees of health care establishments on the issues relating to their activities;
 - 5) within the scope of their competence represent Lithuania in international organisations;
 - 6) perform other functions provided for in its regulations;
 - 7) issue approvals for conducting biomedical research and undertake the ethical review of research and monitoring of the activities of Regional Biomedical Research Ethics committees;
 - 8) the Lithuanian Bioethics Committee shall keep a record of biomedical research, collect, store and provide information about the research, whilst ensuring the protection of confidential information. It shall also design and approve standard forms related to the ethical review of research protocols".

Art. 14 of the same Law deals with the establishment of Regional committees and their competence:

"1. Regional Biomedical Research Ethics Committees shall be formed in the counties having universities and shall be composed proportionally of representatives of the degree-holding academic community, health care specialists and the general public. The quotas of representation in the committees, the number of committee members and composition of the committees, the territory of their jurisdiction shall be established by the Lithuanian Bioethics Committee which shall also approve standard operating procedures for the committees.

2. Regional Biomedical Research Ethics Committees shall:

- 1) grant approvals when mandated this function by the Lithuanian Bioethics Committee;
- 2) monitor biomedical research for which they have given their approval;
- 3) keep a record of biomedical research for which they have given their approval and communicate information from the record to the Lithuanian Bioethics Committee;
- 4) make an annual report about their activities to the Lithuanian Bioethics Committee;
- 5) perform other functions mandated to them by the Lithuanian Bioethics Committee".

2) The scope of biomedical research

The Law establishes a rather broad understanding of biomedical research by defining it as "a verification of hypotheses of biomedicine by methods of scientific investigation and the development of knowledge about characteristics of human health." So the law covers biomedical research carried out on individuals or their groups, fetuses, tissues, organs, cells and genetic material, cadavers and medical documents.

3) Procedural framework

The procedure for issuing approvals is regulated by a Ministry of Health Decree (entitled "Procedure to issue approvals to conduct biomedical research", October 23, 2000, No. 570). It deals with the procedure of approvals and annulments of approvals, the procedure for examination of

complaints and the procedure for payment of the fees for biomedical research expert examination.

- To be given an approval, the sponsor of a biomedical research and/or the principal investigator, shall submit an application and relevant documents (see Lithuanian Bioethics Committee decree on the List of the Documents to be Presented by the Sponsor of Biomedical Research and (or) by the Principal Investigator in Order to be Authorized to Conduct Biomedical Research) to the Lithuanian Bioethics Committee and, in the cases established by this Procedure, to the Regional Biomedical Research Ethics Committee.
- Approvals to conduct clinical research of medicinal products shall be issued upon recommendation of the State Drug Control Agency.
- Approvals to conduct clinical research on medical devices shall be issued upon recommendation by the State Health Care Accreditation Agency.
- When the Lithuanian Bioethics Committee issues approval, the decision to issue approval shall be discussed and approved in a session held by a group of biomedical research experts of the Lithuanian Bioethics Committee.
- Applications and documents shall be examined by the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee, and an approval shall be issued not later than within 45 calendar days after registration of the application and pertinent documents, after the payment of all the fees for biomedical research expert examination, except in the cases laid down in the pertinent laws.

4) Multicenter biomedical research projects

Should biomedical research be carried out in more than one region, the Lithuanian Bioethics Committee shall issue the approval. In this case, the Lithuanian Bioethics Committee shall decide upon the necessity to obtain the approval of the Regional Biomedical

Research Ethics Committees of the regions, where biomedical research will be carried out. The Lithuanian Bioethics Committee shall inform the Regional Biomedical Research Ethics Committees about biomedical research to be carried out in their respective regions.

3. Research involving persons

1) Laws regarding informed consent**▪ Principles**

The following requirements are specified in Art. 8 of the Law on Ethics of Biomedical Research:

"Biomedical research shall be carried out after the research subject has given his/her written consent. Before giving his/her consent, the research subject shall be provided with information, easily understandable to him/her and attested by his/her signature, about the aims, plan of the research and methods to be applied, decisions of the Lithuanian Bioethics Committee or an appropriate Regional Biomedical Research Ethics Committee, as well as about the following:

- benefits of the prospective biomedical research for the subject;
- the rights, foreseeable risks and inconveniences that biomedical research may cause to the subject, as well as the compensation available to the subject in the event of a research related injury;
- the right of the research subject to withdraw in writing his/her consent to participate in biomedical research at any time, and the consequences of discontinuing biomedical research;
- guarantees of confidentiality of the information."

Whether the subject's informed consent is necessary for carrying out biomedical research on tissues, organs, a foetus, cell or genetic material, which had been obtained from the person for other purposes during medical interventions before requesting the

subject to give his/her consent, also when biomedical research involves medical documents, shall be decided by the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee giving their approval.

▪ **Research involving children**

The concept "minor" (person under 18 years of age) instead of "child" is used in the Lithuanian Law on Ethics of Biomedical Research. If the subject is a minor, consent to undertake biomedical research shall be given by both parents or by the legally acceptable representatives of the minor, and the children's rights protection agency of a district or a city. If the parents of a minor are separated, the consent of one of the parents or of the legally acceptable representative and of the district or city children's rights protection agency must be obtained.

▪ **Others unable to consent**

According to the Republic of Lithuanian Constitution and the Lithuanian Law on Ethics of Biomedical Research (Article 8), biomedical research shall be carried out after the research subject has given his/her written consent, therefore, research without informed consent is not allowed in this country.

2) Other legal requirements for research

Following Art. 4 of the Law, besides the requirement of the subject's informed consent biomedical research may not be undertaken unless 4 additional basic requirements are met :

- the biomedical research has scientific and practical value;
- protection of the subject's rights and confidentiality is ensured;
- the investigator and the sponsor of biomedical research are covered by a third party insurance against any harm to the research subjects related to their participation to the research;
- the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee has given approval.

3) Requirements for biomedical research on vulnerable subjects

The Law provides a special safeguard of vulnerable persons. According to Art. 5 of the Law the category of vulnerable persons includes:

- persons with mental disorders but able to give their consent to take part in biomedical research;
- minors;
- students if their participation in biomedical research is related to their studies;
- persons in nursing homes;
- soldiers in active military service;
- personnel of health care institutions, where biomedical research is being conducted who are subordinated to the investigator.

The protection of the rights of vulnerable subjects is regulated by a specific article (Art. 7), which sets certain conditions that must be met in order to obtain approval to conduct a trial:

That:

- This kind of biomedical research can be carried out only on vulnerable persons;
- The results of the biomedical research have the potential to produce real and direct benefit to the health of the research subjects;
- The biomedical research shall not pose any risk to the health or life of a research subject.

The next paragraph of this article also specifies that the consent of a person, who has a mental disorder, but

may give his/her free and informed consent to take part in a biomedical trial, must be attested by two witnesses and the head of a health care institution, where the biomedical trial is conducted. Approval of the Hospital Medical Ethics Commission shall be obtained as well.

Biomedical research may not be performed on persons kept in prisons or other places of detention.

The law does not set a specific regulation on research carried out with pregnant women and nursing mothers.

4. Research involving human biological material

▪ **Laws regarding use of biological material from deceased persons**

Lithuanian law does not provide specific guidelines for research on biological material from deceased persons. The task of defining specific guidelines is delegated to the Lithuanian Bioethics Committee.

▪ **Laws regarding old collections of biological material, preexisting and ongoing research**

Whether the subject's informed consent is necessary for carrying out biomedical research on tissues, organs, cell or genetic material, which had been obtained from the person for other purposes during medical interventions, shall be decided by

the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee giving their approval.

▪ **With reference to recital 26 of Directive 98/44/EC - is consent required for patents developed from or containing human biological material?**

The Patent Law (18 January 1994 No. I-372, as amended by 30 October 2001 No. IX-568) does not specifically deal with the patenting of biotechnological inventions based on biological material of human origin or if it uses such material. The Patent Law does not provide the requirement of informed consent.

5. Research involving human embryos and embryonic stem cells

There is no legal definition of an embryo in Lithuanian laws. An attempt to define it was made by the authors of the draft Law on Artificial Insemination (it is still being debated within the Government). They suggested the following definition: "embryo - is an early stage of development of the human being from the conception until the eighth week of pregnancy".

According to Art. 3 of the Law on Ethics of Biomedical Research, invasive research on embryos as such is prohibited. Human embryos may be subject only to clinical observations (non-invasive

investigations). Other clinical investigations involving human embryos and their creation for purposes of biomedical research are prohibited.

Law regarding human reproductive cloning

Cloning of a human being is prohibited in the Republic of Lithuania. The prohibition of reproductive cloning is regulated by the Law on Ethics of Biomedical Research (Article 3.3.) and the Law on Ratification of the convention of Human Rights and Biomedicine.

6. Personal data

According to the Law on the legal Protection of Personal Data (11 June 1996, No. I-1374, as last amended on 22 January 2002, No. IX-719), personal data shall mean "any information relating to a natural person - the data subject - who is identified or who can be identified directly or indirectly by reference to such data as an identification number or one or more factors specific to his/her physical, physiological, mental, economic, cultural or social identity".

The Lithuanian Law on legal Protection of Personal Data corresponds with the Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Processing of Personal Data for Purposes of Scientific Research

Art. 12 of the Law on Legal Protection of Personal Data regulates the processing of personal data for the purposes of scientific research:

1. Personal data shall be processed in the course of scientific research on the condition that the data subject has given his/her consent. Without this consent personal data may be processed only if the State Personal Data Protection Inspectorate, which must carry out a prior checking, has been duly notified.
2. The personal data which have been used for scientific research must be altered immediately in a manner which renders it impossible to identify the data subject.
3. The data collected and stored for the purposes of scientific research may not be used for any other purposes.
4. In the cases where the research does not require identifiable personal data, the data controller shall provide to the data recipient data from which identification of a person is not possible.
5. Research results shall be made public together with the personal data only if the data subject has given his/her consent to have his/her personal data made public.

In addition, the Law on Ethics of Biomedical Research stipulates the conditions for obtaining consent from the person concerned. According to Art. 8 of this law, the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee giving their approval shall decide whether or not the subject's informed consent is necessary for carrying out biomedical research involving medical documents.

7. Genetic information

Lithuanian laws do not single out a distinct data group such as genetic information. Processing of genetic information would be covered by general regulations on the person's health information.

More specifically, the Law on Ethics of Biomedical Research refers to "genetic material" in its two articles (already mentioned earlier):

Art. 3 ("Objectives, Subjects and Characteristics of Biomedical Research"):

"1. Biomedical research may be carried out with individuals or their groups, foetuses, tissues, organs, cells and *genetic* material, cadavers and medical documents. Individuals or their groups and foetuses may be the subject of biomedical research only where comprehensive data about appropriate non-clinical

research is available. Non-clinical research must be carried out in conformity with the Guidelines for Good Laboratory Practice approved by the Ministry of Health. Clinical research must be conducted in accordance with the Guidelines for Good Clinical Practice approved by the Ministry of Health."

Art. 8 ("Consent of the Research Subject"):

"1. Whether the subject's informed consent is necessary for carrying out biomedical research on tissues, foetuses, cell or *genetic* material which had already been obtained from the person for other purposes during medical interventions, also when biomedical research involves medical documents, this shall be decided by the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee giving their approval."

8. Research involving animals

1) Animal ethics committee structure, role and remit

The Ethics Commission on the Use of Laboratory Animals was first established by the State Food and Veterinary Agency in 1999. It is comprised of representatives of interested institutions and

organisations and is approved by the institutions authorised by the Government (State Drug Control Agency, Lithuanian Association of Laboratory Animals, Department of Biology and Genetics of Vilnius University, National Public Health Centre, Department of Biochemistry and Biophysics of Vilnius University, Lithuanian Academy of Veterinary,

National Laboratory of Veterinary, Institute of Biochemistry, Institute of Immunology, Lithuanian Institute of Veterinary, Institute of Biomedical Research of Kaunas Medical University, Lithuanian Oncology Centre).

Licenses to perform experiments on vertebrate animals shall be issued by the State Food and Veterinary Service upon the recommendation of the Ethics Commission of Lithuania on the Use of Laboratory Animals.

The main objectives of the Commission are:

- to implement requirements for raising and research on vertebrate animals included in European conventions, legal documents of the European Union and national legislation;
- to evaluate vertebrate animal research protocols and propose them for approval of the State Food and Veterinary Agency.

The Commission:

- settles general methodological and ethical requirements for research on vertebrate animals, settles the provisions for the research and research staff;
- settles the requirements for the breeding and keeping environment of vertebrate animals, requirements for the equipment of vivariums;
- approves the use of animals in new scientific projects;
- provides scientists and other persons who deal with the breeding, keeping and use of laboratory animals with methodological support;

- gathers information about, analyses and controls scientific research conducted with animals in Lithuania and proposes them for registration;
- promotes certification and accreditation of the breeding-grounds, vivariums and laboratories, conducting scientific research on animals;
- together with the interested institutions, organises teaching courses for investigators and assisting staff;
- promotes alternative research methods;
- controls whether approved substances and methods for the anesthesia, analgesia and euthanasia of animals are used;
- informs society about its activity;
- informs the State Food and Veterinary Agency about its work and breaches of the requirements.

The Commission has the right to:

- obtain relevant information from state scientific institutions, high schools, departmental scientific institutes and industrial organisations;
- enter laboratories, industrial rooms, as well as rooms where animals are kept; control whether experimental protocols and other requirements are followed;
- advise against the approval of research on laboratory animals by the State Food and Veterinary Agency when an experiment does not provide sufficient safeguards for the welfare of animals;
- stop experimental research of biological materials and drug manufacturing, when rules and experimental methodology are disregarded and when repeated requirements of the Ethics Commission concerning welfare of animals are not executed.

2) Application of the "3Rs" (reduction, refinement, and replacement)

The principles of reduction, refinement and replacement are integrated into the Law on the Care, Welfare and Use of Animals, the Decree of the Veterinary Agency On the Use of Laboratory Animals in Research and into other relevant legal documents. Evaluation criteria for protocols are based on these principles.

It is prohibited to perform animal experimentation, if the necessary goals may be attained through the application of alternative scientific methods, avoiding the use of animals (Art. 14.2. of the Law on the Care, Welfare and Use of Animals).

When the use of animals in research is necessary, the selection of the species of animals shall be well-founded. The researcher should choose those methods which allows him/her to conduct the research and achieve the best results whilst using:

- the least number of animals,
- animals with the least developed neural system.

The researcher should seek to minimise as much as possible pain, suffering, fear and injuries inflicted upon the animals used (Decree of the State Food and Veterinary Agency On the Use of Laboratory Animals in Research).

Experiments, which may induce pain to an animal, must be performed under anaesthesia except when:

- the pain occasioned by the experiment is less harmful to the animal than anaesthesia;
- application of anaesthesia is incompatible with experiment goals.

3) Identification of animals, which can and cannot be used for research

Only animals specifically bred and raised for research purposes may be used for laboratory experimentation.

Experimentation with non-laboratory animals is allowed only where laboratory animals would not be fit for the purposes of experiment.

4) Regulations regarding research purposes for which animals may or may not be used (e.g. research on tobacco, cosmetics, etc.)

The legal documents do not explicitly deal with the prohibition to use animals in research on specific products like tobacco or cosmetics. However, the review of research on animals, performed by the Ethics Commission, is based on the "3Rs" principles, which implies that harm for animals shall be minimised as much as possible.

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