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Food Safety Basic Act (Act No. 48 of 2003)

Chapter I General Provisions

Article 1 (Purpose)

In consideration of the vital importance of precise responses to the development of science and technology, and to the progress of internationalization and other changes in the environment surrounding Japan's dietary habits, the purpose of this Act is to comprehensively promote policies to ensure food safety by establishing basic principles, by clarifying the responsibilities of the national and local governments, and food-related business operators and the roles of consumers, and establishing a basic direction for policy formulation, in order to ensure food safety.

Article 2 (Definition)

The term "Food" as used in this Act shall mean all food and drink (excluding pharmaceutical products or quasi-pharmaceutical products specified by the Pharmaceutical Affairs Act (Act No. 145 of 1960)).

Article 3 (Basic Recognition in Taking Measures for Ensuring Food Safety)

Food safety shall be ensured by taking the necessary measures based on the basic recognition that the protection of the health of our citizens is a top priority.

Article 4 (Appropriate Measures at Each Stage of the Food Supply Process)

Food safety may be affected by every element in a series of internal and external Food supply processes, from the production of agricultural, forestry, and fishery products to Food sales (hereinafter referred to as the "Food Supply Process"); thus

shall be ensured by taking the necessary measures appropriately at each stage of the Food Supply Processes.

Article 5 (Prevention of Adverse Effects on the Health of Citizens)

Food safety shall be ensured by taking the necessary measures on the basis of scientific knowledge and in sufficient consideration of international trends and the opinions of citizens with respect to ensuring Food safety, for the purpose of preventing adverse effects on the health of citizens due caused by ingestion of Food.

Article 6 (Responsibilities of the National Government)

The national government shall be responsible for formulating and implementing comprehensive policies to ensure Food safety on the code of basic principles for ensuring Food safety, provided in the preceding three articles (hereinafter referred to as the "Basic Principles").

Article 7 (Responsibilities of Local Governments)

Local governments shall be responsible, pursuant to the Basic Principles, and based on an appropriate sharing of roles with the national government, for formulating and implementing policies to ensure Food safety that suit their natural and socioeconomic characteristics of the area.

Article 8 (Responsibility of Food-related Business Operators)

- (1) Business operators that produce, import, sell, or conduct other business for fertilizers, agricultural chemicals, feed, feed additives, veterinary medicines and other production materials for agriculture, forestry, or fishery that may have an effect on Food safety, Food (including agricultural, forestry, and fishery products used as raw materials or materials), additives (those provided in Article 4, paragraph (2) of the Food Sanitation Act (Act No. 233 of 1947)), apparatus (that provided in paragraph (4) of the said Article) or containers and packaging (those provided in paragraph (5) of the said Article) (hereinafter referred to as "Food-related Business Operators") shall be responsible for appropriately taking the necessary measures to ensure Food safety at each stage of the Food Supply Processes. This will be done according to the code of the Basic Principles and on the basis of the recognition that they bear the primary responsibility for ensuring Food safety when conducting their business activities.
- (2) In addition to what is prescribed in the preceding paragraph, Food-related Business Operators shall, in conducting their business activities, make efforts to provide accurate and appropriate information concerning Food and other articles related to their own business activities on the code of the basic principles.
- (3) In addition to what is prescribed in the preceding two paragraphs, Food-related

Business Operators shall be responsible for cooperating in policies that are implemented by the national or the local governments, on the code of the Basic Principles, to ensure Food safety.

Article 9 (Consumer's Role)

Consumers shall play an active role in ensuring Food safety by endeavoring to improve their own knowledge and understanding of Food safety and by making efforts to express their opinions about policies to ensure Food safety.

Article 10 (Legislative Measures)

The government shall take legislative or financial measures and other necessary measures to implement policies to ensure Food safety.

Chapter II Basic Direction for Policy Formulation

Article 11 (Implementation of Assessment of the Effect of Food on Health)

- (1) In formulating policies to ensure Food safety, assessment (hereinafter referred to as the "Assessment of the Effect of Food on Health") shall be made for each policy on the effects that potentially harmful biological, chemical, or physical agents likely to be contained in Food, or conditions under which Food is likely to be placed, have on human health, through the ingestion of the Food, provided that this shall not apply to the following cases:
 - (i) Where the Assessment of the Effect of Food on Health is explicitly unnecessary in consideration of the substance of the policy.
 - (ii) Where the substance and degree of adverse effects on human health are clear.
 - (iii) Where there is no time to conduct an Assessment of the Effect of Food on Health in advance in cases where the measure is urgently necessary to prevent or restrain an adverse effect on human health.
- (2) In cases as cited in item (iii) of the preceding paragraph, the Assessment of the Effect of Food on Health shall be conducted subsequently and without delay.
- (3) The Assessment of the Effect of Food on Health provided in the preceding two paragraphs shall be conducted in an objective, neutral, and fair manner on the basis of the state-of-the-art scientific knowledge of the time.

Article 12 (Formulation of Policies on the Basis of the Results of the Assessment of the Effect of Food on Health in Consideration of the Conditions of the Dietary Habits of Citizens and Other Circumstances)

In formulating policies to ensure Food safety, it shall be conducted for the purpose of preventing and restraining the adverse effect of Food ingestion on human health, in consideration of the dietary habits of citizens and other circumstances, and on the

basis of the results of the Assessment of Effect of Food on Health if conducted in accordance with the provisions of paragraph (1) or (2) of the preceding article.

Article 13 (Promotion of Exchanges of Information and Opinions)

In formulating policies to ensure Food safety, necessary measures for promoting the mutual exchange of information and opinions among persons or parties concerned, such as provision of information concerning the policies and the granting of opportunities to comment on those policies, shall be taken to reflect public opinion in the formulation of the policies and to ensure the transparency and fairness of the process.

Article 14 (Establishment of a System to Cope with Emergency and Other Situations)

In formulating policies to ensure Food safety, necessary measures, such as establishment of a system to cope with or prevent emergency situations that cause or are likely to cause serious damage to human health by Food ingestion, shall be taken to prevent such damage.

Article 15 (Close and Mutual Coordination among Relevant Administrative Organs)

In formulating policies to ensure Food safety, close and mutual coordination among relevant administrative organs shall be made to create the necessary measures for ensuring Food safety to be appropriately taken at each stage of the Food Supply Processes.

Article 16 (Establishment of Test and Research and Other Systems)

In formulating policies to ensure Food safety, necessary measures, such as establishment of test and research systems, promotion of research and development, dissemination of results thereof and training of researchers, shall be taken in consideration that efforts to improve scientific knowledge are important for ensuring Food safety.

Article 17 (Collection, Arrangement, and Utilization of Internal and External Information)

In formulating policies to ensure Food safety, necessary measures such as the collection, arrangement, and utilization of internal and external information about ensuring Food safety, shall be taken to appropriately and effectively implement the necessary measures for ensuring Food safety in response to changes in the environment surrounding dietary habits of citizens.

Article 18 (Ensuring Appropriate Labeling)

In formulating policies to ensure Food safety, necessary measures for accurately

transmitting the information on Food, such as ensuring the appropriate operation of a Food labeling system, shall be taken in consideration that Food labeling plays an important role in ensuring Food safety.

Article 19 (Education and Learning regarding Ensuring Food Safety)

In formulating policies to ensure Food safety, necessary measures for improving knowledge and understanding of ensuring Food safety among citizens shall be taken by promoting education and learning and improving public relations activities on ensuring Food safety.

Article 20 (Consideration for Effects on the Environment)

In formulating policies to ensure Food safety, it shall be conducted in consideration of the effects of policies on the environment.

Article 21 (Determination and Publication of Basic Matters Concerning Implementation of Measures)

- (1) The government shall determine basic matters concerning implementation of measures (hereinafter referred to as "Basic Matters") that are to be taken in accordance with the provisions of Articles 11 to 20.
- (2) The Prime Minister shall formulate a draft of Basic Matters after hearing the opinions of the Food Safety Commission and ask the Cabinet for its decision.
- (3) The Prime Minister shall publicize the Basic Matters without delay once the Cabinet has made its decision in accordance with the provision of the preceding paragraph.
- (4) The provisions of the preceding two paragraphs shall apply mutatis mutandis to the changes of the Basic Matters.

Chapter III Food Safety Commission

Article 22 (Establishment)

The Food Safety Commission (hereinafter referred to as the "Commission") shall be established in the Cabinet Office.

Article 23 (Affairs under the Jurisdiction)

The Commission shall take charge of the affairs listed in the following items:

- (i) to offer opinions to the Prime Minister in accordance with the provisions of Article 21, paragraph (2).
- (ii) to conduct an Assessment of the Effects of Food on Health in accordance with the provisions of the following article or at its direction.
- (iii) to make recommendations to relevant ministers through the Prime Minister

about policies to be implemented for ensuring Food safety on the basis of the results of the Assessment of the Effect of Food on Health which was conducted in accordance with the provisions of the preceding item.

- (iv) to monitor the implementation conditions of policies that are implemented on the basis of the results of the Assessment of the Effect of Food on Health, which was conducted in accordance with the provisions of item (ii), and to make recommendations to relevant ministers through the Prime Minister if necessary.
 - (v) to examine and deliberate on important matters regarding policies to be implemented for ensuring Food safety, and to give opinions to the heads of relevant administrative organs if necessary.
 - (vi) to conduct scientific research and study necessary to perform affairs cited in items (ii) to (v).
 - (vii) to plan and implement the mutual exchange of information and opinions among persons or parties concerned with respect of affairs cited in items (ii) to (vi).
 - (viii) to coordinate affairs conducted by relevant administrative organs regarding the mutual exchange of information and opinions among persons or parties concerned with respect to ensuring Food safety.
- (2) When the Commission conducts the Assessment of the Effect of Food on Health in accordance with the provisions of item (ii) of the preceding paragraph, it shall notify relevant ministers of the results of the assessment without delay.
- (3) When the Commission has given notification in accordance with the provisions of the preceding paragraph or made a recommendation in accordance with the provisions of item (iii) or (iv) of paragraph (1), it shall publicize the contents of the notification or the recommendation without delay.
- (4) Relevant ministers shall report to the Commission on policies that they have implemented on the basis of a recommendation in accordance with the provisions of item (iii) or (iv) of paragraph (1).

Article 24 (Hearing of the Commission's opinions)

- (1) In any of the following cases, relevant ministers shall hear the Commission's opinions, provided that this shall not apply to cases that the Commission recognizes as falling under Article 11, paragraph (1), item (i) or that the relevant minister recognizes as falling under item (iii) of the same paragraph:
- (i) When intending to specify cases that involves no risk to human health as provided in the proviso of Article 6, paragraph (2) of the Food Sanitation Act (including cases where it applies *mutatis mutandis* in Article 62, paragraph (2) of the said Act), when intending to prohibit the sales in accordance with the provisions cited in paragraphs (1) to (3) of Article 7 of the said Act or to rescind the prohibition in whole or in part in accordance with the provision of paragraph

- (4) of the said Article, when intending to enact, amend or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 9, paragraph (1) of the said Act, when intending to specify cases as having no risk to human health as provided in Article 10 of the said Act, when intending to establish criteria or standards in accordance with the provisions of Article 11, paragraph (1) of the said Act (including cases where it applies mutatis mutandis in Article 62, paragraph (2) of the said Act), when intending to specify substances as clearly having no risk to human health or the quantity as having no risk to human provided Article 11, paragraph (3) of the said Act, when intending to establish criteria or standards in accordance with the provisions of Article 18, paragraph (1) of the said Act (including cases where it applies mutatis mutandis in Article 62, paragraph (3) of the said Act), or when intending to establish standards in accordance with the provisions of Article 50, paragraph (1) of the said Act.
- (ii) When intending to set, change, or abolish official specifications in accordance with the provisions of Article 1-3 of the Agricultural Chemicals Control Act (Act No. 82 of 1948), when intending to designate or change the designation of specified agricultural chemicals in accordance with the provisions of Article 2, paragraph (1) of the said Act, or when intending to establish or change the standards (excluding standards for determining whether falling under cases cited in Article 3, paragraph (1), item (vi) or (vii) of the said Act) provided in Article 3, paragraph (2) of the said Act (including cases where it applies mutatis mutandis in Article 15-2, paragraph (6) of the said Act).
- (iii) When intending to set, change, or abolish official specifications in accordance with the provisions of Article 3 of the Fertilizer Control Act (Act No. 127 of 1950), when intending to enact, amend, or abolish the Cabinet Order provided in Article 4, paragraph (1), item (iv) of the said Act, when intending to register or register provisionally specified normal fertilizers in accordance with the provisions of Article 7, paragraph (1) or Article 8, paragraph (3) of the said Act (including cases where it applies mutatis mutandis in Article 33-2, paragraph (6) of the said Act), when intending to register or register provisionally changes of specified normal fertilizers in accordance with the provisions of Article 13-2, paragraph (2) of the said Act (including cases where it applies mutatis mutandis in Article 33-2, paragraph (6) of the said Act), or when intending to register or register provisionally changes of specified normal fertilizers, or to abolish registrations or provisional registrations in accordance with the provisions of Article 13-3, paragraph (1) of the said Act (including cases where it applies mutatis mutandis in Article 33-2, paragraph (6) in the said Act).
- (iv) When intending to form a plan for enactment, amendment, or abolishment of the Cabinet Order provided in Article 2, paragraph (1) of the Act on Domestic Animal Infectious Diseases Control (Act No. 166 of 1951), when intending to

- enact, revise, or abolish the Ministry of Agriculture, Forestry and Fisheries Ordinance, which prescribes notifiable infectious diseases referred to in Article 4, paragraph (1) of the said Act, or when intending to form a plan for enactment, amendment, or abolishment of the Cabinet Order provided in Article 62, paragraph (1) of the said Act.
- (v) When intending to designate feed additives in accordance with the provisions of Article 2, paragraph (3) of the Act Concerning Safety Assurance and Quality Improvement of Feed (Act No. 35 of 1953), when intending to establish, amend, or abolish standards or specifications in accordance with the provisions of Article 3, paragraph (1) of the said Act, or when intending to prohibit manufacture, import, sales, or use in accordance with the provisions of Article 23 of the said Act.
- (vi) When intending to enact, amend, or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 6, Article 9, Article 13, paragraph (1), item (iii), or Article 14, paragraph (6), item (ii) or (iii) of the Slaughterhouse Act (Act No. 114 of 1953), or when intending to form a plan for enactment, amendment, or abolishment of the Cabinet Order provided in Article 14, paragraph (7) of the said Act.
- (vii) When intending to enact, amend, or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 4, paragraph (2) (limited to the part pertaining to the provisions of paragraph (1), items (i) to (iii) of the said article) of the Waterworks Act (Act No. 177 of 1957).
- (viii) When intending to give approval for pharmaceutical products, quasi-pharmaceutical products, or medical instruments for the purpose of use for animals (hereinafter referred to as "veterinary medicine, etc.") in accordance with the provisions of Article 14, paragraph (1) of the Pharmaceutical Affairs Act or the provisions of the said paragraph applied, with the necessary replacements, in accordance with the provisions of Article 83, paragraph (1) of the said Act, when intending to give approval for veterinary medicine, etc. in accordance with the provisions of Article 14-3, paragraph (1) of the said Act (including cases where it applies mutatis mutandis in Article 20, paragraph (1) of the said Act; the same shall apply hereinafter) or the provisions of the said paragraph applied, with the necessary replacements, in accordance with the provisions of Article 83, paragraph (1) of the said Act, when intending to conduct a re-examination of veterinary medicine, etc. in accordance with the provisions of Article 14-4, paragraph (1) of the said Act (including cases where it applies mutatis mutandis in Article 19-4, the same shall apply hereinafter) or the provisions of the said paragraph applied, with the necessary replacements, in accordance with the provisions of Article 83, paragraph (1) of the said Act, when intending to conduct re-assessment of veterinary medicine, etc. in accordance with the provisions of

Article 14-6, paragraph (1) of the said Act (including cases where it applies mutatis mutandis in Article 19-4 of the said Act; the same shall apply hereinafter) or the provisions of the said paragraph applied, with the necessary replacements, in accordance with the provisions of Article 83, paragraph (1) of the said Act, when intending to give approval for veterinary medicine, etc. in accordance with the provisions of Article 19-2, paragraph (1) of the said Act or the provisions of the said paragraph applied, with the necessary replacements, in accordance with the provisions of Article 83, paragraph (1) of the said Act, or when intending to enact, amend, or abolish the Ministry of Agriculture, Forestry and Fisheries Ordinance provided in Article 83-5, paragraph (1) of the said Act or the provisions of Article 14, paragraph (2), item (iii) of the said Act applied, with the necessary replacements, in accordance with the provisions of Article 83, paragraph (1) of the said Act.

- (ix) When intending to form a plan for the enactment, amendment, or abolishment of the Cabinet Order (limited to those that designate substances contained in agricultural land soil, which are feared to become the source of the production of agricultural crops, and livestock that are feared to be harmful to human health) provided in Article 2, paragraph (3) of the Agricultural Land Soil Pollution Prevention Act (Act No. 139 of 1970) or the Cabinet Order provided in Article 3, paragraph (1) of the said Act (limited to those that prescribe conditions for areas where the agricultural lands are understood to be used for the production of agricultural crops and livestock that are feared to be harmful to human health or where the fear thereof is understood to be conspicuous).
- (x) When intending to enact, amend, or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 11, Article 15, paragraph (4), item (ii) or (iii), paragraph (6) or Article 19 of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (Act No. 70 of 1990).
- (xi) When intending to erase or exclude the name of additives in accordance with the provisions of Article 2-2, paragraph (1) of Supplementary Provisions of The Act for Partial Revision of the Food Sanitation Act and the Nutrition Improvement Act (Act No. 101 of 1995).
- (xii) When intending to form a plan for enactment, amendment, or abolishment of the Cabinet Order provided in Article 6, paragraph (1) of the Act on Special Measures Concerning Dioxins (Act No. 105 of 1999).
- (xiii) When intending to enact, amend, or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 7, paragraph (1) or (2) of the Act on Special Measures Concerning Bovine Spongiform Encephalopathy (Act No. 70 of 2002).
- (xiv) In addition to those cited in the preceding items, cases provided by the Cabinet Order.

- (2) In cases falling under the proviso of the preceding paragraph (limited to cases recognized by the relevant ministers as falling under Article 11, paragraph (1), item (iii)), relevant ministers shall report such fact to the Commission and hear its opinions within a certain period of time after the formulation of policies to ensure the safety of the Food.
- (3) In addition to cases provided in paragraph (1), relevant ministers may hear the Commission's opinions if they are recognized as necessary for formulating policies to ensure Food safety.

Article 25 (Request of Document Submission)

The Commission may request that the heads of relevant administrative organs submit materials, opinions, and explanations and provide other necessary cooperation, if it is recognized to be necessary for performing affairs under the jurisdiction.

Article 26 (Entrustment of Investigation)

The Commission may entrust necessary investigations to incorporated administrative agencies, juristic persons incorporated in accordance with the provisions of Article 34 of the Civil Code (Law No. 89 of 1896), enterprises and other private bodies, prefectural experimental and research institutes, or persons of learning and experience, if it is recognized to be necessary for performing affairs under the jurisdiction.

Article 27 (Request in an Emergency)

- (1) The Commission may request that the test and research institutes of relevant national administrative organs conduct an investigation, analysis, or examination necessary for the Assessment of the Effect of Food on Health if it is recognized to be necessary for coping with emergency situations that cause or are likely to cause serious damage concerning ensuring Food safety.
- (2) If the test and research institutes of relevant national administrative organs receive a request from the Commission in accordance with the provisions of the preceding paragraph, they shall promptly implement the requested research, analysis, or examination.
- (3) The Commission may request that relevant ministers make a demand in accordance with the provisions of Article 13, paragraph (1) of the Incorporated Administrative Agency, National Institute of Health and Nutrition Act (Act No. 180 of 1999) or a request in accordance with the provisions of Article 12, paragraph (1) of the Incorporated Administrative Agency, Food and Agricultural Materials Inspection Center Act (Act No. 183 of 1999), Article 18, paragraph (1) of the Incorporated Administrative Agency, National Agriculture and Food Research

Organization Act (Act No. 192 of 1999), Article 13, paragraph (1) of the Incorporated Administrative Agency, National Institute for Agro-Environmental Sciences Act (Act No. 194 of 1999), or Article 15, paragraph (1) of the Incorporated Administrative Agency, Fisheries Research Agency Act (Act No. 199 of 1999), if it is recognized to be necessary for coping with emergency situations that cause or are likely to cause serious damage to the ensuring of Food safety.

Article 28 (Organization)

- (1) The Commission shall be organized by seven commission members.
- (2) Three out of the seven Commission Members shall be part-time members.

Article 29 (Appointment of Commission Members)

- (1) Commission Members shall be appointed by the Prime Minister upon obtaining consent of both houses of Diet from among persons who have excellent knowledge and experience of ensuring Food safety.
- (2) In spite of the provisions of the preceding paragraph, the Prime Minister may appoint Commission Members who have qualifications as provided in the preceding paragraph, if he/she cannot obtain consent of the appointment from both houses of Diet due to the Diet's closing or the dissolution of the House of Representatives in cases where the term of the Commission Members has expired or a vacancy for a Commission Member arises.
- (3) In the case of the preceding paragraph, the Prime Minister shall obtain subsequent approval of both houses of Diet at the first Diet session after the relevant appointment. If the Prime Minister cannot obtain subsequent approval of both houses of Diet in such a case, the Prime Minister shall immediately dismiss the Commission Member.

Article 30 (Term of Office of Commission Members)

- (1) The term of office of the Commission Member shall be three years, provided that the term of a substitute Commission Member shall be the remaining term of his/her predecessor.
- (2) The Commission Member may be reappointed.
- (3) When the terms of office of the Commission Member expire, such Commission Members shall perform their duties continuously until their successors are appointed.

Article 31 (Dismissal of Commission Members)

With consent of both houses of Diet, the Prime Minister may dismiss the Commission Member if the Commission member is recognized as being incapable of performing his/her duties due to physical or mental disability or if recognized as

constituting a violation of his/her official obligations or other delinquency inappropriate for a Commission Member.

Article 32 (Discipline of Commission Members)

- (1) The Commission Member shall not divulge any secrecy which becomes known to him/her in connection with his/her duty. The same shall apply after his/her retirement.
- (2) During the term of office, the Commission Member shall not be an officer of a political party or other political bodies nor shall engage in political movements actively.
- (3) During the term of office, the full-time Commission Member shall not engage in other jobs with remuneration, run business for profit purposes or operate other businesses seeking for monetary interest unless he/she is permitted by the Prime Minister.

Article 33 (Salary of Commission Members)

The salary of the Commission Member shall be provided for in a separate Act.

Article 34 (Chairperson)

- (1) The position of Chairperson shall be established in the Commission and the Chairperson shall be appointed by full-time Commission Members by a mutual vote among the Commission Members.
- (2) The Chairperson shall preside over the affairs of the Commission and represent it.
- (3) In the event that the Chairperson has an accident, the full-time Commission Member who has been designated in advance by the Chairperson shall perform the duties of the Chairperson.

Article 35 (Meeting)

- (1) The Chairperson shall convene a meeting of the Commission.
- (2) The Commission shall not hold a meeting nor make any decisions without the attendance of the Chairperson and at least three Commission Members.
- (3) Decisions of the Commission shall be made by the majority of attendees, and in the case of tie, the Chairperson shall make a decision.
- (4) With respect to the application of the provisions of paragraph (2) about cases in which the Chairperson is in an accident, the Committee Member provided in paragraph (3) of the preceding article shall be deemed to be the Chairperson.

Article 36 (Expert Commission Member)

- (1) The Commission may request an Expert Commission Member to examine and

deliberate on specialized matters.

- (2) The Prime Minister shall appoint the Expert Commission Member from among persons with relevant knowledge and experience.
- (3) The Expert Commission Member shall be dismissed upon termination of the examination and deliberation of the relevant specialized matters.
- (4) The Expert Commission Member shall be part-time.

Article 37 (Secretariat)

- (1) The secretariat shall be established in the Commission for the purpose of dealing with the office work of the Commission.
- (2) The secretariat shall have a secretary-general and necessary staffs.
- (3) The secretary-general shall control the matters of the secretariat by following instructions of the Chairperson.

Article 38 (Delegation to a Cabinet Order)

In addition to what is provided for in this Chapter, necessary matters concerning the Commission shall be prescribed by a Cabinet Order.