LABORATORY ANIMAL ACT

[Enforcement Date 19. Mar, 2010] [Act No.9932, 18. Jan, 2010, Other Laws and Regulations Amended]
보건복지부(의약품정책과), 02-2023-7351

CHAPTER I GENERAL PROVISIONS

Article 1 (Purpose)

The purpose of this Act is to contribute to the development of life sciences and improvement in national health by enhancing the ethics and reliability on animal testing through appropriate administration of laboratory animals and animal testing.

Article 2 (Definitions)

The definitions of terms used in this Act shall be as follows:

1. The term "animal testing" means testing conducted for laboratory animals or the scientific procedure for scientific purposes, such as education, testing, research and production of biological medicines or such;
2. The term "laboratory animal" means vertebrate used or raised for the purpose of animal testing;
3. The term "disaster" means infection in humans and animals, occurrence of an infectious disease, exposure of harmful substances and environmental pollution or such, due to animal testing;
4. The term "animal testing facilities" means facilities prescribed by Presidential Decree, as facilities for conducting animal testing or raising laboratory animals therefor;
5. The term "laboratory animal production facilities" means facilities producing and raising laboratory animals;
6. The term "operator" means a person who operates animal testing facilities or laboratory animal production facilities.

Article 3 (Objects of Application)

This Act shall apply to administration of animals used in testing required for any of the following subparagraphs and of animal testing facilities thereof or such:

1. Development, safety control and quality control of foods, functional health foods, medical and pharmaceutical products, non-medical and pharmaceutical products, biomedicines, medical appliances, and cosmetics;
2. Safety control and quality control of narcotics.

Article 4 (Relationship with other Acts)

The Animal Protection Act shall apply to the use or administration of laboratory animals, except matters prescribed by this Act.

Article 5 (Duties of the Korea Food and Drug Administration)

(1) The Commissioner of the Korea Food and Drug Administration shall carry out matters referred to in the following subparagraphs to achieve the purposes referred to in Article 1:

1. Formulation and promotion of policies concerning the use and administration of laboratory animals;
2. Support for the establishment and operation of animal testing facilities;
3. Support for the maintenance, conservation and development of laboratory animals in animal testing facilities;
4. Research support for the improvement in quality of laboratory animals;
5. Support for the collection and management of information, and education in connection with laboratory animals;
6. Formulation and promotion of policies concerning the development and approval of methods which can substitute animal testing;
7. Other matters concerning the use and administration of laboratory animals

(2) Matters necessary for carrying out the matters under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

CHAPTER II SCIENTIFIC USE OF LABORATORY ANIMALS

Article 6 (Duties of Operator of Animal Testing Facilities)

An operator of animal testing facilities shall carry out matters referred to in the following subparagraphs in order to secure the safety and reliability of animal testing:

1. Formulation of guidelines on the scientific use and administration of laboratory animals;
2. Education of those who carry out and engage in animal testing;
3. Preferential consideration of methods which can substitute animal testing;
4. Formulation of plans concerning the appropriate disposal of waste matter of animal testing and the safety of workers.

Article 7 (Establishment of Laboratory Animal Management Committee)

(1) A laboratory animal management committee shall be established and managed in animal testing facilities in order to secure the ethics, safety and reliability of animal testing.

(2) Matters necessary for functions and management of a laboratory animal management committee referred to in paragraph (1) shall be prescribed by Presidential Decree.

CHAPTER III ANIMAL TESTING FACILITIES, ETC.

Article 8 (Registration of Animal Testing Facilities)

(1) Any person who intends to establish animal testing facilities shall register with the Commissioner of the Korea Food and Drug Administration. The same shall also apply to

cases where he/she changes matters registered.

(2) An administrator (hereinafter referred to as "administrator") who has qualifications prescribed by Presidential Decree shall be assigned to animal testing facilities to administer the relevant facilities and laboratory animals.

(3) Matters necessary for standards and procedures for registration referred to in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 9 (Use, etc. of Laboratory Animals)

(1) Where a person uses laboratory animals prescribed by Presidential Decree in animal testing facilities, he/she shall endeavor to preferentially use laboratory animals produced in animal testing facilities or excellent laboratory animal production facilities pursuant to Article 15 (1).

(2) Where a person intends to use laboratory animals imported from abroad, he/she shall use laboratory animals meeting the standard prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 10 (Designation of Excellent Animal Testing Facilities)

(1) The Commissioner of the Korea Food and Drug Administration may, for the appropriate use and administration of laboratory animals, designate animal testing facilities which have appropriate human resources and facilities, and the administration condition of which is excellent as excellent animal testing facilities. In such cases, matters concerning the standard for designation, change of matters designated or such, shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

(2) Any person who intends to be designated as excellent animal testing facilities pursuant to paragraph (1) shall apply for designation as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

(3) The Commissioner of the Korea Food and Drug Administration may advise the relevant business operator who uses laboratory animals or a person who carries out research services to conduct such business in excellent animal testing facilities designated pursuant to paragraph (1).

Article 11 (Guidance and Supervision on Animal Testing Facilities)

(1) Any person who has registered as animal testing facilities pursuant to Article 8 or has been designated as excellent animal testing facilities pursuant to Article 10 shall be guided and supervised by the Commissioner of the Korea Food and Drug Administration.

(2) Matters necessary for details, objects, time and standards of guidance and supervision pursuant to paragraph (1) shall be determined by the Commissioner of the Korea Food and Drug Administration.

CHAPTER IV SUPPLY OF LABORATORY ANIMALS

Article 12 (Registration of Supplier of Laboratory Animals)

(1) Any person who intends to engage in business of production, importation or sale of laboratory animals prescribed by Presidential Decree (hereinafter referred to as "supplier of laboratory animals") shall register with the Commissioner of the Korea Food and Drug Administration, as prescribed by Ordinance of the Ministry of Health and Welfare: Provided, That this shall not apply to cases where he/she supplies laboratory animals produced in the process of maintenance or research in animal testing facilities referred to in Article 8. <Amended by Act No. 9932, Jan. 18, 2010>

(2) When a person intends to change any matters registered pursuant to paragraph (1), he/she shall register for change, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 13 (Matters to be Observed by Supplier of Laboratory Animals)

A supplier of laboratory animals shall observe matters referred to in the following subparagraphs to secure the safety and health of laboratory animals: <Amended by Act No. 9932, Jan. 18, 2010>

1. He/she shall administer laboratory animal production facilities and laboratory animals so that no harm may be caused to health and hygiene and the safety may be secured;
2. When he/she transports laboratory animals, he/she shall do so by method suitable to the ecology of such laboratory animals;
3. Other matters prescribed by Ordinance of the Ministry of Health and Welfare deemed necessary for securing the safety and health care of laboratory animals, as matters equivalent to subparagraphs 1 and 2.

Article 14 (Matters concerning Importation of Laboratory Animals)

The provisions of Articles 32, 34, 35 and 36 of the Act on the Prevention of Contagious Animal Diseases shall apply to importation and quarantine of laboratory animals.

Article 15 (Designation of Excellent Laboratory Animal Production Facilities)

(1) The Commissioner of the Korea Food and Drug Administration may, for the improvement of quality of laboratory animals, designate laboratory animal production facilities which have sufficient human resources and facilities, and the administration condition of which is excellent as excellent laboratory animal production facilities. In such cases, matters concerning the standard of designation, change of any matters designated or such, shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

(2) Any person who intends to be designated as excellent laboratory animal production facilities pursuant to paragraph (1) shall apply for designation, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

(3) No person, other than excellent laboratory animal production facilities designated pursuant to paragraph (1), shall attach a mark of excellent laboratory animal production facilities or a mark similar thereto to transporting containers or documents or such, or

shall publicize such.

Article 16 (Guidance and Supervision on Supplier of Laboratory Animals)

(1) Any person who has registered as a supplier of laboratory animals pursuant to Article 12 or has been designated as excellent laboratory animal production facilities pursuant to Article 15 shall be guided and supervised by the Commissioner of the Korea Food and Drug Administration.

(2) Matters concerning objects, time and standards of guidance and supervision pursuant to paragraph (1) shall be determined by the Commissioner of the Korea Food and Drug Administration.

CHAPTER V SAFETY CONTROL

Article 17 (Education)

(1) Persons referred to in the following subparagraphs shall receive education on the use and administration of laboratory animals:

1. A person who has established animal testing facilities pursuant to Article 8 (1);
2. An administrator pursuant to Article 8 (2);
3. A supplier of laboratory animals pursuant to Article 12;
4. A person who conducts animal testing.

(2) The Commissioner of the Korea Food and Drug Administration shall conduct education pursuant to paragraph (1), and matters necessary for institutions entrusted with education, details of education, the reimbursement of expenses incurred or such, shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 18 (Prevention of Disasters)

(1) Where an operator or an administrator of animal testing facilities conducts animal testing using substances or pathogens or such, which may cause any disasters, he/she shall take the necessary measures for not doing any harm to humans and animals.

(2) Where a disaster caused by animal testing facilities and laboratory animal production facilities is deemed detrimental to national health and public good, an operator or an administrator shall take the necessary measures immediately, such as closure, disinfection or such, and then report the results thereof to the Commissioner of the Korea Food and Drug Administration. In such cases, Article 19 of the Act on the Prevention of Contagious Animal Diseases shall apply mutatis mutandis.

(3) Where a disaster caused by animal testing and laboratory animals is deemed detrimental to national health and public good, an operator or an administrator shall take the necessary measures, such as destruction or such, and then report the results thereof to the Commissioner of the Korea Food and Drug Administration. In such cases, Article 20 of the Act on the Prevention of Contagious Animal Diseases shall apply mutatis mutandis.

Article 19 (Reporting on Use of Biological Harmful Substances)

(1) Where an operator of animal testing facilities intends to use any biological harmful substances prescribed by Ordinance of the Ministry of Health and Welfare for animal testing, he/she shall report it in advance to the Commissioner of the Korea Food and Drug Administration. <Amended by Act No. 9932, Jan. 18, 2010>

(2) Matters concerning reporting referred to in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 20 (Waste Matter, such as Carcass)

(1) An operator and an administrator of animal testing facilities or a supplier of laboratory animals shall dispose of carcass of laboratory animals from the relevant facilities lest it should be taken out to outside and reused, or a disaster occurs.

(2) Waste matter, such as carcass of laboratory animals or such from animal testing facilities and laboratory animal production facilities shall be disposed of pursuant to the Wastes Control Act.

CHAPTER VI DISCLOSURE OF RECORDS AND INFORMATION TO PUBLIC

Article 21 (Records)

Any person who conducts animal testing shall record kinds of laboratory animals, quantity used, procedures for researches conducted, participants in research as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 22 (Reporting on Actual Conditions of Animal Testing)

(1) The Commissioner of the Korea Food and Drug Administration shall prepare and publish a report on the actual conditions of animal testing each year.

(2) Matters referred to in the following subparagraphs shall be included in a report on the actual conditions pursuant to paragraph (1): <Amended by Act No. 9932, Jan. 18, 2010>

1. The kinds and number of laboratory animals used for animal testing;
2. Disposal of laboratory animals after animal testing;
3. The kinds and number of animal testing facilities and laboratory animal production facilities;
4. Matters concerning guidance and supervision on animal testing facilities pursuant to Article 11;
5. Matters concerning the use of substances or pathogens causing disasters or such, pursuant to Article 18;
6. Matters concerning the use of harmful substances pursuant to Article 19;
7. Matters concerning the cancellation of designation pursuant to Article 24;
8. Other matters prescribed by Ordinance of the Ministry of Health and Welfare.

CHAPTER VII SUPPLEMENTARY PROVISIONS

Article 23 (Laboratory Animal Association)

(1) The Laboratory Animal Association (hereinafter referred to as the "Association") may be established for the promotion of reliability of animal testing and the sound development of the laboratory animal industry.

(2) The Association shall be a juristic person.

(3) Persons falling under any of the following subparagraphs may be members of the Association:

1. A person who has registered pursuant to Article 8 (1);
2. An administrator pursuant to Article 8 (2);
3. A person determined by the articles of association of the Association among those who have knowledge and technology in the field of laboratory animals.

(4) Where persons intend to establish the Association, they shall prepare the articles of association, as prescribed by Presidential Decree and obtain approval for the establishment of the Commissioner of the Korea Food and Drug Administration.

(5) Matters to be mentioned in the articles of association and matters necessary for business of the Association shall be prescribed by Presidential Decree.

(6) The provisions concerning incorporated associations of the Civil Act shall apply mutatis mutandis to matters not prescribed in this Act on the Association.

(7) The State may, where deemed necessary for the Association to conduct business pursuant to paragraph (1), support finance or such.

Article 24 (Cancellation of Designation)

(1) When any person who has registered as animal testing facilities pursuant to Article 8 or as a suppler of laboratory animals pursuant to Article 12 falls under any of the following subparagraphs, the Commissioner of the Korea Food and Drug Administration may cancel registration of the relevant facilities or supplier, or suspend the operation of facilities or business within six months:

1. Where he/she is found to have registered by fraud or other unlawful means;
2. Where a disaster, such as a disease or such which injures health of people or public good, has occurred from animal testing facilities or in connection with supply of laboratory animals;
3. Where he/she fails to follow guidance and supervision or fails to meet the standard pursuant to Article 11 or 16.

(2) When any person who is designated as excellent animal testing facilities pursuant to Article 10 or as excellent laboratory animal production facilities pursuant to Article 15 falls under any of the following subparagraphs, the Commissioner of the Korea Food and Drug Administration may cancel such designation or suspend the operation of facilities within six months:

1. Where he/she is found to have been designated by fraud or other unlawful means;
2. Where a disaster, such as a disease or such which injures health of people or public good, has occurred from excellent animal testing facilities or excellent laboratory animal production facilities;
3. Where he/she fails to follow guidance and supervision or fails to meet the standard

pursuant to Article 11 or 16.

(3) The standard of disposal pursuant to paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 25 (Disqualifications)

Any person who falls under any of the following subparagraphs shall not be an operator or an administrator of animal testing facilities and a supplier of laboratory animals:

1. A mental patient pursuant to subparagraph 1 of Article 3 of the Mental Health Act: Provided, That this shall not apply to a person deemed appropriate as an operator or an administrator of animal testing facilities by a medical specialist;
2. A person, as an incompetent or a quasi-incompetent, who has not been reinstated;
3. An addict of narcotics or other toxic substances;
4. A person in whose case two years have not passed since his/her imprisonment without prison labor or heavier punishment was completely executed (including cases where the execution is deemed to have been completed) or exempted by court order, in violation of this Act;
5. A person who is under the suspension of the execution of imprisonment without prison labor or heavier punishment by court order, in violation of this Act;
6. A person in whose case two years have not passed since the suspension of the operation of facilities or the cancellation of registration pursuant to Article 24 (1).

Article 26 (Hearings)

when the Commissioner of the Korea Food and Drug Administration intends to cancel registration, suspend operation, or cancel designation of the relevant facilities pursuant to Article 24, he/she shall hold a hearing in advance.

Article 27 (Guidance and Supervision)

(1) The Commissioner of the Korea Food and Drug Administration may have the relevant public official perform a field investigation or request the presentation of necessary materials for guidance and supervision pursuant to Articles 11 and 16.

(2) A public official who performs an investigation pursuant to paragraph (1) shall carry identification showing his/her authority and produce it to the persons concerned.

Article 28 (Penalty Surcharges)

(1) Where an operator of facilities falls under Article 24, the Commissioner of the Korea Food and Drug Administration may impose a penalty surcharge not exceeding 50 million won in lieu of the suspension of operation of the relevant facilities.

(2) Matters necessary for an amount of a penalty surcharge according to degree of an offense on which the penalty surcharge is imposed pursuant to paragraph (1) shall be prescribed by Presidential Decree.

(3) When an operator of facilities fails to pay a penalty surcharge pursuant to paragraph (1) by the deadline, the Commissioner of the Korea Food and Drug Administration may collect it in the same manner as dispositions on default of national taxes.

Article 29 (Fees)

Any person who falls under any of the following subparagraphs shall pay a fee as prescribed by Ordinance of the Ministry of Health and Welfare: <Amended by Act No. 9932, Jan. 18, 2010>

1. A person who intends to register pursuant to Article 8 or to be designated pursuant to Article 10;
2. A person who intends to register pursuant to Article 12 or to be designated pursuant to Article 15.

Article 30 (Penal Provisions)

Any person who has not registered or has not registered a change, in violation of Article 12 (1) or (2) shall be punished by a fine not exceeding five million won.

Article 31 (Penal Provisions)

Any person who has refused, evaded or interfered with a field investigation without any justifiable grounds, or has failed to comply with a request for presentation of materials pursuant to Article 27 (1), or has presented false materials shall be punished by a fine not exceeding two million won.

Article 32 (Joint Penal Provisions)

The representative of a juristic person, an agent, an employee and other employed person of a juristic person or individual has committed an offense falling under Article 31 with regard to business of the juristic person or individual, not only such offender shall be punished but such juristic person or individual shall also be punished by a fine referred to in the relevant provisions.

Article 33 (Fines for Negligence)

(1) Any person who falls under any of the following subparagraphs shall be punished by a fine for negligence not exceeding one million won:

1. A person who has failed to register pursuant to Article 8;
2. A person who has attached a mark of excellent laboratory animal production facilities or a mark similar thereto or has publicized it, in violation of Article 15 (3);
3. A person who established animal testing facilities, an administrator or a supplier of laboratory animals, who has not received education, in violation of Article 17 (1);
4. A person who has failed to report pursuant to Article 18 (2) and (3) or 19 (1) or has made a false report.

(2) Fines for negligence pursuant to paragraph (1) shall be imposed and collected by the Commissioner of the Korea Food and Drug Administration, as prescribed by Presidential Decree.

(3) Any person who is dissatisfied with the disposition of a fine for negligence pursuant to paragraph (2) may raise an objection to the Commissioner of the Korea Food and Drug Administration within 30 days.

(4) When any person who is subject to the disposition of a fine for negligence pursuant to paragraph (2) raises an objection pursuant to paragraph (3), the Commissioner of the

Korea Food and Drug Administration shall notify the competent court of such fact without delay and the competent court notified shall proceed to a trial on a fine for negligence pursuant to the Non-Contentious Case Litigation Procedure Act.
(5) Where any person who is dissatisfied with the disposition of a fine for negligence fails to raise an objection within the period pursuant to paragraph (3) and to pay a fine for negligence, the Commissioner of the Korea Food and Drug Administration shall collect it in the same manner as dispositions on default of national taxes.

ADDENDA

(1) (Enforcement Date) This Act shall enter into force one year after the date of its promulgation.

ADDENDA <Act No. 9932, Jan. 18, 2010>

Article 1 (Enforcement Date)

This Act shall enter into force two months after the date of its promulgation. (Proviso Omitted.)
Articles 2 through 5 Omitted.