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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 checked="" type="checkbox"/>	<input type="checkbox"/>

National Regulations on Ethics and Research in

Bulgaria

България



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National Regulations
on Ethics and Research in

Bulgaria

България

by
Darina Zinovieva

European Commission contacts:
Barbara Rhode, An Baeyens and David Coles
Brussels, 2003

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Foreword

The question of ethics in research has significance at a national and on an international level, especially for projects submitted under the Sixth Framework Programme for research, technological development and demonstration.

Bulgaria agrees that research projects which raise ethical issues such as scientific research involving people, personal or genetic information or research experimentation that involves animals, after being evaluated and ranked, must undergo an ethical review bearing in mind their future influence on society and in order to avoid unexpected results.

This report appropriately highlights all the basic normative documents protecting human rights in the Republic of Bulgaria. There are also a number of others regulations which address ethical issues in scientific research and projects.

I would like to draw attention on the fact that Bulgaria promotes the improvement of laws and other normative documents about ethics in research. The bill for transplantation of organs, tissue and cells based on the actual legislation in the field of health completes, enlarges and improves the legal framework of this specific and very important subject, concerning the human health and life.

Another very important issue that I would like to draw attention to is that a draft law for the Genetic Non-modified Organisms is under preparation and will replace the acting regulation for the distribution of plants, created with recombinant DNA is prepared. The draft law is drawn up in accordance with the European legislation (Regulation 90/219 and Regulation 2001/18).

In conclusion, I would like to note that in joining the European Union, Bulgaria will harmonise its legislation with Europe and that research projects, submitted under the 6th Research Framework Programme will meet the requirements for ethics in the European Common Home.

Yours Sincerely,
Prof. Dr. Igor Damianov
Minister

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 Programme 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 (version 2000)

These regulations and texts are all well known and can be consulted on the website http://europa.eu.int/comm/research/sciencesociety/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 may arise. It is an advantage if researchers not

(1) See Annex 1.

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 Bulgarian text has been written by Dr. Darina Zinovieva and subsequently approved by the Ministry of Education and Science of Bulgaria.

The Commission has been promoting this project and is now dedicating a bilingual publication (original language and English) to accession and the 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 Bulgaria. ■



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

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1. International instruments in Bulgarian law

The main international act is the Council of Europe Bioethics Convention. The Convention was signed by the Bulgarian Representative at the Council of

Europe on 31 May 2001. Now, it is under the procedure for ratification by the National Assembly.

2. National overview

Bulgaria has a legal regulation in all fields, indicated below. Some of the acts have been voted recently (law for the medicines and pharmacies for human medicine, law for protection of personal data). There are two bills: a Bill for transplantation of organs, tissue and cells and a Bill about GMOs.

All fields are regulated in some sub normative acts: regulations and decrees.

There are some specific acts: Code of professional ethics (ministry of health / SG.79/September 29, 2000) and the National Frame Contract. The first one contains ethical rules for medical practice. The second one is prepared and signed by the professional organizations of physicians and dentists and National Health Insurance Fund.

There are administrative bodies and/or ethics committees in every field of research, indicated below. It is in their competence to permit or to

approve activities in research. For instance Local Ethical Committees (LEC) and the Central Ethical Committee (CEC) have an important role in clinical trials involving human subjects. The LECs, established in the corresponding healthcare entity where the clinical trials will be carried out, permit the performance of clinical trials. The LECs report on their activities to the CEC annually. The CEC also takes decisions when somebody appeals against the LEC's decision. There is a Special Committee for Permission of Clinical Trials (SCPCT) that involve medicines, which are not yet registered in Bulgaria. Besides the ethics committees, there is the Executive Medicine Agency to the Ministry of Healthcare. This Agency is an administrative body and is competent to conduct and manage medicine activities. All basic organs and committees and their competence, concerning ethical and legal issues in different research activities will be described below.

3. Research involving persons

The principal regulation is in the Constitution of the Republic of Bulgaria (SG56/July 13, 1991r.)

According to Art. 29. (2) no one shall be subjected to medical, scientific or any other experimentation without his/her voluntary written consent. Art. 54 (4) states that "No one shall be subjected to compulsory medical treatment or sanitary measures except in circumstances established by law".

Other regulation can be found in the Healthcare Act (Prom. SG 88 1973 ; Corr. SG 92 1973 ; Amend. SG 63 1976 ; Amend. SG 28 1983 ; Amend. SG 66 1985 ; Amend. SG 27 1986 ; Amend. and Suppl. SG 89 1988 ; Amend. SG 87 1989 ; Amend. SG 99 1989 ; Amend. and Suppl. SG 15 1991 ; Corr. SG 24 1991 ; Amend. and Suppl. SG 64 1993 ; Amend. SG 31 1994 ; Amend. SG 36 1995 ; Amend. and Suppl. SG 12 1997 ; Amend. and Suppl. SG 87 1997 ; Amend. SG 124 1997 ; Suppl. SG 21 1998 ; Amend. and Suppl. SG 70 1998 ; Amend. SG 71 1998 ; Amend. and Suppl. SG 93 1998 ; Amend. SG 30 1999 ; Amend. and Suppl. SG 62 1999 ; Amend. and Suppl. SG 67 1999 ; Amend. SG 90 1999 ; Suppl. SG 113 1999 ; Amend. SG 10 2000 ; Amend. SG 36 2000 ; Amend. SG 63 2002).

According to Art. 31, medical specialists shall be obliged to explain in a suitable way to the patient or to his/her next of kin the nature of the disease and the importance of the proposed treatment. The provision of medical care shall be in compliance with the state-of-the-art.

Methods of prophylactics, diagnostics and treatments WHICH ARE NOT GENERALLY APPLIED can be used only in the interest of the patient following an order determined by the Ministry of Health.

Methods of diagnostics and treatment leading to temporary changes of the human mind, such as hypnoses and anaesthetics, can be applied only in duly equipped medical establishments by specially trained persons.

For applying the methods described above, consent of the persons concerned, and, if they are legally incapacitated, of their legal representatives or guardians should be obtained in advance.

The Law for medicines and pharmacies for the human medicine (title amend. SG 10/00 ; Prom. SG 36/1995; Amend. SG 61/1996; Amend. SG 38/1998; Amend. and Suppl. SG 30/1999; Amend. and Suppl. SG 10/2000; Amend. SG 37/2000; Amend. SG 59/2000; Amend. SG 78/2000; Amend. and Suppl. SG 41/2001) contains important rules concerning medical tests on humans.

Chapter 4 of this Act is named "clinical studies of medicines". According to the Art. 37, clinical trials of medicines involving human subjects can be implemented:

1. for the process of their scientific investigation of medicines that are not yet registered in Bulgaria;
2. for proving, where it becomes necessary, the clinical efficiency and safety of medicines permitted for use in Bulgaria.

Permitted for use in the country in the sense of para 1, item 2 shall be medicines that have been entered in the register mentioned in Art. 28.

Clinical studies of medicines involving human subjects shall be implemented while observing the Good Clinical Practice approved by the Minister of Health. The chief investigator and the assignor, who sponsored the investigation or the person empowered by him/her shall send an application and the documents, as defined in the regulation issued by the Minister of Health, to the Executive Agency for medicines in order to receive permission to conduct a clinical trial.

The Minister of Health determines the members, the working conditions and remits of the CEC. It shall consist of at least nine members with representatives of both sexes, and of medical and non medical specialists.

LECs shall be established at the medical institutions performing clinical tests and their members are to be appointed by the head of the institution. Where members are involved in a specific clinical study, they can not participate in the decision on this study.

The CEC governs the LECs, controls their activity and in case of appeal takes the ultimate decision.

The LECs and the Executive Agency for medicines shall, according to their competence exercise, direct control over the clinical trials. In case of violation, they must notify this to the head of the corresponding medical establishment and the CEC.

According to Art. 41 permissions for conducting clinical trials shall be issued by the chairperson of the corresponding specialised commission of Art. 21 on the basis of a reasoned decision of the LEC. The conduct of clinical trials can start if there was no explicit refusal by the director of the Executive Agency for medicines.

The chief investigator, the investigators and the assignors, who sponsored the investigation are co-lialible in case of health damages or death caused by the clinical trial to the trial subject.

A clinical trial of a medicine must be conducted under the supervision of a physician who has not less than two years of practice after obtaining the medical speciality in the corresponding field; is familiar with the pharmacology and toxicology and with the risks of clinical trials as well as with all the documentation related to the medicinal product concerned.

The head of the corresponding clinical unit where the clinical trial of the medicine will be conducted shall give his/her agreement to the participation of the physician, mentioned above.

Clinical studies of medicinal products shall only be permitted on persons who:

1. have given written consent after being informed by the chief researcher about the nature, importance, scope and potential risks from the study;

2. are not in the military service in the Armed forces, not detained, imprisoned or sentenced to death, except in the cases where participation may save their health and life;
3. are covered by insurance taken out by the sponsor of the study in case of death or damage to health.

Consent can only be given by a legally capable person who understands the nature, importance, scope and potential risks from the clinical test. The consent shall be given personally and in writing. It can be withdrawn at any time.

Clinical studies of medicinal products involving minors shall be allowed when:

1. the medical supplies are designated for diagnostics or prophylactics of diseases, specific for minors and underage;
2. the results obtained from the clinical studies on people of age and their interpretation cannot be considered valid also for minors and underage.

For studies on minors the consent of both parents and a decision by the respective regional court are required.

Minors without parents can only be involved in therapeutic studies and the permission by the corresponding district is also required.

A specific case is described in Art. 48. A clinical study with a direct therapeutic purpose can be done if necessary to save the life of the sick person, to restore his/her health or to relieve his/her suffering. For patients underage (under 14) or under full interdict for performing clinical studies, only the written consent by their legal representatives is required. For patients under age (14 to 18) or under restricted interdict for performing clinical studies, it is necessary to obtain their written consent and the written consent of their parents or legal representatives.

The consent of the persons mentioned above, shall be valid only in as far as they have been informed in advance in writing about the nature, importance, scope and potential risks from the studies. However, consent of these persons is not required if immediate decision is necessary in order to save the life of the patient and consent cannot be sought. The decision must then be taken by at least two physicians.

According to Art. 50 clinical studies of medicine cannot be performed on pregnant women or breast feeding mothers, unless the medicine is necessary for their treatment or if it cannot be tested on other groups of patients.

The Regulation 14/22.03.2000 for the conditions and order for conducting clinical human trials (SG.29/30 March 1999r) contains procedure rules, concerning medical tests on humans.

4. Research involving human biological material

The main act, which regulates this area is the Healthcare Act (Prom. SG 88 1973 ; Corr. SG 92 1973 ; Amend. SG 63 1976 ; Amend. SG 28 1983 ; Amend. SG 66 1985 ; Amend. SG 27 1986 ; Amend. and Suppl. SG 89 1988 ; Amend. SG 87 1989 ; Amend. SG 99 1989 ; Amend. and Suppl. SG 15 1991 ; Corr. SG 24 1991 ; Amend. and Suppl. SG 64 1993 ; Amend. SG 31 1994 ; Amend. SG 36 1995 ; Amend. and Suppl. SG 12 1997 ; Amend. and Suppl. SG 87 1997 ; Amend. SG 124 1997 ; Suppl. SG 21 1998 ; Amend. and Suppl. SG 70 1998 ; Amend. SG 71 1998 ; Amend. and Suppl. SG 93 1998 ; Amend. SG 30 1999 ; Amend. and Suppl. SG 62 1999 ; Amend. and Suppl. SG 67 1999 ; Amend. SG 90 1999 ; Suppl. SG 113 1999 ; Amend. SG 10 2000 ; Amend. SG 36 2000 ; Amend. SG 63 2002).

According to Art. 33 organs and tissues can be taken from the body of persons in a state of cerebral death or from healthy persons and transplanted to a sick patient for saving a human life or in the case of seriously endangered health. The decision for the necessity of such transplantation shall be taken by a special commission of physicians-specialists.

The patient or if he/she is legally incapacitated, his/her legal representatives or guardians must give consent for the transplantation.

Organs for transplantation from persons in a state of cerebral death can be removed only in a State or municipal medical establishment equipped for proving cerebral death by specialists trained for that.

Organs can be transplanted only in specialised medical establishments determined by the Minister of Health and by specialists specifically trained for that.

Organs and tissues for transplantation cannot be subject to a paid transaction.

The donor or his/her next of kin cannot receive any financial or material benefit for the donated organs or tissues.

Export of organs and tissues is not allowed except to countries with which the Republic of Bulgaria has concluded an international agreement for mutual exchange of organs and tissues.

Organs and tissues for transplantation may be taken from the bodies of deceased persons, as well as from persons in a state of cerebral death where this has been certified by at least three physicians who are not part of the team performing the transplantation.

Organs and tissues from bodies of persons who have died or who are in a state of cerebral death in a medical establishment can be removed for transplantation without the consent of their legatees, or of their next of kin only if the persons have been legally capable Bulgarian citizens and in as far as they have not refused donation of organs and tissues after their death during their lifetime. The refusal must have been certified by a notice in the health insurance book of the person concerned.

However, if the person is under 18 years of age or he/she is legally incapable the written consent from his/her parents for the removal of organs and tissues will be required. It is not permitted however to remove organs for transplantation from bodies of persons in a state of cerebral death whose identity is not clear.

If the body is subject to a forensic examination, the removal of organs and tissues must be performed in the presence of a forensic expert.

Organs and tissues can also be removed for other medical purposes, as well as for scientific and educational purposes of health care.

In Art. 35 the conditions are laid down for the removal of organs and tissues from a living person. This can only be performed in a State medical establishment; it must not pose any danger to the person's life; and the person concerned must have given his/her written consent, after having been given a full explanation of any risks involved.

In addition, one of a pair of organs can be taken for transplantation from a living person under the following conditions:

- the person from whom the organ will be taken must be of majority age and physically and psychologically healthy. This must have been established by a commission of at least three physicians that must be comprised of one psychiatrist and of two physicians who are not part of the transplantation team;

- it must be established in advance that the organ to be removed and the remaining organ have completely retained functions ;
- the necessary tests must have been performed in advance in order to establish biological compatibility between the patient and the person from whom the organ will be taken.

A living donor must be leave our space a relative in direct line or in collateral line up to the fourth degree. Exceptions can be made in cases of relationship occurred on the grounds of adoption and between spouses.

There are some sub-normative acts regulating the details of transplantation process and organisation.

One of these is the Regulation N 4 from March 22, 1999 for taking organs for implantation (SG. 29/30 Mart 1999); this contains criteria for certification of brain death.

Some acts establish and reorganise the "Eye Bank" in Bulgaria and the National Organisation for management of transplantation Bultransplant (Decree N° 170 from 23 August 1994 (SG.71 - 2 September 1994). For the establishment of the State health entity "Eye Bank" to the Ministry of Health; Decree N° 140 from 21 July 2000 about structural reforms in the healthcare system (SG. 62/28 July 2000). The Decree reorganises the "Eye bank" into the National Centre "Bultransplant", Decree N° 100 from 15 May 2002 about structural reforms in the

healthcare system (SG.62 - 28 July 2000). The Decree divides the activity, concerning cornea tissue, from the activity of governing other transplantation process. The Decree establishes a public healthcare entity "Eye Bank", separately from the "Bultransplant". Finally the Decree N°159/15 July 2002 transfers the "Eye Bank" to the State University Hospital Queen Joanna. There is a sub-normative act, which arranges an organisation of the National Center for management of transplantation "Bultransplant" (Regulation of the Ministry of Healthcare, SG N4, 12 January 2001).

There is the Regulation N7/ SG 30/1996 for the removal and distribution of corneal tissue, which regulates the removal, procurement and transportation of cornea tissue.

At the end of 2002, the Bill for transplantation of organs, tissue and cells was entered at the National Assembly, but to date it has not been voted upon.

5. Research involving human embryos and embryonic stem cells

There is only Regulation 12/1987 for the artificial reproduction of women, issued by the Ministry of Healthcare. According to Art.12, para 2, genetic

material of the donor can be used for scientific purposes after three inseminations.

6. Personal data

The Law for the protection of personal data (SG. 1/4 Jan 2002) is the main normative act.

This law sets out the protection of individuals in the processing of personal data, as well as access to these data.

The purpose of the law is to guarantee the inviolability of the individual and their personal life by protecting individuals from illegal processing of personal data related to them and stipulating the right of access to such collected and processed data.

This law shall not apply for the processing of personal data by an individual for personal use.

Special laws can settle the processing of and the access to personal data for purposes of defence, national security and public peace, as well as for the functioning of executive and judicial competent authorities in applying the penal law.

Personal data are any information about an individual disclosing his/her physical, psychological, mental, marital, economic, cultural or public identity.

The provisions of this law shall also apply to personal data of individuals related to their participation in civil associations or in the bodies of management, control and supervision of corporate bodies, as well as in fulfilment of functions of State bodies.

An administrator of personal data is an individual or a corporate body, as well as a State body determining the type of the processed data, the purpose of processing, the ways of processing and protection with the requirements of this law.

The administrator of personal data shall process the personal data independently or through assignment to a data processor.

The State bodies shall process personal data in cases determined by a law.

Personal data shall be maintained in registers of personal data. Personal data processed by State bodies is official information. The Act establishes the Committee for protection of personal data. It consists of five persons, suggested by the Council of ministers and elected by the Parliament. Its chairperson must be a lawyer. The competences of the Committee are as following:

1. analyse and exercise an overall control over the observance of the normative acts in the sphere of protection of personal data;
2. keep a register of administrators of personal data;
3. carry out inspections of the administrators of personal data in connection with its activity under item 1;
4. express opinions and give permits in the cases stipulated by this law;
5. issue obligatory prescriptions for the administrators in connection with the protection of the personal data;
6. impose, upon prior notice, temporary prohibition for the processing of personal data, which violates the norms of protection of personal data;
7. consider claims against administrators in

connection with refused access of individuals to their personal data, as well as of other administrators or of third persons in connection with their rights according to this law;

8. participate in the elaboration of normative acts related to the protection of personal data.

The order of keeping the register for notifying the commission for giving permits and expressing opinions for considering the complaints, as well as for issuance of obligatory prescriptions and imposing temporary prohibition of processing personal data shall be determined by the regulations under this law.

According to Art. 13, the chairperson and the members of the commission are obliged not to make public any confidential information, which has become known to them in fulfilment of their activity, for a period of three years after the expiration of their mandate.

This obligation shall also apply to employees of the administration of the commission for a period of three years after the termination of the employment or official legal relations.

In taking office the members of the commission and the employees of its administration shall file declarations for these obligations.

The administrator processes personal data after receiving the explicit consent of the physical person concerned. The consent can be given either orally or in writing, but in some cases no consent is required. Written consent must be given if the information contains ethnic, political, religious or health data.

Consent is not needed for the provision of medical care or for the collection of personal data with the purpose of protecting the health of the person or the population. When data are collected for statistic, historical and scientific purposes, the administrator should inform the Commission. The Commission can forbid the use of data, if they are not well protected. Every person has the right of access to his data.

According to Art. 35, the transfer of personal data by the administrator to third persons shall be admitted upon their request when:

1. the respective individual has explicitly given his/her consent thereto;
2. the sources of data are public registers or documents containing public information, for which access is provided by an order determined by a law;
3. it is related to the protection of the life or health of the respective individual, as well as when his/her condition does not allow him/her to give consent or when legal obstacles exist for doing so ;
4. it is necessary to the bodies of the judicial and

executive authority and for protection of competition and of the consumers and this is established by a law;

5. they are necessary for scientific studies or for statistical purposes and in as far as the data is anonymous.

Another Act, which governs personal data issues is the Healthcare Act (Prom. SG 88 1973 ; Corr. SG 92 1973 ; Amend. SG 63 1976 ; Amend. SG 28 1983 ; Amend. SG 66 1985 ; Amend. SG 27 1986 ; Amend. and Suppl. SG 89 1988 ; Amend. SG 87 1989 ; Amend. SG 99 1989 ; Amend. and Suppl. SG 15 1991 ; Corr. SG 24 1991 ; Amend. and Suppl. SG 64 1993 ; Amend. SG 31 1994 ; Amend. SG 36 1995 ; Amend. and Suppl. SG 12 1997 ; Amend. and Suppl. SG 87 1997 ; Amend. SG 124 1997 ; Suppl. SG 21 1998 ; Amend. and Suppl. SG 70 1998 ; Amend. SG 71 1998 ; Amend. and Suppl. SG 93 1998 ; Amend. SG 30 1999 ; Amend. and Suppl. SG 62 1999 ; Amend. and Suppl. SG 67 1999 ; Amend. SG 90 1999 ; Suppl. SG 113 1999 ; Amend. SG 10 2000 ; Amend. SG 36 2000; Amend. SG 63 2002).

According to Art. 91 of this Act, physicians and all other medical staff have a duty of confidentiality with regard to all facts related to the health status of patients, the manner of contracting the illness and all other circumstances, which are in the interest of the patient to be kept secret, unless it is allowed by law to be transmitted to State bodies. This obligation also concerns medical students in medical Universities and Colleges.

7. Research involving animals

The main Act is the Veterinary Medicine Act (SG.42/5 May 1999). Chapter 7 of this Act is entitled "Rules for protection and humane attitude towards animals."

According to Art. 66 animals shall be bred and used in a way corresponding to their development and designation, conforming to their physiological needs and ecological requirements. The owners, who possess animals temporarily or permanently, are obliged to register them, not to abandon them, to take care of their health and to protect them from pain and suffering. Wild animals removed from their natural environment can be raised in regulated zoos, circuses, farms for wild animals and bird cages only for:

1. satisfying the interest of people in furthering knowledge about nature;
2. hunting;
3. investigations and scientific experiments observing the requirements of this law.

Domestic animals can be raised at home observing the rules for protection and humane attitude pointed out in the law.

Experiments with animals shall be performed only in regulated places of experimental research and development and production institutes, stations and laboratories and education establishments by competent persons conducting the experiments, using methods and means sparing the animals.

Stray animals (born as such, lost or abandoned by their owners) shall be accommodated temporarily in isolation places of the municipalities and the mayoralties. The animals not claimed within two weeks shall be subject to euthanasia.

The euthanasia of the animals shall be implemented by a veterinary doctor.

Euthanasia shall be allowed :

1. in the cases of Art. 70, para 2; 2. hopelessly ill animals with irreversible pathological changes causing them pain and suffering;
3. if needed for prevention and liquidation of an acute infectious animal disease or any other disease that is a danger for the health and life of people (zoonoses);
4. to finish the experiments of Art. 68, para 1, item 3;
5. on animals, or the conduct of which represents a proved danger for the life and health of people and animals.

According to Article 75, the following is prohibited :

1. the transportation of animals under transport conditions causing pain injuries and suffering;
2. causing pain, injuries, suffering, stress or fear to the animals without grounded reason for this;
3. using animals for specially organised fights or performances leading to pain, injuries and damages;

4. implementing veterinary medical manipulations by persons without the necessary qualification for this;
5. doping of animals with the objective to enhance sport or other results;
6. training of animals in a way causing to them pain or suffering;
7. walking of wild animals in the streets with the objective of performances or trade.

Another normative act, which tackles this problem, is the Regulation for allaying of the veterinary medicine Act (SG55/7 July 2000/., amd. SG.4/12 January 2001r).

According to Art. 110, there exists a National Veterinary Medicine Office that controls whether the rules for protecting of animals are being observed. The office works together with the Organizations for protections of animals. All academic entities and veterinary medicine specialists involved in education must respect the rules for animal protection.

The owners of dogs, from 6-months of age, are obliged to register them at a regional veterinary medicine office or at a licensed veterinary physician. The dog receives a passport and

identification tag, which contains a unique identification number.

Physical and legal persons who look after animals for trade purposes or govern animal houses are obliged to declare their activity at the RVMO (Regional Veterinary Medical Office).

The legislation defines 'trial animals' as animals for scientific and experimental aims. They can be used to prove scientific hypotheses, to obtain new information; for the application of new diagnostic or treatment methods; for preclinical trials of new medicines, foods, or biological products and finally education. Persons, conducting trials with animals, must register their activity at the competent RVMO.

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