SAFETY, MANAGEMENT, ETC. OF HUMAN TISSUE ACT

Act No. 7097, Jan. 20, 2004 Amended by Act No. 7375, Jan. 27, 2005 Act No. 8852, Feb. 29, 2008 Act No. 9932, Jan. 18, 2010 Act No. 10564, Apr. 7, 2011 Act No. 10610, Apr. 28, 2011

CHAPTER I GENERAL PROVISIONS

Article 1 (Purpose)

The purpose of this Act is to provide matters necessary for donation, management and transplant of human tissue for the purpose of physical completion and recovery of biological functions, to promote balanced supply and safety of human tissue, and to contribute to the improvement of public health.

Article 2 (Basic Ideology)

- (1) Donation, management and transplant of human tissue shall be carried out in a humanitarian spirit.
- (2) Expression of intentions regarding donation of human tissue of a person shall be respected. In such cases, such intention shall be voluntary.
- (3) A person in need of a transplant of human tissue shall have an equal opportunity to receive transplant regardless of social or economic conditions.
- (4) Donation, management and transplant of human issue shall be conducted in ethically reasonable and medically accepted manners.

Article 3 (Definitions)

For the purposes of this Act: (Amended by Act No. 7375, Jan. 27, 2005; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)

- 1. The term "human tissue" means any of the following items (hereinafter referred to as "tissue"), which is not an organ under subparagraph 1 of Article 3 of the Internal Organs, etc. Transplant Act:
 - (a) Bones, joints, myofascia, skin, amnion, ligament, and tendon;
 - (b) Heart valves and veins;

- (c) Body parts which may be recovered and transplanted for a person's health, physical recovery and prevention of disability, and which may be determined by Presidential Decree;
- 2. The term "tissue donor" means a person who donates specific tissue without compensation under Ordinance of the Ministry of Health and Welfare;
- 3. The term "tissue transplant" means transplantation of tissue which is donated from a tissue donor and safety of which is guaranteed for the purpose of treatment of illness of a patient;
- 4. The term "tissue bank" means an institution authorized under Article 13 (1) for the management of tissue for the purpose of transplantation;
- 5. The term "tissue management" means recovery, storage, processing, preservation, and allocation of tissue;
- 6. Article 3 of the Internal Organs, etc. Transplant Act shall apply *mutatis mutandis* to the definitions of the terms "living donor," "brain-dead donor," "family," or "surviving family member."

Article 4 (Applicability)

This Act shall apply to tissue produced within Korea, or imported from outside of Korea, for donation from a living donor, a brain-dead donor, or a deceased donor, for management, or for transplantation for the purposes of physical completion and recovery of biological functions: *Provided*, That each of the following subparagraphs shall be excluded: (Amended by Act No. 10564, Apr. 7, 2011)

- 1. Tissue for self-transplant;
- 2. Categories of items or items governed by the Pharmaceutical Affairs Act, the Medical Devices Act, and other Acts and subordinate statutes.

Article 5 (Prohibition of Purchase or Sale, etc. of Tissue)

- (1) No one shall do or promise to do any of the following acts in exchange for money, financial gain, or other consideration:
 - 1. Giving tissue of a brain-dead donor or a deceased donor to a third person, receiving such tissue to give to a third person, or promising to do either act;
 - 2. Giving one's own tissue to another person, receiving tissue from another to transplant into one's own body, or promising to do either act;
 - 3. Assisting another to do any act under subparagraph 1 or 2.
- (2) No person aware of an act in violation of paragraph (1) shall manage or transplant any tissue relating to such act.

Article 6 (Human Tissue Safety and Management Advisory Committee)

(1) The Human Tissue Safety and Management Advisory Committee (hereinafter referred

to as "Committee") shall be established in the Ministry of Health and Welfare, to deliberate on the following matters when the Minister of Health and Welfare requests consultation in connection with donation, management and transplantation of tissue: (Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)

- 1. Matters concerning authorization criteria for tissue banks and their operation;
- 2. Matters concerning management plans for imported tissue;
- 3. Matters concerning accuracy evaluation of tissue quality, tissue testing, or tissue management (hereinafter referred to as "quality control").
- Other matters submitted by the Minister of Health and Welfare in connection with surveys, research, etc. on donation, management and transplantation of tissue.
- (2) Matters necessary for organization and operation of the Committee shall be prescribed by Presidential Decree.

CHAPTER II MANAGEMENT OF TISSUE

Article 7 (Consent to Donate Tissue)

- (1) Article 11 of the Internal Organs, etc. Transplant Act shall apply *mutatis mutandis* to consent to donate tissue.
- (2) Consent under paragraph (1) shall include the following matters: (Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)
- 1. The period of preservation of tissue and other matters concerning such preservation;
- 2. Matters concerning the right of the person who consents to donation, such as revocation of consent, and confidentiality of information;
- 3. Other matters prescribed by the Minister of Health and Welfare.
- (3) When consent under paragraph (1) is obtained, a person who intends to recover tissue shall fully explain matters under paragraph (2) in advance.
- (4) Matters necessary for consent forms, preservation of tissue, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare. (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010)

Article 8 (Requirements for Recovery of Tissue)

(1) Tissue may be recovered from a brain-dead donor or a deceased donor only in cases falling under either of the following: *Provided*, That, in cases of a mentally ill person or a developmentally disabled person, tissue may recovered only under subparagraph 1:

- 1. Cases where a person consents to recovery of tissue before brain death or death: *Provided*, That cases where such person's family or surviving family members clearly express objection to recovery of tissue, etc. shall be excluded;
- 2. Cases where it is unclear whether a person consented or objected to recovery of tissue before brain death or death and the person's family or surviving family members consent to recovery of tissue: Provided, That the parents' consent to recovery is required, in cases where a person is under 16 years of age.
- (2) Where tissue is recovered from a living donor, the persons' consent is required: *Provided*, That, in cases where tissue is recovered from a minor, the parent's consent is required in addition to the persons' consent.
- (3) A person who consents to recovery under paragraph (1) or (2) may revoke his or her consent to recovery anytime before surgery for tissue recovery.

Article 9 (Prohibition of Allocation or Transplant of Tissue)

No tissue falling under any of the following subparagraphs shall be allocated nor transplanted: (Amended by Act No. 7375, Jan. 27, 2005; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)

- Tissue infected or suspected of being infected with contagious diseases unsuitable for transplant, such as hepatitis B or C, shyphilis, Acquired Immune Deficiency Syndrome;
- 2. Tissue from a donor having Alzheimer's disease or a degenerative neurological disease;
- 3. Tissue from a donor with certain cause of death;
- 4. Tissue from a donor exposed to hazardous substances;
- 5. Tissue from a donor whose cancer might have spread and affected such tissue;
- 6. Tissue that is equivalent to those under subparagraphs 1 through 5, that is deemed unsuitable for transplant due to risk of causing harm to the life or body of a transplant recipient, and that is determined as such by Ordinance of the Ministry of Health and Welfare.

Article 10 (Guarantee of Safety of Tissue)

- (1) The Minister of Health and Welfare shall screen and test tissue processed by domestic tissue banks and tissue imported from outside of Korea for suitability of tissue for transplant, as prescribed by Ordinance of the Ministry of Health and Welfare, and shall order destruction of tissue the safety of which is not ensured. (Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)
- (2) The criteria for determination of suitability of tissue transplants under paragraph
- (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. (Amended

by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010

Article 11 (Quality Control of Tissue Banks)

- (1) The Minister of Health and Welfare may order a tissue bank to be subject to quality control and may disclose the results of quality control. (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010)
- (2) The procedures for quality control under paragraph (1), the disclosure of the results of quality control, and other matters necessary for quality control shall be prescribed by Ordinance of the Ministry of Health and Welfare. (Amended by Act No. 9932, Jan. 18, 2010)

Article 12 (Priority for Tissue Transplant)

Where a tissue bank distributes tissue among medical institutions that perform tissue transplants (hereinafter referred to as "tissue transplant hospital"), such tissue bank shall apply the priority ranking for distribution in consideration of the gravity of the urgency and expected results of tissue transplant in medical respect.

Article 13 (Authorization for Tissue Bank)

- (1) A person who intends to establish a tissue bank shall acquire the facilities, equipment, human resources, quality control system, etc. prescribed by Presidential Decree and shall obtain authorization from the Minister of Health and Welfare. (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010)
- (2) A person falling under any of the following subparagraphs may be granted authorization for a tissue bank: *Provided*, That no person falling under subparagraph 3 or 4 may engage in tissue donation or tissue recovery:
- 1. Medical institutions under Article 3 of the Medical Services Act;
- 2. Non-profit corporations whose main purpose of establishment is a business relating to human tissue;
- 3. Tissue processing business operators;
- 4. Tissue importers.
- (3) Activities of tissue banks shall be as follows:
- 1. Recovery, storage, processing, preservation and distribution of tissue;
- 2. Management of tissue donors and public relations work and consultation for tissue donation;
- 3. Selection of tissue donors and guaranteeing tissue quality;
- 4. Other matters necessary for ensuring safety of tissue transplants prescribed by Presidential Decree.

Article 14 (Renewal of Authorization for Tissue Bank)

(1) The Minister of Health and Welfare may order an authorized tissue bank to renew its authorization every three years. (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932,

Jan. 18, 2010>

(2) Matter necessary for the criteria and procedures for authorization renewal under paragraph (1) shall be prescribed by Presidential Decree.

Article 15 (Tissue Bank Rules)

- (1) A tissue bank shall comply with detailed operating guidelines prescribed by the Minister of Health and Welfare in order to endure tissue safety. (Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)
- (2) Where a tissue bank carries out activities in cooperation with other tissue banks, their cooperative relationship and contract relationship shall be clearly set forth.
- (3) A tissue bank shall comply with non-profit principles in provision to a tissue transplant hospital of tissue necessary for surgery: *Provided*, That a tissue bank may demand such tissue transplant hospital to reimburse the costs for donation, preservation, transplant, etc., as prescribed by Ordinance of the Ministry of Health and Welfare. *(Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010)*
- (4) Medical practitioners who handle tissue and other employees, prescribed by Ordinance of the Ministry of Health and Welfare, employed at a tissue bank shall receive a required training prescribed by Ordinance of the Ministry of Health, Welfare and Family Affairs.
 (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010)
- (5) The procedures for provision of tissue, the volume of tissue preservation, the persons in charge of management, the reporting of management status, and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. (Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)

Article 16 (Rules regarding Recovery of Tissue)

- (1) A tissue bank which intends to recover tissue shall comply with the following subparagraphs:
 - 1. A tissue bank shall confirm consent under Articles 7 and 8 (1) and (2);
- 2. A tissue bank shall fully explain the following matters to donors or persons who are authorized to give consent:
 - (a) Matters relating to the completion of questionnaires on medical history, blood serum test, etc.;
 - (b) Details of surgery for tissue recovery;
 - (c) Advance explanation of funeral procedures after tissue donation;
 - (d) Other matters a person must be aware of before tissue donation.
- (2) The details of the procedures, matters to be explained and other necessary matters, which shall be complied with when an explanation under paragraph (1) is given to donors and persons who are authorized to give consent, shall be prescribed by Ordinance of the Ministry of Health and Welfare. (Amended by Act No. 8852, Feb. 29, 2008: Act No.

Article 17 (Importation of Tissue)

- (1) No one, other than tissue banks, may import tissue.
- (2) Specific matters concerning tissue importation shall be prescribed by Presidential Decree.

Article 18 (Priority of Autopsy or Postmortem Examination)

No recovery of tissue may be performed before autopsy or postmortem examination in cases where an autopsy or postmortem examination is required under the Criminal Act or the Quarantine Act: Provided, that tissue recovery may be performed with authorization by a public prosecutor of a competent District Public Prosecutors' Office or its branch office or the director of a competent quarantine station and with consent of the surviving family members, in cases where a medical care provider making diagnosis determines that there is no correlation between the tissue to be recovered and the cause of death and that, if recovery is delayed until after autopsy or postmortem examination, tissue might not be recovered at all within the period that allows recovery.

Article 19 (Compilation, Reporting, etc. of Records)

- (1) A tissue bank shall keep records of data relating to donation, management and transplantation of tissue and report to the Minister of Health and Welfare annually, as prescribed by Ordinance of the Ministry of Health and Welfare. (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010)
- (2) A tissue transplant hospital shall notify tissue banks of the results of transplant, as prescribed by Ordinance of the Ministry of Health and Welfare. The tissue bank so notified shall include such notice in its report submitted under paragraph (1). (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010)
- (3) Where any serious side effects prescribed by Ordinance of the Ministry of Health and Welfare, such as infection, occur in connection with a tissue transplant, tissue banks and tissue transplant hospitals shall immediately report such occurrence to the Minister of Health and Welfare. (Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)

Article 20 (Maintenance of Records)

The head of a tissue bank or tissue transplant hospital shall maintain the records relating to donation, management and transplantation of tissue for 10 years, as prescribed by the Minister of Health and Welfare. (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010)

Article 21 (Perusal, etc. of Records)

Where a donor or a donor's surviving family member demands perusal of, or issuance of copies of, the records relating to recovery or transplant of relevant tissue, the head of the relevant tissue bank shall allow perusal or issue copies of the records of overall process of tissue donation or the records relating to transplant: *Provided*, That, when a medical care provider making diagnosis determines that such act might seriously interfere with the treatment or recovery of a tissue donor or a tissue recipient, such medical care provider may refuse to allow perusal or issuance of copies of the records.

Article 22 (Confidentiality)

- (1) Unless otherwise provided for in this Act, a person who is employed by a tissue bank or a tissue transplant hospital or who engages in business relating to donation, management or transplantation of tissue shall not convey information falling under any of the following subparagraphs to persons other than those who engage in business relating to recovery and transplant of tissue of a relevant tissue donor:
 - 1. Matters concerning tissue donors and recovered tissue;
- 2. Matters concerning transplant recipients and transplanted tissue;
- 3. Matters concerning persons who wish to donate tissue.
- (2) Paragraph (1) shall not apply to the following cases:
- 1. Where a criminal investigation agency requests data relating to recovery or transplant of tissue;
- 2. Where a judge requests, in connection with a trial, any data relating to recovery or transplant of tissue.

CHAPTER III SUPERVISION

Article 23 (Reporting, Inspection, etc.)

- (1) The Minister of Health and Welfare may issue the head of a tissue bank or a tissue transplant hospital or its employee necessary orders relating to his/her duties or may order reporting or submission of relevant documents, where the Minister deems it necessary in relation to donation, management or transplant of tissue. (Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)
- (2) The Minister of Health and Welfare may order relevant public officials to inspect relevant documents of tissue banks, etc. under paragraph (1), as prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, the relevant public officials in charge of inspection shall carry proof of authority and shall produce such proof to relevant persons. (Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)
- (3) The head of a tissue bank or a tissue transplant hospital or its employee shall comply with an order or cooperate with inspection under paragraphs (1) and (2), unless justifiable

grounds exist to the contrary.

Article 24 (Corrective Orders)

Where the head of a tissue bank or a tissue transplant hospital or its employee falls under any of the following subparagraphs, the Minister of Health and Welfare may order the head of a relevant organization to make corrections within a set period: (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010)

- 1. Failing to file a report under Article 19;
- 2. Failing to maintain the records under Article 20.

Article 25 (Revocation of Authorization)

- (1) Where a tissue bank falls under any of the following subparagraphs, the Minister of Health and Welfare may revoke authorization for the tissue bank or may fully or partially suspend the business for a set period of not more than one year, as prescribed by Ordinance of the Ministry of Health and Welfare: \(\lambda mended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010 \rangle \)
 - 1. Failing to acquire facilities, equipment, human resources, quality control system, etc. under Article 13 (1);
 - 2. Failing to comply with an order under Article 23 (1) or failing to cooperate with inspection under paragraph (2) of the same Article;
 - 3. Failing to comply with a corrective order under Article 24.
- (2) Where a tissue bank carries out its business in violation of an order of business suspension under paragraph (1), the Minister of Health and Welfare may revoke authorization for such tissue bank. (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010)
- (3) No tissue bank whose authorization is revoked under paragraph (1) or (2) may obtain authorization for tissue bank within one year after the date on which such authorization is revoked.
- (4) Detailed guidelines regarding administrative dispositions under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare in consideration of the types and degree of violations. (Amended by Act No. 9932, Jan. 18, 2010)

Article 26 (Reporting Termination of Business, etc. and Transfer of Data)

- (1) Where a tissue bank intends to terminate its business, such tissue bank shall report to the Minister of Health and Welfare the matters relating to tissue donors and processed or preserved tissue. (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010) (2) The head of a tissue bank which terminates its business under paragraph (1) or whose authorization is revoked under Article 25 shall transfer relevant data to the Minister
- whose authorization is revoked under Article 25 shall transfer relevant data to the Minister of the Minister of Health and Welfare, as prescribed by Presidential Decree. (Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)

CHAPTER IV SUPPLEMENTARY PROVISIONS

Article 27 (Aid for Tissue Banks, etc.)

The State or local governments may provide necessary aid for tissue banks or tissue donors within budget limits.

Article 28 (Delegation of Authority)

The Minister of Health and Welfare may delegate part of his/her authority to the head of a subordinate agency, the Administrator of the Korea Food and Drug Administration, the Special Metropolitan City Mayor, the Metropolitan City Mayor, the Do Governor, the head of a Si/Cun/Cu (referring to the head of an autonomous Cu; hereinafter the same shall apply), as prescribed by Presidential Decree. (Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)

Article 29 (Obligation to Cooperate)

The Minister of Health and Welfare may request the heads of relevant agencies to take measures necessary for safe and speedy recovery, transport or transplant of tissue. In such cases, the heads of relevant agencies shall comply with such request unless justifiable grounds exist to the contrary. (Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010)

Article 30 (Hearings)

When the Minister of Health and Welfare intends to revoke authorization for a tissue bank under Article 25, he/she shall hold a hearing. (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010)

Article 31 (Responsibility for Costs)

- (1) A person who receives tissue transplant shall bear the costs of recovery and transplant of tissue: *Provided*, that the payment of such costs shall be made as prescribed by other Acts and subordinate statutes if such other Acts and subordinates statutes expressly provide otherwise.
- (2) Computation of costs under paragraph (1) shall be made under the National Health Insurance Act: *Provided*, That computation of costs not provided for in the National Health Insurance Act shall be made as prescribed by Ordinance of the Ministry of Health and Welfare. *Amended by Act No. 9932, Jan. 18, 2010*

CHAPTER V PENAL PROVISIONS

Article 32 (Penal Provision)

A person who distributes tissue falling under any subparagraph of Article 9 for transplantation into another person or who transplants such tissue, in violation of Article 9, shall be punished by imprisonment for life or imprisonment for not less than two years.

Article 33 (Penal Provisions)

- (1) A person who gives, receives, or promises to give or receive money, etc. and violates Article 5 (1) 1 or 3 shall be punished by imprisonment for not more than seven years.
- (2) A person who gives, receives, or promises to give or receive money, etc. and violates Article 5 (1) 2 shall be punished by imprisonment for not more than five years or by a fine not exceeding 30 million won, or may be punished by both such fine and imprisonment.
- (3) Any money, financial gain, or other consideration exchanged in violation of paragraph
- (1) or (2) shall be confiscated: *Provided*, That, in cases where such confiscation is not feasible, an amount equivalent to the value thereof shall be collected.

Article 34 (Penal Provisions)

A person falling under any of the following subparagraphs shall be punished by imprisonment for not more than two years or a fine not exceeding 10 million won:

- 1. A person who manages or transplants tissue in violation of Article 5 (2);
- 2. A person who establishes a tissue bank without authorization, in violation of Article 13;
- A person who conveys information relating to tissue donors or recovered tissue in violation of Article 22.

Article 35 (Concurrent Imposition of Suspension)

Where a person who violates this Act is punished by imprisonment for a limited term, he/she may also be punished by suspension of qualification for not more than 10 years.

Article 36 (Joint Penal Provisions)

Where a representative of a corporation, or an agent, employee or other servant of a corporation or an individual violates Article 33 (2) or 34 in relation to the duties of the corporation or individual, not only shall such offender be punished accordingly, but the corporation or individual shall also be punished by a fine prescribed in the relevant provisions: Provided, That the same shall not apply where the corporation or individual has not been negligent in giving due attention and supervision concerning the relevant duties in order to prevent such violation. (Amended by Act No. 10610, Apr. 28, 2011)

Article 37 (Fines for Negligence)

(1) A person who falls under any of the following subparagraphs shall be punished

by a fine for negligence not exceeding five million won:

- 1. A person who fails to confirm consent or fails to give full explanation, in violation of Article 16 (1);
- 2. A person who recovers tissue in violation of the main sentence of Article 18.
- (2) A person who falls under any of the following subparagraphs shall be punished by a fine for negligence not exceeding three million won:
- 1. A person who fails to keep records or fails to report, in violation of Article 19;
- 2. A person who fails to maintain records, in violation of Article 20;
- 3. A person who fails to comply with a request for perusal of records or issuance of copies, in violation of the main sentence of Article 21;
- 4. A person who fails to comply with an order under Article 23 (1);
- 5. A person who fails to comply with an order under Article 24;
- 6. A person who fails to report or fails to transfer data, in violation of Article 26.

Article 38 (Imposition of Fines for Negligence and Collection Procedure)

- (1) The Minister of Health and Welfare, the head of a subordinate agency, the Special Metropolitan City Mayor, the Metropolitan City Mayor, the Do Governor, or the head of a Si/Gun/Gu (hereinafter referred to as "imposing authority") may impose and collect fines for negligence under Article 37, as prescribed by Presidential Decree. (Amended by Act No. 8852, Feb. 29, 2008: Act No. 9932, Jan. 18, 2010)
- (2) A person who is dissatisfied with a fine for negligence under paragraph (1) may raise an objection to the imposing authority within 30 days after the notice of fine.
- (3) Where a person who has been punished by a fine for negligence under paragraph
- (1) raises an objection under paragraph (2), the imposing authority shall immediately notify the competent court of such fact; and the competent court in receipt of such notice shall proceed to a trial on the fine for negligence under the Non-Contentious Case Litigation Procedure Act.
- (4) When a person fails to raise an objection or to pay the fine for negligence within the period under paragraph (2), the fine for negligence shall be collected in accordance with the practices of dispositions of default on national or local taxes.

ADDENDA

Article 1 (Enforcement Date)

This Act shall enter into force on January 1, 2005.

Article 2 (Preparation for Organization of Human Tissue Safety and Management Advisory

Committee)

The Minister of Health, Welfare and Family Affairs may carry out necessary duties for the purpose of organizing the Human Tissue Safety and Management Advisory Committee under Article 6 before the Act enters into force.

Article 3 (Preparation for Establishment of and Authorization for Tissue Bank)
The Minister of Health, Welfare and Family Affairs and the heads of tissue banks
may carry out duties necessary for the establishment and authorization of tissue
banks under Article 13 before the Act enters into force.

ADDENDUM (Act No. 7375, Jan. 27, 2005)

This Act shall enter into force on the date of its promulgation.

ADDENDA (Act No. 8852, Feb. 29, 2008)

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 7 Omitted.

ADDENDA (Act No. 9932, Jan. 18, 2010)

Article 1 (Enforcement Date)

This Act shall enter into force two months from the date of its promulgation. (Proviso Omitted.)

Articles 2 through 5 Omitted.

ADDENDA (Act No. 10564, Apr. 7, 2011)

Article 1 (Enforcement Date)

This Act shall enter into force six months from the date of its promulgation. (Proviso Omitted.)

Articles 2 through 9 Omitted.

ADDENDUM (Act No. 10610, Apr. 28, 2011)

This Act shall enter into force on the date of its promulgation.