REGULATIONS

From the Ministry of Forestry and Water Affairs:

WORKING PROCEDURES AND RULES OF ANIMAL EXPERIMENTATION ETHICS COMMITTEES

REGULATION ON PRINCIPLES

CHAPTER ONE

Purpose, Scope, Basis, Definitions and Abbreviations

Aim

ARTICLE 1 – (1) The purpose of this Regulation is to determine the principles regarding the determination of acceptable ethical standards regarding the methods and materials used in basic activities such as scientific research, testing, education and training to be conducted with experimental animals, the establishment and work of the animal experimentation central ethics committee and animal experimentation local ethics committees, the presentation of planned procedures, the examination and permission of research and study proposals, the monitoring of applications, the recording of all procedures performed on experimental animals and the ability to trace these procedures instantly or retroactively, the provision of auditability of all procedures and the termination of relevant procedures when necessary.

Scope

ARTICLE 2 – (1) This Regulation covers the permits to be obtained before the use of animals to be used for experimental purposes in public institutions and organizations and private institutions, the establishment of the central animal experimentation ethics committee and local animal experimentation ethics committees for this purpose, the working procedures and principles, duties, training, inspection and responsibilities of these committees.

(2) This Regulation;

a) Non-experimental agricultural practices,

b) Non-experimental clinical veterinary practices,

c) Clinical trials required for marketing authorization of veterinary health products,

ç) The practices that registered or approved livestock enterprises are obliged to carry out,

d) Applications whose primary purpose is to identify an animal ,

does not cover .

Rest

ARTICLE 3 – (1) This Regulation has been prepared based on Articles 9 and 17 of the Animal Protection Law No. 5199 dated 24/6/2004 and in parallel with the European Union Directive on the Protection of Animals Used for Scientific Purposes No. 2010/63/EU.

Definitions and abbreviations

ARTICLE 4 – (1) In this Regulation;

a) Ministry: Ministry of Forestry and Water Affairs,

b) CITES Convention: The Convention on International Trade in Endangered Species of Wild Fauna and Flora, published in the Official Gazette dated 20/6/1996 and numbered 22672.

c) Work permit: The document given by the Ministry of Food, Agriculture and Livestock to experimental animal user, producer and supplier organizations,

c) Experiment: Any procedure or set of procedures to be performed on animals for scientific purposes,

d) Experimental animal: Any non-human vertebrate used in procedures, including free-living or reproducing larval forms, live cephalopods and mammals from the last third of their normal fetal development,

e) Experimental unit: Units that have a work permit from the Ministry of Food, Agriculture and Livestock and where any procedure or procedures are performed on animals.

f) Ethics: Limits of actions that can be taken in sciences concerning human and animal life regarding animals to be used in research, universal rules guiding the attitude and behavior towards animals,

g) General Director: General Director of Nature Conservation and National Parks,

g) General Directorate: General Directorate of Nature Conservation and National Parks,

h) HADMEK: Animal Experiments Center Ethics Committee,

i) HADYEK: Local Animal Experiments Ethics Committee,

i) Animal welfare unit: A unit that is required to be established in producers, suppliers, users and research-authorized institutions, and is responsible for the welfare and care of animals, consisting of at least one person with the title of veterinarian, veterinary health technician or veterinary health technician, or in user institutions, consisting of one person with one of these titles and a maximum of three people, one of whom is a member of the local ethics committee.

j) Humane killing method: Ending the life of the animal in a way that will cause the least physical and sensory pain, suffering and distress, specific to its species,

k) In vivo experiment: Experiment conducted in a living environment,

l) Good laboratory practices: The quality system related to the conditions and management procedures for planning, conducting, monitoring, recording, archiving and reporting of health and environmental safety studies other than clinical studies,

m) User: Person authorized to use animals in procedures ,

n) Establishment: Any fixed or portable facility, building or group of buildings, whether open, closed, semi-open, with its annexes, that has an operating permit from the Ministry of Food, Agriculture and Livestock,

o) Project: A work program that has a defined scientific purpose and includes one or more procedures ,

ö) Procedure: The use of animals for experimental, other scientific or educational purposes , with known or unknown results, in a manner that may cause pain, suffering, distress or permanent damage equal to or greater than that caused by the insertion of a needle in accordance with good veterinary practices, including the processes of giving birth, hatching or continuing the genetically modified animal breed,

p) Secretariat : Person or persons who ensure the necessary coordination in ethics committees, carry out correspondence and keep records,

r) Technician: A person who has graduated from a two-year Veterinary Health Associate Degree program after high school education,

s) Technician: A person who graduated from the Veterinary Health Department of the Agricultural Vocational High School affiliated to the Ministry of National Education, or from the Veterinary Health Vocational High School, Animal Health Officers School, or Animal Health Officers Vocational High School, which were previously affiliated to the Ministry of Food, Agriculture and Livestock.

ş) TÜBİTAK: The Scientific and Technological Research Council of Türkiye,

t) Species: A biological group that includes related organisms that share common characteristics and can reproduce by fertilization among themselves .

u) 3R principle: Wherever possible, instead of live animals, the application of another scientifically valid alternative method or trial strategy, the reduction of the number of animals to be used as much as possible without compromising the project objectives, the improvement of procedures that will cause pain, suffering, pain or permanent damage to animals, and the enhancement of animal welfare,

expresses .

CHAPTER TWO

Purposes of Using Experimental Animals, Establishment of Ethics Committees,

Term of Office, Working Method, Duties and Powers

Purposes of using experimental animals

ARTICLE 5 – (1) The purposes of using experimental animals are stated below:

a) Basic research.

b) Translational or applied research having any of the following purposes :

1) Prevention, diagnosis, treatment or avoidance of disease, disorders and other abnormalities in humans, animals or plants.

2) Study, determination, correction or modification of physiological disorders in humans, animals or plants.

3) Improving animal welfare and production conditions of animals raised for agricultural purposes.

c) Development, production and testing of the quality, effectiveness and reliability of medicines, food raw materials, feed raw materials, other substances and products for any of the purposes specified in paragraph (b).

c) Protection of the natural environment for human and animal health and welfare.

d) Research aimed at the protection of species.

e) Higher education or training for the acquisition, maintenance or development of professional skills.

f) Forensic medicine investigations.

HADMEK's establishment and working method

ARTICLE 6 – (1) HADMEK shall be established within six months from the date of publication of this Regulation. HADMEK;

a) From the Ministry; general director, deputy general director, department head, branch manager and a legal member from the legal consultancy,

b) Three representatives from the Ministry of Food, Agriculture and Livestock with at least two years of experience in animal testing,

c) Three representatives from the Ministry of Health with at least two years of experience in animal experiments,

c) Three faculty members from veterinary faculties with at least two years of experience in animal experiments,

d) Three faculty members from medical faculties with at least two years of experience in animal experiments,

e) One representative from the Turkish Medical Association and the Turkish Veterinary Association,

f) A veterinary representative from TUBITAK,

g) One member of a non-governmental organization for the protection of animals,

It consists of twenty-one members, including :

(2) Election of HADMEK members;

a) General Manager, deputy general manager, department head, branch manager and legal member are permanent members of HADMEK .

b) HADMEK members, except for permanent members, are appointed by the Ministry, as determined by other institutions and organizations.

(3) The HADMEK meeting is chaired by the highest-level representative from among the members of the Ministry.

(4) The term of office of other members, except for permanent members, is four years. A member whose term of office has expired may be reappointed. The membership of a member who fails to attend three consecutive meetings within a calendar year without permission or excuse will automatically cease. In the event of termination of membership due to any reason such as death, retirement, separation, or termination of membership, a new member with the same procedure and the qualifications of the departing member will be appointed to complete the remaining term.

(5) Coordination between HADMEK and HADYEK is provided by the general directorate. HADMEK secretariat services are carried out by the relevant branch directorate.

(6) HADMEK meets once every three months with an agenda determined by the chairman. The invitation letter including the meeting agenda is sent to HADMEK members at least ten days before the meeting date. If deemed necessary by the chairman, the board may also meet by giving notice to the members at least ten days in advance.

(7) HADMEK meets with the participation of at least two-thirds of the members. Decisions are taken by majority vote, in case of equality of votes, the decision is made by the vote of the chairman.

HADMEK's duties

ARTICLE 7 – (1) HADMEK's duties are as follows:

a) To determine ethical principles regarding the use of experimental animals.

b) To approve HADYEK directives and to terminate them in accordance with article 21.

c) To inspect whether HADYEKs operate in accordance with the provisions of this Regulation and to evaluate their annual reports.

ç) To suspend the operations of HADMEKs that act contrary to the directive approved by HADMEK and this Regulation, in accordance with Article 21.

d) To inspect the test conditions and laboratories in the producer and user institutions and organizations to which HADYEK provides service, within the framework of the provisions of this Regulation.

e) To take the necessary steps to prevent the use of experimental animals in violation of the provisions of this Regulation.

f) To evaluate the objections made to the decisions of HADYEKs and, if deemed necessary, to send the files back to the relevant HADYEK for re-examination with the justifications .

g) To determine and supervise the procedures and principles of the training programs provided to researchers, technicians, animal caretakers and other auxiliary personnel of HADYEKs regarding the use and care of experimental animals.

g) To evaluate the equivalence of laboratory animal use certificates.

h) To collect and publish annual statistical information on the use of laboratory animals in experiments nationwide.

i) To organize training programs when necessary.

HADYEK's establishment and working method

ARTICLE 8 – (1) HADYEK is established as follows:

a) In accordance with the provision of Article 9 of Law No. 5199, official and private institutions and organizations with experimental animal units that have a work permit from the Ministry of Food, Agriculture and Livestock, and higher education institutions can establish HADYEK. Animal experiments cannot be conducted in institutions and organizations that do not have a HADYEK and animal welfare unit.

b) In order to establish HADYEK, it is mandatory to have an experimental animal unit with a work permit from the Ministry of Food, Agriculture and Livestock, where veterinary services are provided and where animals can live a stress-free and calm life, taking into account their species characteristics.

(2) HADYEK must have at least the following members:

a) A veterinarian who is responsible for the breeding and production of experimental animals within the institution or organization, who has an experimental animal use certificate, who works full-time in the unit, and who has at least one year of experience in animal experiments.

b) A representative from the units within the institution or organization that work with experimental animals.

c) A citizen of the Republic of Turkey who does not conduct experimental studies on animals and does not have any conflict of interest with the organization and his/her first-degree relatives.

c) A citizen of the Republic of Türkiye who is a member of a non-governmental organization and has no conflict of interest with the institution or organization.

(3) At least one member of HADYEK must have at least one year of experience in in vivo animal experiments and must have a doctorate or medical specialization degree. It is preferable for HADYEK to include medical or veterinary ethics experts. Institutions and organizations may determine the composition of HADYEK according to their needs and administrative structure. HADYEK may seek opinions from experts in other fields and invite them to meetings when necessary. HADYEK consists of at least five and at most 21 members.

(4) Regarding the appointment of HADYEK members;

a) HADYEK president, vice president and members are appointed with the approval of the rectors in universities and the highest level administrators in other institutions and organizations.

b) HADYEK president and veterinarian must be full-time employees of the institution or organization. Other members may also be appointed from outside the institution or organization.

c) Changes regarding appointments or approval and assignments are notified to HADMEK within one month .

c) Persons who are found to have acted contrary to the provisions of this Regulation cannot be appointed as HADYEK members.

(5) HADYEK secretariat is appointed with the approval of the rectors in universities and the highest level administrator in other institutions and organizations. A separate working unit is established for the regular operation of HADYEK and for the receipt, evaluation and archiving of applications.

(6) The term of office of HADYEK members is four years. A member whose term of office has expired may be reassigned or assigned with approval. If a member fails to attend three consecutive meetings within a calendar year without permission or excuse, his/her membership will be terminated. In the event of termination of membership due to any reason such as death, retirement, or resignation, a new member with the same procedure and the qualifications of the resigned member will be assigned to complete the remaining term.

(7) HADYEK starts its activities after its directive is approved by HADMEK.

(8) HADYEK operates as follows:

a) HADYEK meets at least once a month, with the participation of at least two-thirds of the members, with the agenda determined by the chairman of the board.

b) Decisions at the HADYEK meeting are taken by majority vote. In case of a tie, the decision is made by the vote of the chairman.

c) Each board prepares a directive that determines its own working procedures and principles.

c) Records regarding all experimental animals used in institutions are kept or have kept by the veterinarian responsible for breeding, production and care of experimental animals working in the animal welfare unit. The records in question include the number of animals provided, their types, the places they were provided, the date they arrived at the user institution and all procedures performed. These records are kept for at least five years.

d) HADYEK prepares a form to evaluate the applications. The form must include the following information:

1) Project name.

2) Name, address, place of duty and signature of the project manager and other researchers.

3) Place and duration of the procedure.

4) Training certificates for those who will perform procedures on live animals .

5) Application date.

6) Project proposal.

7) Non-technical project summary written in everyday language.

8) Animal resources, estimated number of animals, species and age.

9) Procedures to be performed on animals .

10) The level of pain, suffering, distress and permanent damage that the procedures will cause .

11) How the 3R principle is applied in procedures .

12) Anesthesia, analgesia and other pain relief methods planned to be used.

13) Measures to be taken to prevent animals from suffering or to reduce the suffering they suffer throughout their lives .

14) Determining the humane killing method in terminating the procedures.

15) Experimental or observational strategies and data analysis procedures to minimize the number of animals and the pain, suffering, distress or possible environmental effects of the procedures .

16) Whether animals will be used in more than one project.

17) Conditions for housing, raising and caring for animals.

18) Competence of those involved in the project.

19) Letter of Undertaking.

e) HADYEK grants permission for projects for a maximum period of five years. In case of a request for extension, additional time may be granted provided that the request is justified.

f) All applications and decisions taken are recorded by giving the date and number. Records are kept for at least five years.

g) Applications are made by the project manager. For thesis studies, the manager is the advisor faculty member.

g) HADYEK, as a result of its evaluation, decides whether it is suitable, requires correction, conditionally suitable or not suitable. Decisions are notified to the applicant in writing within forty working days from the date of application. This period also includes the project evaluation. In cases where the project is complex or involves more than one scientific discipline, HADYEK may extend the mentioned period once for a period not exceeding fifteen working days. The reason for the extension and the period are justified and the implementer is informed before the period ends. HADYEK may request that preliminary experiments be conducted on a small number of animals in order to test the feasibility of a project. In this case, the final decision is made according to the procedures in projects where a “conditionally suitable” decision is given.

h) While the applications of HADYEK members are being discussed, the relevant board member cannot participate in the discussions and cannot vote.

i) Projects that are decided to be “requiring correction” are re-evaluated after correction. Projects that are decided to be “conditionally suitable” are monitored by the animal welfare unit for a period to be determined by HADYEK, and after evaluating whether the required conditions are met, a decision is made as suitable or not suitable, and a report is given to HADYEK regarding the project .

i) The local ethics committee monitors whether there are any changes in the permitted projects that will negatively affect animal welfare. If the approved project is not followed, the local ethics committee cancels the permission. In the event of cancellation of the permission, the animal welfare unit ensures that the welfare of the animals used or planned to be used in the project is not negatively affected.

j) After HADYEK approval is received, any changes in the project and the people who will participate in the study are notified to HADYEK in writing by the project manager and approval is obtained.

k) The following interventions are not subject to HADYEK permission:

1) Clinical applications for diagnosis and treatment.

2) Procedures performed with dead animals or their tissues, slaughterhouse materials, and waste fetuses .

3) Milking.

4) Collecting stool or litter samples.

5) Taking a sample by swabbing .

l) In the use of wild animals from nature for species identification, the permission obtained from the General Directorate replaces the HADYEK permission.

m) If field research is carried out in more than one province, it is sufficient to obtain HADYEK approval for only one location.

n) Records are kept open to the inspection of HADMEK and the Ministry. HADYEK may, when necessary, obtain written opinions from experienced experts or may request oral or written opinions by inviting them to a HADYEK meeting.

HADYEK's duties

ARTICLE 9 – (1) HADYEK's duties are as follows:

a) To prepare guidelines on its own working procedures and principles within the framework of the provisions of this Regulation and the ethical principles and good laboratory practices determined by HADMEK .

b) To determine the ethically acceptable limits of all procedures to be performed on experimental animals and to approve or reject the protocols regarding the procedures to be performed with justification .

c) To supervise whether the process of using experimental animals within the institution is in accordance with the 3R principles and ethical rules, and to make the necessary arrangements for this purpose.

c) To contribute to the development and validation of alternative methods that can provide the same or higher level of information than those obtained using laboratory animals, but that do not use animals, or use the fewest animals, or involve less painful procedures , and to implement practices that will encourage research in this field.

d) To ensure that procedures to be performed on experimental animals are carried out in accordance with the approved protocol and to decide on their termination when necessary.

e) To ensure that personnel who will work with laboratory animals receive the necessary training and to permit animal experiments to be conducted provided that they have a laboratory animal use certificate. To this end, to organize certification programs when necessary.

f) To inspect whether the production, breeding, housing and transportation conditions of experimental animals and the laboratory conditions and equipment where the experiments are conducted are ethically appropriate.

g) To prepare statistical data tables and annual activity reports regarding the use of experimental animals and submit them to HADMEK .

g) To ensure the disposal of wastes and medical wastes resulting from experimental studies within the framework of the Environmental Law No. 2872 dated 9/8/1983 and relevant legislation .

h) To ensure that experimental animals are registered and monitored within the framework of the provisions of the Animal Protection Law No. 5199 and the relevant legislation.

i) To notify HADMEK of the training certificate programs to be organized thirty days in advance .

i) To report to HADMEK information about the certification training programs they organize and the trainees who successfully receive certificates at the end of the training .

j) To decide whether there is any harm in adopting the animals used in the experiment or returning them to the farming system after the procedure .

HADYEK's working principles

ARTICLE 10 – (1) HADYEK operates in accordance with the following principles:

a) To prevent ill-treatment of experimental animals that must be used in scientific research.

b) To ensure that experimental animals are used within the scope of the purposes specified in Article 5.

c) To ensure that an animal is not used more than once in experiments that cause severe pain, stress or equivalent suffering, and that if it must be used, this is based on sound scientific justification.

d) To ensure that pain and painful experiments are not performed at educational congresses, conferences and seminars.

d) To ensure that scientifically reliable data is obtained by causing animals as little suffering and stress as possible.

e) To prepare conditions appropriate to the species of laboratory animals used during research and to ensure the best physiological, behavioral and environmental conditions.

f) To ensure that laboratory animals are cared for under appropriate conditions by suitably trained personnel.

g) To ensure that experimental studies on live animals are carried out under the supervision of the responsible veterinarian.

g) To ensure that researchers determine target points regarding the conditions under which experiments will be terminated.

h) If there are alternative methods of proven validity in obtaining the information being researched, to consider animal experiments as unethical and to prevent the repetition of experiments that have been previously conducted in detail.

i) To ensure that the most appropriate animal species and method are selected for the experiment and that the minimum number of animals that will yield scientifically meaningful results are used.

i) To ensure that an appropriate anesthesia method is applied in experiments that will cause unnecessary pain and suffering to laboratory animals and that appropriate painkillers and anesthesia are used in research.

j) To prevent anesthesia from being administered if it is more traumatic for the animal than the experiment itself and is not compatible with the purpose of the experiment.

k) In order for the experiment to be conducted within the framework of ethical principles and in accordance with its purpose, with the decision of the veterinarian ;

1) The animal, which will be exposed to significant pain when it comes out of anesthesia, should be treated with painkillers, or if treatment is not possible, it should be killed by a humane method.

2) The termination of the life of the experimental animal during or at the end of the research process must be done with appropriate justifications,

3) The life of laboratory animals that are in severe and constant pain or are unable to continue their normal lives, and those that pose a risk to their health and environment, should be terminated by a humane method.

to ensure .

l) To ensure that the experimental animals used in the research and continuing to live are provided with healthy living conditions at the end of the experiment.

m) To decide on conducting experiments that will subject animals to severe and prolonged pain, taking into account ethical principles, the benefits to be obtained from the research, and the suffering that the animals will suffer.

n) To reduce the number of animals used in experiments by performing more than one application on animals, as long as the scientific objective is not deviated from and the animal's welfare is not compromised.

o) To ensure that other applications are evaluated within the scope of sharing the tissues and organs of animals that died after being used in experiments.

ö) To avoid practices that are likely to result in severe pain, suffering and distress that are likely to last for a long time and are not reversible.

p) To allow procedures to be carried out only under the supervision of the animal welfare unit within the organization.

r) To monitor changes to be made in approved projects, content and people who will participate in the work and to ensure that the necessary permissions are obtained.

CHAPTER THREE

Experimental Animal and Research Related Practices

Experimental animals

ARTICLE 11 – (1) Matters regarding the animals to be used in HADYEK's work:

a) All procedures to be performed on experimental animals must be approved by HADYEK.

b) To be used in experiments unless there is a general or special exception taken in accordance with the regulations made by HADYEK;

1) Mouse (Mus musculus),

2) Rat (Rattus norvegicus),

3) Guinea pig (Cavia pocellus),

4) Syrian (golden) hamster (Mesocricetus auratus),

5) Chinese hamster (Cricetulus griseus),

6) Mongolian gerbil (Meriones unguiculatus),

7) Rabbit (Oryctolagus cuniculus),

8) Dog (Canis familiaris),

9) Cat (Felis catus),

10) All species of non-human primates

11) Frog [Xenopus (laevis , tropicalis), Rana (temporaria , pipiens)],

12) Zebra fish (Danio rerio),

It is required that the species and all animals to be used in the experiment are purchased from registered legal laboratory animal producers and suppliers.

c) Stray domesticated species such as cats and dogs are not used in experiments. However, if there is a need for studies on the health and welfare of animals, if they pose a serious threat to the environment, human and animal health, and if there are scientific justifications that the purpose of the study can only be achieved using stray animals, these animals may be used in experiments.

c) The use of non-human primates in experiments is permitted in exceptional cases and if there is a scientific justification that the purpose of the procedure cannot be achieved using a species other than non-human primates.

d) Great apes cannot be used in experiments.

e) The use of endangered and protected species within the framework of national legislation and international agreements and species listed in Appendix-1 of the CITES Convention is permitted in the following cases:

1) If the procedure has one of the purposes specified in subparagraph (1) of paragraph (b) of the first paragraph of Article 5 and in paragraphs (c) and (d).

2) If there is a scientific justification that the purpose of the procedure cannot be achieved with species other than the species in question.

f) An experiment to be conducted on a wild animal taken from nature is approved only if there is a scientific justification; other animals are not sufficient for the purpose of the experiment. In studies conducted on this subject, permission is obtained from the General Directorate after HADYEK approval.

Procedures related to anesthesia and anesthesia administration, killing and severity classification in experiments

ARTICLE 12 – (1) Procedures regarding anesthesia and anesthesia application, killing and severity classification in experiments are carried out in accordance with Articles 21 and 22 of the Regulation on the Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes, published in the Official Gazette No. 28141 dated 13/12/2011 by the Ministry of Food, Agriculture and Livestock, and Annex - 8 and Annex-9.

Reuse of animals in experiments

ARTICLE 13 – (1) The re-use of an animal that has been used in one or more experiments is permitted under the following circumstances:

a) If the actual severity of previous experiments was “mild” or “moderate”.

b) If the animal's general health status has completely returned to its previous state.

c) If the new test is classified as “mild”, “moderate” or “incorrect”.

c) If it is deemed appropriate by a veterinarian who can evaluate the procedures previously performed on the animal .

(2) In exceptional cases, in a manner that excludes the application of subparagraph (a), and after the animal has been examined by a veterinarian, the re-use of an animal may be permitted, provided that the animal is not used more than once in an experiment involving severe pain, suffering or the equivalent.

Termination of the experiment

ARTICLE 14 – (1) If no further observation can be made regarding the experiment, or if genetically modified animal strains and generations are no longer followed, or if it is expected that the animal will experience pain, suffering, agony and permanent damage equivalent to or greater than being pricked with a needle on an ongoing basis, the experiment is terminated.

(2) At the end of the experiment, the decision as to whether an animal should be kept alive is made by a veterinarian. If an animal is kept alive, it is provided with appropriate care and accommodation for its health. If the animal continues to suffer moderate or severe pain, suffering, distress or permanent damage, it is killed.

Evaluation of projects

ARTICLE 15 – (1) Projects;

a) Scientific, educational or legal reasons,

b) Reasons for animal use,

c) Designing procedures to be carried out in the most humane and environmentally friendly manner possible,

d) Estimated scientific benefits and educational value,

d) Compliance with the 3R principle,

e) Classification of procedure severity,

f) The benefit to be obtained and the pain that the animals will suffer,

g) Compliance of killing methods, procedures , anesthesia, re-use, care and shelter conditions with the current legislation,

g) Deciding whether and when a retrospective evaluation will be conducted,

evaluated by HADYEK according to its criteria .

(2) HADYEK will select experts who will conduct project evaluation based on their competence in the 3R principle, experimental design, practical applications of animal experiments, practical applications of wild animal experiments or animal care and nutrition.

(3) Project evaluation should be transparent. To protect intellectual property rights and confidential information, project evaluation is carried out impartially and may include the opinions of independent parties.

Project summaries

ARTICLE 16 – (1) Subject to the protection of intellectual property rights and confidential information, the non-technical project summary covers the following matters:

a) Information about the objectives of the project, including the estimated damages and benefits and the identity of the animals used .

b) The 3R principle is complied with.

(2) The non-technical project summary is prepared anonymously and does not include the names and addresses of users and personnel.

(3) HADYEK may request that the non-technical project summary specify whether the project will be subject to a retrospective evaluation process and the time limit for this process. In this case, HADYEK will ensure that the non-technical project summary is updated with the results of the retrospective evaluation.

(4) In case a database is created by the Ministry, non-technical project summaries of authorized projects and updates made to them are published in this database.

Retrospective evaluation

ARTICLE 17 – (1) If a decision is made to conduct a retrospective evaluation regarding projects that have been finalized with HADYEK permission, the following issues are evaluated according to the documents submitted to HADYEK :

a) Whether the project's objectives have been achieved.

b) The number of animal species used, the harm to the animals and the severity of the procedures .

c) Elements that can contribute to the implementation of the 3R principle.

(2) All projects involving non-human primates and procedures classified as “violent,” including procedures that involve prolonged and irreparable pain, suffering, or distress, are subject to retrospective evaluation.

(3) Projects other than those in the second paragraph may be exempted from retrospective evaluation.

CHAPTER FOUR

Education

Training of personnel who will handle experimental animals

ARTICLE 18 – (1) The issues that must be followed in the training of personnel who will work with experimental animals are stated below:

a) HADYEK is responsible for organizing training programs for researchers who work or will work with laboratory animals, and for opening, organizing and executing laboratory animal use certificate programs. Those who are successful in these programs are given laboratory animal use certificates by the relevant HADYEK.

b) Students, researchers, academic, health, technical and administrative personnel who want to conduct any kind of education, research, application and test using laboratory animals or who contribute to the implementation of these programs by touching laboratory animals are considered laboratory animal users.

c) Experimental animal users cannot perform experiments, training or testing on these animals without obtaining a certificate, and cannot keep these animals in their work areas . In research conducted with farm animals, a veterinarian must be present in the research team. In this case, the veterinarian is not required to have an experimental animal use certificate.

c) HADYEK prepares an in-service training program that includes the procedures and principles that must be followed and that the personnel responsible for the production and breeding of experimental animals must be informed at a minimum level, and periodically monitors its implementation.

d) In a study submitted for HADYEK approval, if the person using the experimental animal does not have a usage certificate, this study will not be approved.

e) A researcher may apply to HADYEK to conduct joint studies with other people as a research conductor if he/she does not have his/her own certificate . Researchers who participate in the research but do not directly perform procedures with experimental animals may continue their experiments with the help of certified experimental animal users.

f) The content of the experimental animal use certificate programs is determined by the decision to be taken by HADMEK and notified to all HADMEKs .

g) HADMEK may update the certification programs when necessary.

g) Attendance at 80% of the courses in laboratory animal use certificate programs is mandatory.

h) In order for trainees to receive a certificate, they must receive at least 70 points out of 100 in the exam at the end of the course.

i) How the certification training programs will be conducted is determined by HADYEK.

i) "Experimental Animal Use Certificate" is given to trainees who register for the experimental animal use certificate programs organized in accordance with the provisions of this Regulation and meet the attendance and success conditions. The experimental animal use certificate is signed by the relevant HADYEK president and the rectors in universities and by the highest level administrator in other institutions and organizations.

j) HADYEKs are obliged to notify HADMEK of the certification training programs they will organize thirty days in advance .

k) HADYEKs are obliged to report to HADMEK the information about the trainees who successfully receive certificates at the end of the certification training programs they organize .

l) HADMEK decides whether the experimental animal use certificates or similar certificates obtained from institutions other than those in accordance with the provisions of this Regulation are equivalent in accordance with the provisions of this Regulation.

m) HADYEK decides whether the undergraduate or graduate level training on the use of experimental animals is equivalent to a certification program, and HADYEK issues certificates to those who complete the training programs deemed appropriate.

CHAPTER FIVE

Miscellaneous and Final Provisions

Registration and identification of experimental animals

ARTICLE 19 – (1) Registration and identification of experimental animals are carried out in accordance with articles 34, 35 and 36 of the Regulation on the Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes published in the Official Gazette dated 13/12/2011 and numbered 28141 by the Ministry of Food, Agriculture and Livestock. Records include the information specified in the statistical forms requested by the Ministry in accordance with the decision of HADMEK.

Supervision and inspection

ARTICLE 20 – (1) Pursuant to Article 17 of the Animal Protection Law No. 5199, all provisions of this Regulation are subject to the inspection of the Ministry in line with the opinion to be given by HADMEK . Inspections may be carried out by the Ministry without notice.

Penalties

ARTICLE 21 – (1) Administrative fines are imposed on those who do not comply with the matters specified in this Regulation and who conduct animal experiments without authorization, in accordance with subparagraph (f) of the first paragraph of Article 28 of the Animal Protection Law No. 5199.

(2) As a result of the inspections conducted by HADMEK, HADYEKs that act contrary to this Regulation are given a written warning to complete their deficiencies within one month and HADYEK activities are suspended for one month until the necessary arrangements are made. If the necessary arrangements are not made, HADYEK activities are stopped for six months. The directive of HADYEK that does not correct the specified deficiencies within six months is terminated.

Security

ARTICLE 22 – (1) The correspondence of local ethics committees is confidential and no information is given to third parties other than the authorized institutions specified in this Regulation.

(2) The Ministry shares information regarding the implementation of this Regulation with institutions and organizations within the scope of international agreements to which our country is a party, when deemed necessary.

(3) Objective information is provided to inform the public about projects where live animals are used, provided that it does not violate property rights and does not disclose confidential information.

The repealed regulation

ARTICLE 23 – (1) The Regulation on the Working Principles and Procedures of the Animal Experimentation Ethics Committees published in the Official Gazette dated 6/7/2006 and numbered 26220 has been repealed.

Transitional provisions

ARTICLE 24 – (1) The current HADMEK continues its duties until a new HADMEK is established.

(2) It is mandatory for the HADYEKs whose directives have been approved to make their directives compatible with this Regulation within two years from the date of entry into force of this Regulation.

Force

ARTICLE 25 – (1) This Regulation shall enter into force on the date of its publication.

Executive

ARTICLE 26 – (1) The Minister of Forestry and Water Affairs shall execute the provisions of this Regulation.