

# Enforcement Decree of the Health Functional Food Act

Enacted by Presidential Decree No. 18164, Dec. 18, 2003

Amended by Presidential Decree No. 19513, Jun. 12, 2006

Amended by Presidential Decree No. 19836, Jan. 18, 2007

**Article 1 (Purpose)** The purpose of this Decree is to provide matters delegated by the 「Health Functional Food Act」 and matters necessary for the enforcement thereof.  
<Amended on January 18, 2007>

**Article 2 (Types of business)** The detailed types and scope of business referred to in Article 4(2) of the 「Health Functional Food Act」 (hereinafter referred to as the “Act”) are as follows <Amended on January 18, 2007>:

1. Health functional food manufacture business

- (a) Health functional food manufacture-specializing business: a business which specializes in manufacture health functional food.
- (b) Health functional food manufacture venture business : a business in which a venture business under the provisions of Article 2 of the 「Act on Special Measures for the Promotion of Venture Businesses」 entrusts a health functional food manufacture- specializing business person under item (a) with manufacturing a health functional food.

2. Health functional food import business: a business engaged in importing a health functional food

3. Health functional food sales business

(a) Health functional food general sales business : a business which sells a health functional food in a business place, by the door-to-door sale, the multi-level sale or the telephone solicit sale under the provisions of Article 2 of the 「Door-to-Door Sales」 , etc. Act, or by the electronic commerce transaction or the mail order, etc. under the provisions of Article 2 of the 「Act on the Consumer Protection in the Electronic Commerce Transactions」 , etc.

(b) Health functional food distribution-specializing sales business: a business in which a person distributes and sells under his trade mark such health functional food manufactured at his request by a health functional food manufacture-specializing business person under subparagraph 1 (a).

**Article 3 (Modification permission of matter subject to permission)** The modification matter subject to permission under the latter part of Article 5(1) of the Act shall be the modification of the location of business establishment.

**Article 4 (Qualification criteria of quality manager)** The qualification criteria of quality manager as provided in Article 12(5) of the Act shall be as follows:

1. A certified food engineer under the National Technical Qualifications Act;
2. A certified food technician under the National Technical Qualifications Act, who has engaged in a manufacturing work of health functional food, its ingredients and

components, general food or food additive (hereinafter referred as “health functional food, etc.” in this Article) for one year or more;

3. A person who has graduated from a department or faculty in the fields related to food, such as food processing science, food chemistry, food manufacturing science, food engineering, sitology, nutritional science, sanitary science, zymologic engineering, agricultural chemistry, microbiology, genetic engineering, biotechnology etc. (hereinafter referred to as “food-related fields” in this Article) at a school under the provisions of the subparagraphs of Article 2 of the Higher Education Act (except a college under paragraph (4) of the same Article, hereinafter referred to as “a university, etc.” in this Article) or a certified food technician under the National Technical Qualifications Act, who has engaged in a manufacturing work of health functional food etc. for three years or more;
4. A person who obtained a bachelor degree in food-related fields at a university etc., obtained a master degree in food-related fields at a graduate school under the provisions of Article 29 of the Higher Education Act (hereinafter referred to as “a graduate school” in this Article), and engaged in a manufacturing work of health functional food etc. for one year or more;
5. A person who obtained a bachelor degree not in food-related fields at a university etc., obtained a master degree in food-related fields at a graduate school, and engaged in a manufacturing work of health functional food etc. for three years or more;
6. A person who has graduated from a college under the provisions of Article 2(4) of the Higher Education Act (including the person who was recognized to have an

academic background equivalent to this by laws and ordinances, and engaged in a manufacturing work of health functional food etc. for five years or more;

7. A person who has graduated from a high school or technical high school under the provisions of Article 2(4) of the Elementary and Secondary Education Act (including the person who was recognized to have an academic background equivalent to this by laws and ordinances, and engaged in a manufacturing work of health functional food etc. for eight years or more; and

8. A person recognized by the Minister of Health and Welfare that he has a qualification, academic background or career equivalent to and above subparagraphs 1 through 7.

[Wholly amended on January 18, 2007]

**Article 5 (Duties of quality manager)** The duties of quality manager as provided in Article 12(5) of the Act are as follows:

1. To secure safety of health functional food;
2. To manage qualities of products and ingredients through the self quality examination, etc. under the provisions of Article 21 of the Act;
3. To maintain manufacturing facilities and products to be sanitary; and
4. To direct and supervise the employees and to educate and train them.

**Article 6 (Head of subordinated agencies)** The term “his subordinate agencies as prescribed by the Presidential Decree” in Article 20(1) of the Act means the Commissioners of the Regional Food and Drug Administrations referred to in the

provisions of Article 20(1) of the 「Service Regulations of the Food and Drug Administration and Its Subordinate Agencies」 . <Amended on January 18, 2007>:

**Article 7 (Composition of health functional food Deliberation Committee)** (1) The Health

Functional Food Deliberation Committee referred to in the provisions of Article 27 of the Act (hereinafter referred to as the “Deliberation Committee”) shall be composed of between thirty and eighty members including one chairman and two vice-chairmen.

(2) The chairman shall be elected from among its members, and the vice-chairmen shall be appointed by the chairman from among the members.

(3) The members shall be <Amended on June 12, 2006, January 18, 2007> -:

1. appointed by the Minister of Health and Welfare from the fifth-ranking and above public officials in charge of relevant health functional food affairs or the public officials in general service of the Senior Executive Service; or

2. commissioned by the Minister of Health and Welfare from-

(a) persons with extensive learning and experience in foods, medicines, nutrition and health care; or

(b) persons recommended by heads of health functional food related organizations, citizen's organizations (referring to the non-profit non-governmental organization under Article 2 of the 「Assistance for Nonprofit Non-Governmental Organizations Act」 ), health functional food related academic societies, or universities.

(4) The members under paragraph (3)1 shall hold office as long as he holds his office, and the terms of office of the members under paragraph (3)2 shall be two years.

**Article 8 (Operation of the Deliberation Committee)** (1) The chairman shall represent the

Deliberation Committee and exercise general control over the business of the Deliberation Committee.

(2) The vice-chairmen shall assist the chairman and the vice-chairman, designated by the chairman, acts on behalf of the chairman when the chairman is unable to perform his duties due to unavoidable reasons.

(3) The chairman shall convene meetings and preside over the meetings.

(4) The meeting of the Deliberation Committee shall start a deliberation with the attendance of a majority of the total members and make a decision with a concurring vote of a majority of those present.

(5) In the case where a request for the convocation of a meeting is filed by the Minister of Health and Welfare, the Commissioner of the Food and Drug Administration or not less than one-third of the members, the chairman shall convene the meeting without delay.

**Article 9 (Subcommittees)** (1) The Deliberation Committee may have subcommittees by

specialized field in order to discharge its duties efficiently.

(2) Matters decided by a subcommittee shall be reported to the chairman and deliberated by the Deliberation Committee. Provided, that if the chairman deems matters minor, he may substitute a decision by the Deliberation Committee upon the matters with one by a subcommittee upon them.

**Article 10 (Research fellows)** (1) The Deliberation Committee may appoint twenty or fewer research fellows for the purpose of researches and studies on the standards and specifications of the health functional food and the labeling and advertising thereof, etc.

(2) The research fellows shall be appointed by the Minister of Health and Welfare from persons with extensive learning and experience in the health functional foods, or the foods, etc.

(3) The research fellows may attend and have a say in meetings of the Deliberation Committee or a subcommittee.

**Article 11 (Audience of opinions)** The chairman may request for attendance of the persons concerned and ask their opinions, if he determines it necessary to do so in regard to matters on the agenda of the Deliberation Committee or a subcommittee.

**Article 12 (Secretary)** (1) One secretary shall be put in the Deliberation Committee to deal with general affairs of the Deliberation Committee.

(2) The secretary shall be appointed by the Minister of Health and Welfare from the competent public officials of the Ministry of Health and Welfare.

**Article 13 (Report)** The chairman shall report matters deliberated by the Deliberation Committee to the Minister of Health and Welfare without delay.

**Article 14 (Allowances and travel expenses)** (1) The members present at the meetings of the Deliberation Committee may be provided, within the budget limit, with allowances, travel expenses and other required expenses: Provided, That the same shall not apply to the public officials present at the meetings directly related to affairs under their jurisdiction.

(2) The Minister of Health and Welfare or the Commissioner of the Food and Drug Administration may, within the budget limit, provide the research fellows with research and study funds, and other related expenses for their researches, studies, etc.

**Article 15 (Detailed regulations of operation)** Other matters than those prescribed by this Decree, the matters for the operation of the Deliberation Committee and those necessary for the services of research fellows shall be prescribed by the Minister of Health and Welfare.

**Article 16 (Establishment authorization of associations)** (1) The term “type of business as determined by the Presidential Decree” in Article 28(1) of the Act means the type of business described in Article 2.

(2) Any person who intends to obtain an authorization of an association establishment pursuant to the provisions of Article 28(3) of the Act shall submit to the Minister of Health and Welfare the documents(including electronic documents) prescribed in the Ordinance of the Ministry of Health and Welfare. <Amended on January 18, 2007>



**Article 17 (Time limit of business permission revocation, etc.)** In case where a hearing under Article 36 of the Act has been held or an opinion has been received under Article 27 of the 「Administrative Procedures Act」 in order to impose sanctions, such as the business permission revocation, the business suspension, the business establishment closure, the item or items manufacturing suspension, etc., the Commissioner of the Food and Drug Administration or the Special Metropolitan City Mayor, Metropolitan City Mayor, or *Do* governor (hereinafter referred to as “Mayor/*Do* governor”) shall impose the sanction within fourteen days after the relevant procedures are finished unless there exist any special reasons. <Amended on January 18, 2007>

**Article 18 (Types of offense to be imposed a penalty surcharge and the amount thereof)** The amount of penalty surcharges imposed under the provisions of Article 37(2) of the Act shall be assessed, in consideration of the types, the degree, etc. of a violation in question, by applying the standards listed in annexed the Table 1 in accordance with the period of business suspension or item or items manufacturing suspension as prescribed by the Ordinance of the Ministry of Health and Welfare.

**Article 19 (Procedures for imposing and paying penalty surcharges, etc.)** (1) In case where intending to impose a penalty surcharge pursuant to the provisions of Article 37 of the Act, the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor shall specify the type of offense and its corresponding amount of penalty surcharge in a written form and give a notice of the payment of the penalty surcharge.

(2) A person received a notice under paragraph (1) shall pay the penalty surcharge to a receiving agency designated by the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor within twenty days from the day he has received the notice. Provided, That if the person is not able to pay the penalty surcharge within the specified days due to *force majeure* or other unavoidable causes, the person shall pay it within seven days from the day the cause has ceased to exist.

(3) When it receives the penalty surcharge under the provisions of paragraph (2), the receiving agency shall issue a receipt and inform, without delay, the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor that it has received the penalty surcharge.

(4) The procedures for the penalty surcharge levy shall be prescribed by the Ordinance of the Ministry of Health and Welfare.

(5) The required expenses granted by the Mayor/*Do* governor under the provisions of Article 37(5) of the Act shall be equivalent to one-tenth of the amount levied by the head of local government (it means the head of autonomous *Gu*; hereinafter the same shall apply). In this case, the Mayor/*Do* governor shall give the required expenses from the penalty surcharges paid to the Food Promotion Fund to the head of local government concerned by the following month after monthly calculation.

**Article 20 (Delegation and entrustment of authority)** (1) The Commissioner of the Food and Drug Administration shall delegate his authority related to the following subparagraphs to the Commissioner of the Regional Food and Drug Administration under Article 41(1) of the Act: <Amended on January 18, 2007>

1. The business operation report and the modification report of the health functional food import business under Articles 6(1) and (3) of the Act;
2. The import report and the examination of the health functional food under Articles 8(1) through (3) of the Act, excluding the import report and the examination in a district which is under the jurisdiction of the head of the National Quarantine Service, from among districts under the jurisdiction of the Commissioner of the Regional Food and Drug Administration;
3. The business person status succession report of the health functional food import business under Article 11(3) of the Act;
4. The administrative sanctions under Articles 29 through 32, 35, 36, and 38(2) of the Act (excluding cases where the item manufacturing suspension measure under Article 59 of the 「Food Sanitation Act」 shall be applied *mutatis mutandis*), etc. against a business person of the health functional food import business under Article 4(1)2 of the Act ; and
5. The imposing and collecting a penalty surcharge and a fine for negligence under Articles 37 and 47 of the Act against a business person of the health functional food import business under Article 4(1)2 of the Act.

(2) From among the authority of the Mayor/*Do* governor, the authority related to the following subparagraphs shall be delegated to the head of local government pursuant to Article 41(2) of the Act<Amended on January 18, 2007>:

1. The business operation report and the modification report of the health functional food sales business under Articles 6(2) and (3) of the Act;

2. The business person status succession report of the health functional food sales business under Article 11(3) of the Act;
3. The administrative sanctions under Articles 29 through 32, 35, 36, and 38(2) of the Act (excluding cases where the item manufacturing suspension measure under Article 59 of the 「Food Sanitation Act」 shall be applied *mutatis mutandis*), etc. against a business person of the health functional food sales business under Article 4(1)3 of the Act ; and
4. The imposing and collecting a penalty surcharge and a fine for negligence under Articles 37 and 47 of the Act against a business person of the health functional food sales business under Article 4(1)3 of the Act.

(3) With respect to districts under the jurisdiction of the head of the National Quarantine Service, from among districts under the jurisdiction of the Commissioner of the Regional Food and Drug Administration, the Commissioner of the Food and Drug Administration shall, pursuant to Article 41(1) of the Act, entrust his authority related to the import report and the examination of health functional food under Article 8 of the Act to the head of the National Quarantine Service.

**Article 21 (Procedures for imposing and collecting a fine for negligence)** (1) In the case where intending to impose a fine for negligence pursuant to the provisions of Article 47(2) of the Act, the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor shall investigate and confirm the violation in question and then notify the party subject to the disposition of fine for negligence with a fine for negligence payment notice specifying the fact of violation in question, the

corresponding amount of fine for negligence, the due date for payment, the receiving agency, the appeal method, the period for raising the appeal, etc.

(2) In case where intending to impose the fine for negligence pursuant to the provisions of paragraph (1), the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor shall give the party subject to the disposition of fine for negligence an opportunity to state his opinion in writing or orally specifying the time limit not less than 10 days: Provided, That the party subject to the disposition concerned shall be deemed to have no objection in case he fails to respond to such opportunity within the specified time limit.

(3) The standards of fine for negligence to be imposed shall be as listed in annexed the Table 2. Provided, That the detailed standards of fine for negligence related to matters as determined by the Ordinance of the Ministry of Health and Welfare, that shall be complied by the business person under Article 10(1)5 of the Act, shall be prescribed by the Ordinance of the Ministry of Health and Welfare.

(4) The Commissioner of the Food and Drug Administration or the Mayor/*Do* governor may reduce the amount within the limit of one half of the amount under paragraph (3) by taking account of the motives, the facts, the recall, etc. of the violation.

#### **ADDENDA** <Presidential Decree No. 18164, Dec. 18, 2003>

**Article 1 (Enforcement Date)** This Decree shall enter into force on the date of its promulgation.

**Article 2 (Transitional measures concerning the business report of health functional food sales business)** Any person, who sells a health functional food or has filed a distribution specializing

business under Article 13 of the Food Sanitation Act at the time this Decree enters into force, shall equip with the facilities by type of business in accordance with the Ordinance of the Ministry of Health and Welfare and file a report of business within six months after this Decree enters into force.

**Article 3 (Amendment to other subordinated statutes)** The Enforcement Decree of the Food Sanitation Act shall be amended as follows:

Subparagraph 4-2 shall be prescribed in Article 13(2) as follows:

4-2. Where a person carries on the business after obtaining a business permission for or filing a report of the health functional food manufacturing business, the health functional food import business and the health functional food sales business under the provisions of Articles 5 and 6 of the Health Functional Food Act. “food sanitation, national nutrition and health functional food” shall replaces “food sanitation and national nutrition” in the subparagraphs of Article 42 (1), and subparagraph 7 shall be prescribed in the same Article as follows:

7. Assistance to the business person who complies with the Good Manufacturing Practices under the provisions of Article 22 of the Health Functional Food Act, or intends to install related facilities, etc. to comply with it.

**ADDENDA (Personnel Regulation on the Senior Executive Service)**

<Presidential Decree No. 19513, June 12, 2006>

**Article 1 (Enforcement Date)** This Decree shall enter into force on July 1, 2006.

**Articles 2 and 3** Omitted.

**Article 4 (Amendment to other subordinated statutes)** (1) Omitted.

(2) The Enforcement Decree of the Health Functional Food Act shall be amended as follows: “the fifth-ranked and above public officials or the public officials in general service of the Senior Executive Service” shall replaces “the fifth-ranked and above public officials” in Article 7(3)1.

(3) through (241) Omitted.

**ADDENDA** <Presidential Decree No. 19836, Jan. 18, 2007>

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

[Annexed the Table 1]

The standards to calculate penalty surcharge  
(related to Article 18)

**1. General standard**

- (a) The base period of one month of business suspension shall be 30 days.
- (b) The standard annual sales for the calculation of penalty surcharge in lieu of the business suspension shall be the total sales of the previous year of the disposition. Provided, that if it is unable to calculate the total sales of the whole year due to the new business or the business close, etc., it shall be calculated by the quarterly, monthly or daily total sales.
- (c) The standard annual sales for the calculation of penalty surcharge in lieu of the items manufacturing suspension shall be the item total sales, which falls under the items in question, of the previous year of the disposition. Provided, that if it is unable to calculate the item total sales, which falls under the items in question, of the whole year due to the new manufacture or the business close, etc., it shall be calculated by the quarterly, monthly or daily total sales.
- (d) The standard annual sales for the calculation of penalty surcharge in lieu of the item manufacturing suspension shall be calculated by multiplying 4 by the total sales of the previous three months which are retroactive from the month of the disposition date. Provided, That if it is unable to calculate the total sales of the latest three



months due to the new manufacture or the business close, etc., it shall be calculated by multiplying 365 by one day average sales of the previous month (when it is unable to identify the previous month sales, it shall be the said month).

## 2. The standard of penalty charge

| Type of business Grade | The annual sales(unit : million won)  |   |  | The penalty surcharge on one day of the business or manufacturing suspension (unit : won) |
|------------------------|---|---|--|---|
|                        | health functional food import business and sales business (exceeding ~ not exceeding) | health functional food manufacture business (exceeding ~ not exceeding) | the item or items manufacturing suspension (exceeding ~ not exceeding) |   |
| 1                      | ~ 30  |   |  | 80,000  |
| 2                      | 30 ~ 50   | ~ 100   | ~ 100  | 120,000   |
| 3                      | 50 ~ 100  | 100 ~ 200   | 100 ~ 200  | 200,000   |
| 4                      | 100 ~ 150   | 200 ~ 310   | 200 ~ 300  | 280,000   |
| 5                      | 150 ~ 210   | 310 ~ 430   | 300 ~ 400  | 360,000   |
| 6                      | 210 ~ 270   | 430 ~ 560   | 400 ~ 500  | 440,000   |
| 7                      | 270 ~ 330   | 560 ~ 700   | 500 ~ 650  | 520,000   |
| 8                      | 330 ~ 400   | 700 ~ 860   | 650 ~ 800  | 600,000   |
| 9                      | 400 ~ 470   | 860 ~ 1,040   | 800 ~ 950  | 680,000   |
| 10                     | 470 ~ 550   | 1,040 ~ 1,240   | 950 ~ 1,100  | 760,000   |
| 11                     | 550 ~ 650   | 1,240 ~ 1,460   | 1,100 ~ 1,300  | 820,000   |
| 12                     | 650 ~ 750   | 1,460 ~ 1,710   | 1,300 ~ 1,500  | 880,000   |
| 13                     | 750 ~ 850   | 1,710 ~ 2,000   | 1,500 ~ 1,700  | 940,000   |
| 14                     | 850 ~ 1,000   | 2,000 ~ 2,300   | 1,700 ~ 2,000  | 1,000,000   |
| 15                     | 1,000 ~ 1,200   | 2,300 ~ 2,600   | 2,000 ~ 2,300  | ,060,000  |
| 16                     | 1,200 ~ 1,500   | 2,600 ~ 3,000   | 2,300 ~ 2,700  | 1,120,000   |
| 17                     | 1,500 ~ 2,000   | 3,000 ~ 3,400   | 2,700 ~ 3,100  | 1,180,000   |
| 18                     | 2,000 ~ 2,500   | 3,400 ~ 3,800   | 3,100 ~ 3,600  | 1,240,000   |
| 19                     | 2,500 ~ 3,000   | 3,800 ~ 4,300   | 3,600 ~ 4,100  | 1,300,000   |
| 20                     | 3,000 ~ 4,000   | 4,300 ~ 4,800   | 4,100 ~ 4,700  | 1,360,000   |
| 21                     | 4,000 ~ 5,000   | 4,800 ~ 5,400   | 4,700 ~ 5,300  | 1,420,000   |
| 22                     | 5,000 ~ 6,500   | 5,400 ~ 6,000   | 5,300 ~ 6,000  | 1,480,000   |
| 23                     | 6,500 ~ 8,000   | 6,000 ~ 6,700   | 6,000 ~ 6,700  | 1,540,000   |
| 24                     | 8,000 ~ 10,000  | 6,700 ~ 7,500   | 6,700 ~ 7,400  | 1,600,000   |
| 25                     | 10,000 ~ 12,000   | 7,500 ~ 8,600   | 7,400 ~ 8,200  | 1,660,000   |
| 26                     | 12,000 ~ 15,000   | 8,600 ~ 10,000  | 8,200 ~ 9,000  | 1,720,000   |
| 27                     | 15,000 ~ 20,000   | 10,000 ~ 12,000   | 9,000 ~ 10,000   | 1,780,000   |
| 28                     | 20,000 ~ 25,000   | 12,000 ~ 15,000   | 10,000 ~ 11,000  | 1,840,000   |
| 29                     | 25,000 ~ 30,000   | 15,000 ~ 20,000   | 11,000 ~ 12,000  | 1,900,000   |
| 30                     | 30,000 ~ 35,000   | 20,000 ~ 25,000   | 12,000 ~ 13,000  | 1,960,000   |
| 31                     | 35,000 ~ 40,000   | 25,000 ~ 30,000   | 13,000 ~ 15,000  | 2,020,000   |
| 32                     | ~ 40,000  | 30,000 ~ 35,000   | 15,000 ~ 17,000  | 2,080,000   |
| 33                     |   | 35,000 ~ 40,000   | 17,000 ~ 20,000  | 2,140,000   |
| 34                     |   | ~ 40,000  | ~ 20,000   | 2,200,000   |

[Annexed the Table 2]

The standard of fine for negligence (related to Article 21)

| NO. | Act           | The type of violation   | Fine for negligence(won)         |
|-----|---------------|---|----------------------------------|
| 1   | Article 5(2)  | A business person who has not reported the modification of the business permission  | 3 million                        |
| 2   | Article 6(3)  | A business person who has not reported the modification of the business report  | 1 million                        |
| 3   | Article 7(1)  | A business person who has not reported the modification of the item manufacture report  | 1 million                        |
| 4   | Article 10(1) | (a) A business person who has not controlled the manufacturing facilities and products (including raw materials) in order to prevent sanitary hazard and to ensure safety<br><br>(b) A person who has not complied with matters as prescribed by the Ordinance of the Ministry of Health and Welfare, which are other matters corresponding to subparagraph (a) for the purpose of ensuring safety and controlling quality of health functional food, and promoting public health | 3 million<br><br>1 million       |
| 5   | Article 10(2) | A business person who has not notified of the production records or has notified a false production records   | 1 million<br><br>3 million       |
| 6   | Article 12(3) | A business person who has obstructed the quality manager's work   | 2 million                        |
| 7   | Article 12(4) | A business person who has not reported the appointment or the dismissal of a quality manager  | 1 million<br>300,000             |
| 8   | Article 13(1) | (a) A business person who has not received the education<br><br>(b) A employee who has not received the education   | 2 million<br>500,000<br>3million |

|    |               |  |           |
|----|---------------|--|-----------|
| 9  | Article 13(2) | A business person who has not received the education   | 3 million |
| 10 | Article 13(3) | A quality manager who has not received the education   |           |
| 11 | Article 21(1) | A business person who has not kept the records or has made a false data after the self quality examination |           |
| 12 | Article 31(1) | A business person who fails to improve or repair the facilities according to the order issued              |           |