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Autodeclaración de restitución de estatus libre de influenza aviar en aves de corral enviada por Japón

Declaración enviada a la OIE el 15 de abril de 2018 por el Dr. Kazuo ITO, Delegado de Japón ante la OIE, Director del Servicio de cuarentena animal, Ministerio de Agricultura, Silvicultura y Pesca de Japón (MAFF por sus siglas en inglés)

I. Situación de la influenza aviar de alta patogenicidad en Japón - 2018

El 10 de enero de 2018, un productor avícola reportó una mortalidad más elevada de esperado. El 12 de enero de 2018 el caso sospechoso se confirmó como IAAP subtipo H5N6, y se notificó a través del Sistema Mundial de Información Zoonosaria de la OIE (WAHIS). La explotación afectada se encontraba en ciudad de Sanuki, Prefectura de Kagawa, y tenía alrededor de 51 000 pollos parrilleros al momento.

El caso de IAAP H5N6 anterior en una granja de aves de corral había ocurrido el 24 de marzo de 2017 y la última autodeclaración de estatus para la influenza aviar había sido enviada a la OIE a través de WAHIS el 28 de junio de 2017.

II. Medidas de control y vigilancia para investigación de brotes

La vigilancia se llevó a cabo acorde con los Artículos 10.4.27. a 10.4.33. del *Código Sanitario para los Animales Terrestres* de la OIE (*Código Terrestre*) y no se ha notificado ningún otro caso de influenza aviar.

Se aplicaron las siguientes medidas de emergencia:

- (1) Medidas de control en la granja afectada y en una granja epidemiológicamente relacionada (que es administrada y alimentada por el mismo equipo, en adelante la “granja relacionada”).
 - Matanza de todas aves de corral
 - Incineración/enterramiento/compostaje con restos y material infectado/heces, etc.
 - Desinfección de las granjas

(2) Otras medidas de control

- Establecimiento de zonas de restricción
- Establecimiento de puntos de desinfección de vehículos y desinfección de vehículos en dichos puntos
- Vigilancia de rastreo durante el brote y vigilancia para demostrar ausencia de infección

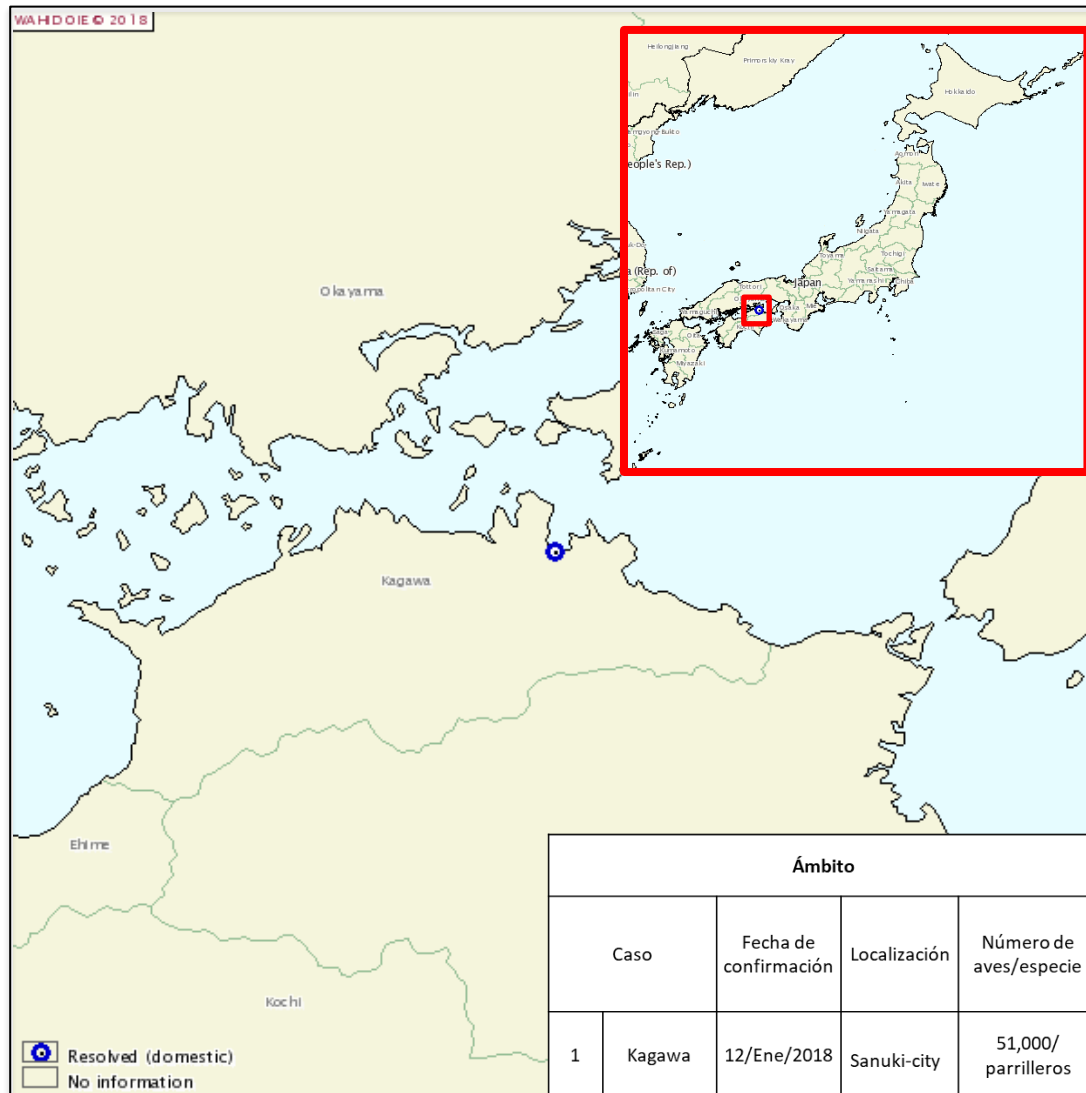


Figure 1. Brote de influenza aviar en aves de corral, Sanuki-Kagawa, Japón, 2018

El MAFF de Japón no adoptó la vacunación de emergencia y en las zonas con restricción de movimiento, ninguna granja estuvo exenta de la vigilancia de rastreo durante el brote o la vigilancia para demostrar ausencia de infección.

Establecimiento de zonas de restricción

Área: en un radio de 3 km de la granja afectada y de la granja relacionada

Destinada a: aves de corral (vivas y muertas), huevos, heces, equipo, piensos, camas, otras mercancías que podrían propagar el virus

Contenido de la restricción: movimiento de mercancías definidas.

Levantamiento: la restricción fue levantada una vez que las zonas cumplieron con las siguientes condiciones:

- (i) Vigilancia para demostración de ausencia de infección con resultados negativos para por IAAP;
- (ii) Pasados los 21 días desde la realización de las medidas de control en la granja afectada y la granja relacionada.

Restricciones de transporte aplicadas como se indica a continuación

Área: en un radio de 3 km de la granja afectada y de la granja relacionada

Destinada a: aves de corral (vivas y muertas), huevos, heces, equipo, piensos, camas, otras mercancías que puedan propagar el virus

Contenido de la restricción: movimiento de las mercancías definidas hacia el exterior de las zonas de restricción (excluyendo las aves enviadas directamente al matadero y los huevos enviados al centro de clasificación y embalaje). Se autorizó el transporte entre zonas de restricción.

Levantamiento: se levantó la restricción una vez que las zonas cumplieron con la condición (i) mencionada anteriormente.



Figure 2. Zonas bajo restricción sanitaria para el control de la influenza aviar, Kagawa, Japan, 2018

Situación			
Medidas de control efectuadas			
(0 días)	→ 10 días	→	21 días
Medidas de control (sacrificio y desinfección)	Vigilancia para demostración de ausencia de infección	Levantamiento de la restricción de traslado	Levantamiento de la restricción de movimiento
Del 11 al 14 de enero Concluído	Del 25 al 29 de enero Concluído	30 de enero Levantada	5 de febrero Levantada

* Área bajo restricción de movimiento (Circulo naranja), Área con restricción de transporte (circulo verde)

Vigilancia para investigación de brotes

Según la Guía para el control de enfermedades infecciosas específicas de los animales domésticos en lo relativo a la influenza aviar de alta patogenicidad y la influenza aviar de baja patogenicidad (en adelante la “Guía”) elaborada por el MAFF, en caso de brote de IAAP, los veterinarios oficiales deben visitar inmediatamente todas las granjas avícolas (donde se crían al menos 100 aves), en principio en un plazo de 24 horas, en la zona de restricción movimientos alrededor de la granja afectada, y llevarán a cabo inspección clínica, aislamiento del virus y pruebas serológicas de anticuerpos.

Vigilancia para demostrar ausencia de infección

La Guía estipula que la vigilancia para demostrar ausencia de infección, aplicando los mismos procedimientos de prueba que la vigilancia para la investigación de brotes, debe llevarse a cabo 10 días después de la finalización de las medidas de control en todas las granjas afectadas ubicadas dentro de la zona de restricción de movimientos.

Tras la aparición de IAAP en la granja de Sanuki-shi en enero de 2018, seis granjas localizadas en la zona de restricción de movimiento fueron muestreadas y todas las muestras dieron negativo tanto para la vigilancia de rastreo durante los brotes como para la vigilancia para demostración de ausencia de infección.

Table 1. Control measures and surveillance of avian influenza in areas under sanitary restrictions, Kagawa, Japan, 2018

Area	Numero de granjas	Tipo de restricción	Vigilancia de rastreo durante el brote		Vigilancia para demostración ausencia de infección	
			Pruebas de anticuerpo negativas	Aislamiento viral negativo	Pruebas de anticuerpo negativas	Aislamiento viral negativo
Dentro de un radio de 3 km	6 farms	Restricción de movimiento	Pruebas de anticuerpo negativas	Aislamiento viral negativo	Pruebas de anticuerpo negativas	Aislamiento viral negativo
Entre 3 y 10 km de radio	19 granjas	Restricción de traslado				

III. Programa de vigilancia de influenza aviar

Vigilancia pasiva

En Japón, la IAAP y la IABP son enfermedades de notificación obligatoria de conformidad con la [Ley de control de enfermedades infecciosas de los animales domésticos](#). Los propietarios de aves de corral tienen la obligación de notificar inmediatamente a la prefectura cualquier sospecha de presencia de virus de IAAP o IABP en aves de corral. La sospecha se plantea cuando hay un aumento en la mortalidad diaria de aves de corral (en particular, en caso de que en el mismo gallinero se registre un aumento de al menos el doble de la mortalidad promedio de aves de corral en el período de 21 días previos a la fecha de envío de la notificación), cuando un ave de corral muestra signos clínicos como cianosis de la cresta y las barbillas, etc., depresión o descenso de la producción de huevos. La notificación debe enviarse al MAFF de la prefectura. En caso de detección de anomalías en aves de corral, cada prefectura deberá enviar inmediatamente a un inspector de sanidad animal (ISA) a la granja pertinente para confirmar cualquier cambio en el número de aves muertas y llevar a cabo una inspección clínica y una prueba rápida según sea necesario. Asimismo, los inspectores recogen muestras y realizan pruebas genéticas, pruebas de aislamiento de virus y pruebas serológicas de anticuerpos, cuando proceda. Estos resultados también se informarán inmediatamente al MAFF.

Además, de conformidad con la ley de control de sacrificio de aves de corral y de inspección de la avicultura (en adelante, "Ley de inspección avícola"), toda la carne de aves de corral producida en una planta de sacrificio de aves de corral que maneja más de 300 000 aves de corral al año (97% del total) debe someterse a inspección por parte de veterinarios locales oficiales o veterinarios de agencias de inspección designadas y autorizadas por el Ministerio Salud, Trabajo y Bienestar de Japón. En la inspección ante mortem, el diagnóstico se realiza en bases clínicas; para la inspección post mortem (inspección posterior a la eliminación de plumas y la inspección posterior a la evisceración), se lleva a cabo un examen patológico y, si es necesario, exámenes detallados para el diagnóstico.

En las plantas de sacrificio pequeñas certificadas de aves de corral que manejan hasta 300 000 aves, no es obligatoria la inspección de cada ave por parte de los veterinarios oficiales. Sin embargo, de conformidad con la Ley de inspección avícola, se debe designar un supervisor para los controles sanitarios que se lleven a cabo en las aves de corral ("controlador de calidad"), garantizando que se controlen las anomalías de las aves de corral y sus cadáveres, y se informe a las prefecturas.

Vigilancia activa

De conformidad con la Guía establecida por el MAFF, los gobiernos de las prefecturas toman muestras en granjas específicas y llevan a cabo aislamiento del virus y pruebas serológicas de anticuerpos una vez al mes. Además, durante la migración de aves silvestres a Japón (básicamente de octubre a mayo), los gobiernos locales seleccionan al azar una cantidad representativa de granjas para detectar una prevalencia del 10% con un nivel de confianza del 95% por lo menos, toman muestras de esas granjas y efectúan pruebas serológicas de anticuerpos. Los resultados de estos programas de vigilancia se comunican al Departamento de sanidad animal del MAFF mensualmente (los casos positivos deben notificarse de inmediato). En caso de detección de casos sospechosos, los gobiernos de las prefecturas envían inmediatamente inspectores a la granja para que controlen el registro de mortalidad en las aves de corral, realicen una inspección clínica y, de ser necesario, efectúen una prueba rápida en la explotación. Posteriormente, toman muestras para realizar pruebas genéticas, aislamiento de virus y pruebas serológicas de anticuerpos. Los resultados de estas pruebas se comunican inmediatamente al Departamento de sanidad animal.

Tabla 2. Resultados del monitoreo de influenza aviar in aves de corral, Japón, 2015 -2018*

Año	Prueba para aislamiento viral			Prueba de anticuerpos		
	No. de granjas	No. of aves observadas	No. de resultados positivos	No. de granjas	No. of aves observadas	No. de resultados positivos
2015	5,895	59,079	0	8,057	80,400	0
2016	5,879	58,802	0	8,007	79,997	0
2017	5,842	58,335	0	7,865	78,198	0
2018 ¹	981	9,810	0	667	6,640	0

¹Resultados correspondientes a enero y febrero de 2018

Japón también ha implementado vigilancia de IAAP en aves silvestres (realizada por el Ministerio del Medio Ambiente). Hasta el 15 de abril de 2018, se confirmaron 7 casos de hallazgos de IAAP en Shimane y 1 caso en Tokio, así como 38 casos confirmados en Hyogo.

IV. Medidas para el mantenimiento del estatus

Adicionalmente a lo mencionado del sistema de notificación temprana, ejercicios de simulación anuales de la ocurrencia de brote de IAAP son realizados al nivel nacional, regional y prefectural. También, la inspección de cuarentenal es realizada por el Servicio de Cuarentena Animal para prevenir la entrada de infección a Japón de acuerdo a la Ley de control de enfermedades infecciosas de los animales domésticos. A fin de prevenir la introducción de enfermedades infecciosas animales a granjas, el MAFF estableció las medidas estándar de bioseguridad (Estándares de bioseguridad) a ser cumplidos por los propietarios de animales de granja, para todo ganado sujeto a la Ley de control de enfermedades infecciosas de los animales domésticos. Los ISA confirman el cumplimiento de los estándares de bioseguridad por parte de los productores a través de al menos una inspección por año.

V. Conclusiones

Teniendo en cuenta que:

- el último evento de IAAP en aves de corral había sido notificado el 29 de noviembre de 2016 y el fue cerrado el 27 de marzo de 2017;
- antes de la confirmación del brote de IAAP del 12 de enero de 2018, Japón había estado libre de influenza aviar en aves de corral;
- se aplicaron medidas de control oportunas y eficaces, matanza, desinfección y enterramiento seguro de los cadáveres;
- se ha llevado a cabo vigilancia acorde con los Artículos 10.4.27. a 10.4.33. del *Código Sanitario para los Animales Terrestres*;
- han transcurrido tres meses desde que se aplicaron la matanza y la desinfección sin que aparezcan nuevos brotes.

El Delegado de Japón ante la OIE declara que el país ha recuperado su estatus libre de influenza aviar en aves de corral domésticas a partir del 15 de abril de 2018, de conformidad con el Artículo 10.4.3. del *Código Sanitario para los Animales Terrestres* (2017).

Drawn up on: 15/April/2018

Signature of the Delegate

Annex 1

POULTRY SLAUGHTER BUSINESS CONTROL AND POULTRY INSPECTION ACT (ACT No. 70, June 29, 1990)

Last amendment: ACT No. 69, June 13, 2014

CHAPTER 1. GENERAL PROVISIONS

(Purpose of Act)

Article 1. The purpose of this Act is to prevent any health hazard arising from poultry parts so as to protect the health of citizens exercising necessary controls and other measures over a poultry slaughter business from the viewpoint of public health and by establishing an appropriate poultry inspection system.

(Responsibilities of National Government and Prefectures, etc.)

Article 1-2 The national government, prefectures and cities designated by the Cabinet Order under the provisions of Paragraph 1, Article 5 of the Health Center Act (Act No.101, 1947) (referred to as “city establishing health centers” hereinafter) and special wards shall take necessary measures to prevent occurrence of health hazards caused by poultry parts based on the understanding of the actual situation of production of poultry and occurrence of disease among poultry.

(Definitions)

Article 2. For the purpose of this Act, the following terms shall be construed as defined below:

- (1) “Poultry” means chickens, ducks, turkeys, and other fowls usually supplied for food that are prescribed by the applicable Cabinet Order.
- (2) “Carcass of poultry” means slaughtered poultry from which the feathers have been removed but the viscera remain unremoved.
- (3) “Eviscerated carcass of poultry” means a carcass of poultry from which the viscera have been removed.
- (4) “Poultry parts” means the meat, viscera, bones, and skin of eviscerated poultry.
- (5) “Poultry slaughter” means any one or both of the processes as listed below:
 - a. to slaughter and defeather any poultry; and
 - b. to remove the viscera from any carcass of poultry.
- (6) “Poultry slaughter plant” means a plant established to carry out poultry slaughter.

CHAPTER 2. LICENSE FOR POULTRY SLAUGHTER BUSINESS

(License for Poultry Slaughter Business)

Article 3. Any person who intends to carry on a poultry slaughter business shall obtain a license for each of that person’s poultry slaughter plants from the governor of the prefecture where the plant is located (hereinafter referred to

as “Governor”), or from the mayor of the city establishing health centers where the plant is located. In the provisions set forth below, the term “Governor” shall be construed as “mayor” mentioned above, if necessary.

(Application for License)

Article 4. Any person who wishes to be granted the license referred to in the preceding article shall submit to the governor of the prefecture where the poultry slaughter plant is located (that is, the Governor as defined above) an application form stating:

- (1) the applicant’s name or title and address, and, in the case of a juridical person, the name of its representative;
- (2) the title and location of the poultry slaughter plant;
- (3) the kind of poultry to be handled; and
- (4) a brief description of the structure and facilities of the plant.

2. The application referred to in the preceding paragraph shall be accompanied with drawings for the plant and other drawings and documents describing necessary items as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance.

(Disqualification for License)

Article 5. The Governor shall not issue any license for poultry slaughter business referred to in Article 3 to the applicant falling under any of the following categories:

- (1) a person who has been sentenced to a penalty in violation of this Act or any order or disposition made under this Act, if two years have not elapsed from the date of completion or invalidation of the sentence;
- (2) a person whose license has been revoked under the provisions of Article 8 or 9, if two years have not elapsed from the date of the revocation;
- (3) a person declared to be incompetent;
- (4) a juridical person any of whose executives falls under any of Subparagraphs (1) through (3) above.

2. The Governor shall not issue any license for poultry slaughter business referred to in Article 3 to the applicant if the Governor has determined that any of the structure and facilities of the poultry slaughter plant stated in the application does not comply with the Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance.

(Permission for Changes or Modifications)

Article 6. Any person who has been granted the license referred to in Article 3 (hereinafter referred to as “poultry slaughterer”) shall, when intending to make changes or modifications to the structure or facilities of the poultry slaughter plant for which the license has been granted (for simplicity, hereinafter referred to as “poultry slaughter plant”), ask for permission of the Governor; provided, however, that this shall not apply where minor changes or modifications as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance are to be made.

2. The provisions of Paragraph 2 of the preceding article shall apply to the permission under Paragraph 1 of this article.

3. A poultry slaughterer shall, without delay, give notice to the Governor whenever there have been changes or modifications in the items listed in Subparagraphs (1)

Annex 1

through (3), Paragraph 1, Article 4 or whenever minor changes or modifications as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance have been made, as mentioned in the proviso of Paragraph 1 above.

(Succession)

Article 7. When any inheritance or merger has occurred for a poultry slaughterer, the inheritor (or one selected from among two or more inheritors to succeed to the licensed poultry slaughter business with the consent of the others) or a juridical person existing after the merger or resulting from the merger shall succeed to the position or status of that poultry slaughterer.

2. The inheritor or inheriting juridical person who succeeds to the position or status of that poultry slaughterer under the provisions of the preceding paragraph shall, without delay, give notice of that succession to the Governor by submitting necessary documents to prove that fact.

(Revocation of License for Poultry Slaughter Business)

Article 8. The Governor may revoke the license granted to a poultry slaughterer under the provisions of Article 3 or may order that poultry slaughterer to wholly or partly suspend the licensed business for a designated period of time of not more than six months, if that poultry slaughterer:

- (1) violates this Act or any order or disposition made under this Act;
- (2) falls under any of the categories listed in Subparagraphs (1), (3), and (4), Paragraph 1, Article 5;
- (3) violates any conditions attached to the license under the provisions of Paragraph 1, Article 36.

Article 9. If the poultry slaughter plant of a poultry slaughterer no longer complies with the standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 2, Article 5, the Governor may order that poultry slaughterer to correct any noncompliant conditions of the plant or prohibit that poultry slaughterer from using all or part of the plant until an appropriate measure has been taken for correction, or may revoke the license granted to that poultry slaughterer under the provisions of Article 3 or order that poultry slaughterer to wholly or partly suspend the licensed business for a designated period of time of not more than six months.

(Prohibition against Name Lending)

Article 10. No poultry slaughterer shall allow any other person to carry on a poultry slaughter business under the name of that poultry slaughterer.

CHAPTER 3. OBLIGATIONS OF POULTRY SLAUGHTERER

(Sanitary Control)

Article 11. Any poultry slaughterer shall, in accordance with the standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance, keep the poultry slaughter plant under sanitary conditions, handle any poultry, carcasses of poultry, eviscerated carcasses of poultry, and

poultry parts in a sanitary manner, and take other measures necessary for public health.

(Quality Controller)

Article 12. Any poultry slaughterer shall appoint and station an appropriate number of quality controllers at each of the poultry slaughter plants so that they may conduct sanitary controls over the poultry slaughter processes performed therein, in accordance with the applicable Ministry of Health, Labour and Welfare Ordinance.

2. Those quality controllers shall supervise every employee engaged in poultry slaughter, control the structure and facilities of poultry slaughter plants, and give appropriate instruction concerning poultry slaughter so as to prevent any violation of this Act or any order or disposition made under this Act.

3. Those quality controllers shall give necessary comments to poultry slaughter business to prevent any violation of this Act or any order or disposition made under this Act.

4. Poultry slaughter business shall respect comments from quality controllers based on the preceding provisions.

5. Each quality controller shall fall under any of the following categories:

- (1) a veterinarian;
- (2) a person who has finished a required course of veterinary or animal science at a university under the School Education Act (Act No. 26, 1947), a university under the University Order (Imperial Ordinance No. 388, 1918), or a college under the College Order (Imperial Ordinance No. 61, 1903) and graduated from that university or college;
- (3) a person who has finished a required course at a quality controller training institution registered by the Minister of Health, Labour and Welfare;
- (4) a person as prescribed in Article 57 of the School Education Act or as determined to be equal to or surpass that person in scholastic achievement in accordance with the applicable Ministry of Health, Labour and Welfare Ordinance, who has been engaged in poultry slaughter for three or more years and has finished a required training course registered by the Minister of Health, Labour and Welfare.

6. Any poultry slaughterer shall, when stationing an appropriate number of quality controllers, give notice to the Governor of the name of each quality controller and other necessary items as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance within fifteen days. The same shall apply when replacing any of the quality controllers with others.

7. Necessary matters pertaining to registration of a training institution under Subparagraph (3), Paragraph 5 and a training course under Subparagraph (4), Paragraph 5 shall be stipulated by the Cabinet Order, while other necessary matters pertaining to a training institution such as subjects under Subparagraph (3), Paragraph 5 and programs under Subparagraph (4), Paragraph 5 shall be stipulated by the Ministry of Health, Labour and Welfare Ordinance.

Article 13. The Governor may order a poultry slaughterer to dismiss any of the appointed quality controllers if the Governor determines that said quality controller is disqualified for performing the duties when:

Annex 1

- (1) said quality controller violates this Act or any order or disposition made under this Act;
- (2) said quality controller neglects any of the duties as prescribed in Paragraph 2 of the preceding article; or
- (3) any of the conditions subject to the verification as prescribed in Paragraph 7, Article 15 does not comply with the Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to therein.

(Notice of Cessation or Suspension)

Article 14. Any poultry slaughterer shall give notice to the Governor, without delay, when the poultry slaughterer ceases or suspends any of the poultry slaughter plants or resumes any suspended plant.

CHAPTER 4. POULTRY INSPECTION

(Poultry Inspection)

Article 15. Any poultry slaughterer shall, before slaughtering any poultry, undergo the inspection performed by the Governor for the conditions of the live poultry.

2. Any poultry slaughterer shall, before removing the viscera from any carcasses of poultry, undergo the inspection performed by the Governor for the surface conditions of those carcasses of poultry (hereinafter referred to as “post feather-removal inspection”).

3. Any poultry slaughterer shall, after having removed the viscera from any carcasses of poultry, undergo the inspection performed by the Governor for the conditions of those viscera and the inner surfaces condition of those carcasses (hereinafter referred to as “post-evisceration inspection”).

4. Inspection under the preceding Paragraph shall be conducted to determine whether any of the following are applicable:

- (1) Domestic animal diseases designated by Paragraph 1, Article 2 of the Domestic Animal Infectious Diseases Prevention Act (Act No. 166, 1951), and other diseases to be notified under Paragraph 1, Article 4 of the said Act;
- (2) Other diseases than those mentioned in the preceding Subparagraph that are designated by the Ministry of Health, Labour and Welfare Ordinance; and
- (3) Abnormalities designated by the Ministry of Health, Labour and Welfare Ordinance such as adherence of lubricant.

5. When the poultry slaughter plant of a poultry slaughterer complies with the requirements for structure and facilities as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance, the poultry slaughterer may, regardless of the provisions of Paragraph 2 above, ask the Governor to perform the post feather-removal inspection simultaneously with the post-evisceration inspection.

6. In addition to the inspection as prescribed in the preceding Paragraph 2, those inspections as prescribed in Paragraphs 1 through 3 above (hereinafter referred to as “poultry inspections”) shall be performed by following the methods and procedures as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance.

7. If a poultry slaughterer has the quality controllers, of whom necessary notice was given under the provisions of Paragraph 6, Article 12, verified in accordance with the

applicable Ministry of Health, Labour and Welfare Ordinance that the surface conditions of carcasses of poultry and the inner surface conditions of eviscerated carcasses of poultry and the conditions of viscera related thereto comply with the Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance, the Governor may use simplified methods as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance to perform the post feather-removal inspection and the post-evisceration inspection.

(Exemption from Poultry Inspections for Certified Small Scale Poultry Slaughterer)

Article 16. If a poultry slaughterer intends to handle a certain number of poultry not exceeding the number as prescribed by the applicable Cabinet Order at a poultry slaughter plant, that poultry slaughterer may prepare verification plans and regulations describing verification methods and other items as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance in connection with the verification referred to in Paragraph 5 below, submit the verification plans and regulations to the Governor, and ask the Governor to authorize that the verification plans and regulations comply with the Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance.

2. Any poultry slaughterer who has obtained authorization under the preceding paragraph (hereinafter referred to as “authorized small scale poultry slaughterer”) shall, when intending to make a revision of the authorized verification plans and regulations, gain the approval of the Governor on that revision.

3. The provisions of Paragraphs 1 through 3 of the preceding article shall not apply to any poultry slaughter process performed at a poultry slaughter plant in connection with the authorization which a authorized small scale poultry slaughterer has obtained.

4. Any authorized small scale poultry slaughterer shall handle, at a poultry slaughter plant in connection with the authorization, up to a number of poultry not exceeding the number as prescribed by the applicable Cabinet Order.

5. Any authorized small scale poultry slaughterer shall, when carrying out poultry slaughter at an authorized poultry slaughter plant in connection with the authorization, instruct the quality controllers to verify in accordance with the applicable Ministry of Health, Labour and Welfare Ordinance whether the conditions of live poultry, the surface conditions of carcasses of poultry and the inner surface conditions of eviscerated carcasses of poultry and the conditions of the viscera related thereto (if the carcasses of poultry have been purchased under Subparagraphs (3) through (5) of the succeeding article and then eviscerated at the poultry slaughterer’s plant, the inner surface conditions of the eviscerated carcasses of poultry and the conditions of the viscera related thereto) comply with the Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance in accordance with the methods described in the authorized verification plans and regulations (if any revision has been approved under Paragraph 2, the revised verification plans and regulations).

6. If any condition subject to the verification required

Annex 1

under the preceding paragraph is incompliant with the Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to therein and the Governor determines that any quality controller who has performed the verification is disqualifiable for performing further verification, the Governor may order the authorized small scale poultry slaughterer to dismiss that quality controller.

7. Any authorized small scale poultry slaughterer shall, in accordance with the applicable Ministry of Health, Labour and Welfare Ordinance, report to the Governor the results of the verification performed under Paragraph 5.

8. When an authorized small scale poultry slaughterer notifies the Governor to the effect that the poultry slaughterer intends to abolish the authorized verification plans and regulations, the authorization for those verification plans and regulations shall become invalid on a date before April 1 in the year after that notice (if the notice is given on a date between January and March in a certain year, before April 1 in that year) that is designated by the Governor.

9. The Governor shall give any authorized small scale poultry slaughterer necessary technical guidance and advice for proper execution of the verification required under Paragraph 5.

(Prohibition against Transportation of Unverified Poultry)

Article 17. No person shall transport outside a poultry slaughter plant any carcasses of poultry, eviscerated carcasses of poultry, or poultry parts until those carcasses or parts have passed the poultry inspections required hereunder or until those carcasses or parts have been verified for compliance with the Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 5 of the preceding article, except for the following cases where:

(1) an officer of the prefecture where the poultry slaughter plant is located (or the city where the poultry slaughter plant is located if that city is a city establishing health centers mentioned above; this alternate shall apply to the succeeding provisions, if necessary) or an inspector as prescribed in Paragraph 2, Article 25 takes any of the carcasses of poultry, eviscerated carcasses of poultry, or poultry parts out of the plant, if deemed necessary for the required poultry inspections;

(2) an officer of the prefecture collects and takes away any of the carcasses of poultry, eviscerated carcasses of poultry, or poultry parts under the provisions of Paragraph 1, Article 38;

(3) a poultry slaughterer (but not an authorized small scale poultry slaughterer; this limitation shall also apply to the following subparagraph) transfers to an authorized small scale poultry slaughterer any carcasses of poultry which have passed the post feather-removal inspection;

(4) a poultry slaughterer transfers to a person who carries on a meat selling business (that is, a person who has obtained the license under Paragraph 1, Article 52 of the Food Sanitation Act (Act No. 233, 1947)) and who has registered himself or herself with the governor of the prefecture where that person's office is located (hereinafter referred to as "registered meat seller") any carcasses of poultry which have passed the post feather-removal inspection;

(5) an authorized small scale poultry slaughterer, after having the quality controllers verified in accordance with Paragraph 5 of the preceding article that the conditions of live poultry and the surface conditions of carcasses of poultry comply with the Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in the same paragraph, transfers any of the verified carcasses of poultry to another authorized small scale poultry slaughterer;

(6) a poultry slaughterer for purposes of disinfection, disposal, or any other measures taken to prevent any rejectable poultry from being supplied for food as prescribed in Article 19, or an officer of the prefecture for purposes of disposal or any other measures as prescribed in Subparagraph (3), Article 20, takes out of the poultry slaughter plant any carcasses of poultry, eviscerated carcasses of poultry, or poultry parts that have not passed the required poultry inspections or that have been verified incompliant with the Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 5 of the preceding article as a result of the verification performed thereunder; and

(7) any transportation that may cause no sanitary problem is performed as prescribed by the applicable Cabinet Order.

2. No registered meat seller shall transfer any carcasses of poultry which have passed the post feather-removal inspection to any person other than authorized small scale poultry slaughterers.

(Prohibition against Transfer)

Article 18. No person shall accept, for the purpose of sale for human consumption (including non-sale delivery to unspecified or numerous persons; this inclusion shall also apply to the following paragraph), any carcasses of poultry, eviscerated carcasses of poultry, or poultry parts dressed in a location other than poultry slaughter plants, or any carcasses of poultry, eviscerated carcasses of poultry, or poultry parts transported outside any poultry slaughter plant in violation of the provisions of the preceding article.

2. No person other than authorized small scale poultry slaughterers shall accept, for the purpose of sale for human consumption, any carcasses of poultry which have passed the post feather-removal inspection from any registered meat seller.

(Disposal and Other Measures)

Article 19. For any poultry, carcasses of poultry, eviscerated carcasses of poultry, or poultry parts which have not passed the required poultry inspections or which have been determined incompliant with the Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 5, Article 16 as a result of the verification performed thereunder, a poultry slaughterer shall, without delay, disinfect or dispose of them or take some other measures to prevent them from being supplied for food in accordance with the applicable Ministry of Health, Labour and Welfare Ordinance.

Article 20. When the Governor determines that any poultry referred to in the preceding article suffer from a disease, or any carcasses of poultry, eviscerated carcasses of poultry, or poultry parts referred to therein are related to any

Annex 1

diseased poultry, or when any abnormality is found in poultry, carcasses of poultry, eviscerated carcasses of poultry, or poultry parts referred thereunder, and thereby those poultry, carcasses of poultry, eviscerated carcasses of poultry, or poultry parts are not capable of use for human consumption, or that any poultry, carcasses of poultry, eviscerated carcasses of poultry, or poultry parts referred to therein or any of the slaughter, defeathering, and evisceration processes referred to therein may be liable to spread infection, the Governor may take the following measures to the extent necessary for the public health, unless the disinfection or disposal performed or the measure taken to prevent them from being supplied for food thereunder can accomplish the purposes of the following measures:

- (1) prohibiting said poultry from being slaughtered, defeathered, or eviscerated;
- (2) ordering the owner or manager of said poultry, the poultry slaughterer concerned, or other persons concerned to isolate said poultry, to disinfect the premises of the poultry slaughter plant, or to take other appropriate measures, or ordering the personnel concerned to take these measures;
- (3) ordering the prefectural personnel to dispose of said poultry, carcasses of poultry, eviscerated carcasses of poultry, or poultry parts or to take other appropriate measures.

CHAPTER 5. DESIGNATED INSPECTION AGENCY

(Authorization of Designated Inspection Agencies for Poultry Inspection)

Article 21. The Governor may authorize any juridical person designated by the Minister of Health, Labour and Welfare (hereinafter referred to as “designated inspection agency”) to conduct, wholly or partly, the poultry inspections required hereunder.

2. The Minister of Health, Labour and Welfare shall, upon application from a person who intends to conduct any of the poultry inspections, designate that person as a designated inspection agency referred to in the preceding paragraph.

3. The Governor, when deciding to authorize any designated inspection agency to conduct, wholly or partly, the poultry inspections under the provisions of Paragraph 1, shall not conduct the part of the poultry inspections that will be conducted by the designated inspection agency.

(Requirements and Disqualification for Designation)

Article 22. The Minister of Health, Labour and Welfare shall not designate any juridical person as a designated inspection agency referred to in Paragraph 1 of the preceding article, unless the application referred to in Paragraph 2 thereof proves that the following requirements are met:

- (1) A poultry inspection program prepared by the applicant which covers personnel, inspection facilities and equipment, and inspection methods and procedures, shall be suitable for proper and effective performance of the poultry inspection service required hereunder.
- (2) The applicant shall have enough financial and technical capabilities to conduct the poultry inspection service as described in the poultry inspection program referred to in the preceding subparagraph.
- (3) If the applicant is engaged in any service other than the

poultry inspection service required hereunder, the other service shall not conflict with the required poultry inspection service.

2. The Minister of Health, Labour and Welfare shall not designate any applicant who made an application in accordance with Paragraph 2 of the preceding article as a designated inspection agency referred to in Paragraph 1 thereof, if that applicant falls under any of the following categories:

- (1) a person who is not a general incorporated association or a general incorporated foundation;
- (2) a person who has been sentenced to a penalty in violation of this Act or any order or disposition made under this Act, if two years have not elapsed from the date of completion or invalidation of the sentence;
- (3) a person whose designation has been revoked under the provisions of Paragraph 1 or 2 of Article 33 prescribed below, if two years have not elapsed from the date of the revocation;
- (4) a juridical person any of whose executives falls under any of the following categories:
 - a. a person who falls under Subparagraph (2) above;
 - b. a person who was dismissed by any order made under the provisions of Paragraph 3 of Article 26, if two years have not elapsed from the date of the dismissal.

(Public Notice of Designation)

Article 23. The Minister of Health, Labour and Welfare shall, when designating any person as a designated inspection agency referred to in Paragraph 1, Article 21 above, give a public notice of the name and the principal place of business of that designated inspection agency and the date of such designation.

2. Any designated inspection agency shall, when intending to change its name or principal place of business, notify the Minister of Health, Labour and Welfare of such change at least two weeks before the date on which the change becomes effective.

3. The Minister of Health, Labour and Welfare shall, when notified of such change as referred to in the preceding paragraph, give public notice of the change.

Article 24. The Governor who decides to authorize any designated inspection agency to conduct the poultry inspections under the provisions of Paragraph 1, Article 21 (hereinafter referred to as “authorizing Governor”) shall give public notice of the name, the principal place of business, and the location of each poultry inspection office of that designated inspection agency, the scope of the poultry inspection service that the authorizing Governor authorizes the agency to conduct, and the date on which the agency starts the poultry inspection service.

2. Any designated inspection agency shall, when intending to change its name, its principal place of business, or the location of any of its poultry inspection offices, notify the authorizing Governor (or the authorizing Governor concerned if the agency intends to change the location of any of its poultry inspection offices) of such change at least two weeks before the date on which the change becomes effective.

3. The authorizing Governor shall, when notified of such change as referred to in the preceding paragraph, give public notice of the change.

Annex 1

(Obligations for Poultry Inspection)

Article 25. Any designated inspection agency shall, upon receipt of a request for the poultry inspections, conduct them without delay unless there is a due reason.

2. Any designated inspection agency shall cause a person having the qualifications as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance (in the succeeding paragraph and article, referred to as “inspector”) to conduct the poultry inspections in accordance with the methods as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance.

3. Any designated inspection agency shall, when causing any inspector to conduct the poultry inspections, make a report to the authorizing Governor on the items as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance without delay in accordance with the applicable Ministry of Health, Labour and Welfare Ordinance.

(Appointment and Dismissal of Executives and Inspectors)

Article 26. Appointment or dismissal of an executive of any designated inspection agency engaged in the poultry inspection service shall not become effective until the agency gains the approval of the Minister of Health, Labour and Welfare.

2. Any designated inspection agency shall, when appointing or dismissing an inspector, notify the Minister of Health, Labour and Welfare of such appointment or dismissal without delay.

3. When any one of the executives or inspectors of a designated inspection agency violates this Act or any order or disposition made under this Act or the inspection service plans and regulations referred to in Paragraph 1, Article 28, the Minister of Health, Labour and Welfare may order that designated inspection agency to dismiss such executive or inspector.

(Legal Status of Executives and Personnel)

Article 27. For the purpose of applying the Penal Code (Act No. 45, 1907) and other penal provisions, any executive or personnel of a designated inspection agency engaged in the poultry inspection service shall be deemed as personnel engaged in public service by Act.

(Inspection Service Plans and Regulations)

Article 28. Any designated inspection agency shall establish appropriate inspection service plans and regulations stating the items for the poultry inspection service as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance, and shall gain the approval of the Minister of Health, Labour and Welfare on the plans and regulations or any revision thereof.

2. Any designated inspection agency shall, when intending to make a revision of the inspection service plans and regulations referred to in the preceding paragraph, consult with the authorizing Governor.

3. The Minister of Health, Labour and Welfare may, when determining that the inspection service plans and regulations approved under Paragraph 1 above are no longer suitable for

proper and effective performance of the poultry inspection service, order the designated inspection agency to revise the plans and regulations.

(Approval of Business Plan)

Article 29. Any designated inspection agency shall prepare a business plan and an operating budget for each business year and shall gain the approval of the Minister of Health, Labour and Welfare for the business plan and the operating budget and any revision thereof before that business year starts (or as soon as the inspection agency is designated as referred to in Paragraph 1, Article 21 if such designation is performed in that business year).

2. Any designated inspection agency shall, when intending to prepare a business plan and an operating budget or to make a revision thereof, consult with the authorizing Governor.

3. Any designated inspection agency shall prepare a business report and a statement of revenues and expenditures for each business year and submit them to the Minister of Health, Labour and Welfare within three months after the end of that business year.

(Accounting Books)

Article 30. Any designated inspection agency shall prepare and keep accounting books as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance, record therein necessary data and information on the items for the poultry inspection service as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance, and store them in place for a certain period.

(Supervisory Order)

Article 31. The Minister of Health, Labour and Welfare may, if deemed necessary to enforce this Act, give any designated inspection agency an order necessary to supervise the agency’s poultry inspection service.

2. The authorizing Governor may, if deemed necessary to ensure proper performance of the poultry inspection service authorized to any designated inspection agency, instruct the agency to take measures necessary for such proper performance of the poultry inspection service.

(Cessation or Suspension of Inspection Service)

Article 32. No designated inspection agency shall cease or suspend, wholly or partly, its poultry inspection service without permission from the Minister of Health, Labour and Welfare.

2. The Minister of Health, Labour and Welfare shall permit any designated inspection agency to cease or suspend, wholly or partly, its poultry inspection service as referred to in the preceding paragraph, only when determining that such cessation or suspension may not adversely affect proper and effective performance of the required poultry inspection service.

3. The Minister of Health, Labour and Welfare shall, when intending to give permission as referred to in Paragraph 1 above, consult with the authorizing Governor concerned.

4. The Minister of Health, Labour and Welfare shall, when giving permission as referred to in Paragraph 1 above, notify the authorizing Governor concerned and give public notice of

Annex 1

such permission.

(Revocation of Designation)

Article 33. The Minister of Health, Labour and Welfare shall revoke the designation given to a designated inspection agency when that agency falls under any of the categories as prescribed in the subparagraphs of Paragraph 2, Article 22 (excluding Subparagraph (3)).

2. The Minister of Health, Labour and Welfare may revoke the designation given to a designated inspection agency or may order that designated inspection agency to wholly or partly suspend its poultry inspection service for a designated period of time of not more than six months, if that designated inspection agency:

- (1) violates the provisions of this article;
- (2) no longer meets any of the requirements as prescribed in the subparagraphs of Paragraph 1, Article 22;
- (3) violates any order made under the provisions of Paragraph 3 of Article 26, Paragraph 3 of Article 28, or Paragraph 1 of Article 31;
- (4) conducts its poultry inspection service in disregard of the inspection service plans and regulations approved under the provisions of Paragraph 1, Article 28; or
- (5) has gained such designation in an unfair manner.

3. The Minister of Health, Labour and Welfare shall, when revoking the designation given to a designated inspection agency under the provisions of Paragraph 1 above or the preceding paragraph or when ordering that designated inspection agency to wholly or partly suspend its poultry inspection service under the provisions of the preceding paragraph, notify the authorizing Governor concerned and give public notice of that revocation or order.

(Revocation of Authorization for Poultry Inspection)

Article 34. The authorizing Governor shall, when deciding to prohibit any designated inspection agency from conducting all or any of its poultry inspection services, notify that designated inspection agency of such decision at least six months before such decision becomes effective.

2. The authorizing Governor shall, when deciding to prohibit any designated inspection agency from conducting all or any of its poultry inspection services, give a public notice of such decision.

(Poultry Inspection Service Conducted by Authorizing Governors)

Article 35. The authorizing Governor shall conduct all or any of the poultry inspection services to be conducted by a designated inspection agency, in the event that the designated inspection agency wholly or partly suspends its poultry inspection services with the permission of the Minister of Health, Labour and Welfare as prescribed in Paragraph 1, Article 32, that the Minister of Health, Labour and Welfare orders the designated inspection agency to wholly or partly suspend its poultry inspection service under the provisions of Paragraph 2, Article 33, or that the designated inspection agency is unable to conduct all or any of its poultry inspection services due to force majeure or other causes, if deemed necessary by the Minister of Health, Labour and Welfare.

2. The Minister of Health, Labour and Welfare shall notify

the authorizing Governor as soon as it is deemed necessary or unnecessary by the Minister of Health, Labour and Welfare that the authorizing Governor conduct all or any of the poultry inspection services under the provisions of the preceding paragraph.

3. The authorizing Governor shall, when receiving such notification as referred to in the preceding paragraph, give public notice to that effect.

4. When the authorizing Governor decides to conduct all or any of the poultry inspection services under the provisions of Paragraph 1 above, or the Minister of Health, Labour and Welfare permits a designated inspection agency to cease its poultry inspection services under the provisions of Paragraph 1, Article 33 or revokes the designation given to a designated inspection agency under the provisions of Paragraph 1 or 2, Article 33, necessary procedures including the transfer of such inspection services shall be prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance.

CHAPTER 6. MISCELLANEOUS

(Conditions for License and Permission)

Article 36. Any license issued under Article 3 or any permission given under Paragraph 1, Article 6 may be subject to conditions, which may be modified from time to time.

2. The conditions referred to in the preceding paragraph shall be limited to a minimum scope and extent required to prevent any health hazard arising from poultry parts and shall not impose unfair obligations on the person who obtains such license or permission.

(Reporting Obligations)

Article 37. The Governor may, to the extent required to enforce this Act, request a poultry slaughterer, a quality controller, or a registered meat seller to report the operating conditions in addition to the reports required by Paragraph 7, Article 16, in accordance with the applicable Ministry of Health, Labour and Welfare Ordinance.

2. The Minister of Health, Labour and Welfare or the authorizing Governor may, to the extent required to enforce this Act, request a designated inspection agency to report the operating and/or financial conditions for its poultry inspection services in addition to the report required by Paragraph 3, Article 25.

(Onsite Inspection)

Article 38. The Governor may, to the extent required to enforce this Act, authorize his personnel to enter a poultry slaughter plant or the offices, warehouses, or other facilities of a poultry slaughterer or a registered meat seller, to inspect the facilities, accounting books, documents, and other properties thereof, to inquire of the persons concerned, or to collect and take away without compensation a certain quantity of carcasses of poultry, eviscerated carcasses of poultry, or poultry parts.

2. The Minister of Health, Labour and Welfare or the authorizing Governor may, to the extent required to enforce this Act, authorize his personnel to enter the offices of a designated inspection agency, to inspect the accounting

Annex 1

books, documents, and other properties thereof, or to inquire of the persons concerned.

3. The personnel who conducts the onsite inspection in accordance with any of these two preceding paragraphs shall bear a certificate for identification and present it to any person concerned upon request.

4. The power given under the provisions of Paragraph 1 or 2 above shall not be deemed to be accepted for criminal investigation.

(Personnel for Poultry Inspection)

Article 39. Official work for any poultry inspection, the duties of the prefectural personnel referred to in Article 20 and Paragraph 1 of the preceding article and the educational duties pertaining to poultry slaughter shall be performed by Food Sanitation Inspectors, Meat inspectors, or any other personnel as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance who have the qualifications as prescribed by the applicable Cabinet Order and have been designated by the Governor.

2. The Governor shall have a person designated by the Governor mentioned in the preceding paragraph conduct work or duties designated by the preceding paragraph according to the Prefectural Food Sanitation Control and Guidance Plan under Paragraph 1, Article 24 of the Food Sanitation Act.

(Requests for Investigation by the Minister of Health, Labour and Welfare)

Article 40. The Minister of Health, Labour and Welfare may ask the Governor to implement inspections based on Paragraph 1-3, Article 15 and to take measures based on Paragraph 1, Article 37 and Paragraph 1, Article 38 for a designated period in order to identify the causes of food poisoning and to report the results, when he/she asks for a report based on the provisions of Article 60 of the Food Sanitation Act and specifically recognizes the necessity for prevention of health hazard caused by poultry parts.

(Hearing)

Article 40-2. The Minister of Health, Labour and Welfare shall, when he/she intends to establish, revise or rescind the Ministry of Health, Labour and Welfare Ordinance under Article 11, Subparagraph (2) or (3), Paragraph 4 or Paragraph 6, Article 15, or Article 19, publish its reasons, details and other necessary matters to ask for public comments; provided, however, that this shall not apply for prevention against the occurrence of sanitary hazard caused by poultry parts in emergencies when he/she cannot afford the time.

2. The Minister of Health, Labour and Welfare shall postetiori ask for public comments without delay in emergencies as mentioned in the preceding paragraph.

(Contact and Cooperation)

Article 40-3. The Minister of Health, Labour and Welfare and the Minister of Agriculture, Forestry and Fishery shall maintain close and mutual contact and cooperation for matters pertaining to prevention against the occurrence of sanitary hazard caused by poultry parts in implementing this

Act.

(Appeal)

Article 41. With respect to the results of any poultry inspection performed hereunder, no appeal under the Complaints Against Administrative Acts Inquiries Act (Act No. 160, 1962) shall be allowed.

2. With respect to any order or disposition (excluding the results of any poultry inspection) or omission in connection with any poultry inspection performed hereunder by a designated inspection agency, a request for examination under the Complaints Against Administrative Acts Inquiries Act may be made to the Minister of Health, Labour and Welfare.

3. Any person who made a request for examination with respect to any order or disposition based on paragraph 1, Article 38 made by the mayor of a city establishing health centers and still has any objection to a decision resulting from the examination may make a request for reexamination to the Minister of Health, Labour and Welfare.

(Inspection Fee)

Article 42. Prefectures may, in accordance with the Ministerial Ordinance, when they collect a fee pertaining to the poultry inspection under the provisions of Article 227 of the Local Government Act (Act No. 67, 1947), order to a person intending to undergo a poultry inspection performed by a designated inspection agency under the provisions of Paragraph 1, Article 21, to pay the relevant inspection fee to the relevant inspection agency. The paid fee shall be considered as an income of the designated inspection agency.

(Classification of administrative works)

Article 42-2. Administrative works that need to be treated by prefectures under the provision of Paragraph 1, Article 37 and Paragraph 1, Article 38 shall be regarded as the entrusted legal works of type 1 stipulated in Subparagraph 1, Paragraph 9, Article 2 of the Local Government Act.

(Delegation of Authority)

Article 42-3. Authority of Minister of Health, Labour and Welfare stipulated in this Act could be delegated to chief of Regional Bureau of Health and Welfare.

2. Authority delegated to chief of Regional Bureau of Health and Welfare under the preceding paragraph could be delegated to chief of Regional Branch of Health and Welfare.

(Transitional Measures)

Article 43. When any order of the Minister of Health, Labour and Welfare is established, amended, or abolished under the provisions of this Act, transitional measures (including those related to penal provisions) may be established to such an extent as deemed to be reasonably necessary in establishing, amending, or abolishing said order.

(Entrustment to Ministerial Ordinances)

Article 44. Procedures required for the execution of this Act and other particulars, in addition to those stipulated in this Act, shall be stipulated in the applicable ordinances of the Ministry of Health, Labour and Welfare.

CHAPTER 7. PENAL PROVISIONS

Article 45. Any person who falls under any of the following categories shall be punished by imprisonment of not more than three years or by a fine of not more than 3,000,000 yen:

- (1) a person who carries on a poultry slaughter business without any license under Article 3;
- (2) a person who allows any other person to carry on a poultry slaughter business in violation of the provisions of Article 10;
- (3) a person who transports outside a poultry slaughter plant any carcasses of poultry, eviscerated carcasses of poultry, or poultry parts in violation of the provisions of Paragraph 1, Article 17;
- (4) a person who transfers any carcasses of poultry in violation of the provisions of Paragraph 2, Article 17.

Article 46. Any person who falls under any of the following categories shall be punished by imprisonment of not more than one year or by a fine of not more than 1,000,000 yen:

- (1) a person who violates any order made under the provisions of Article 8;
- (2) a person who violates any order or prohibition made under the provisions of Article 9;
- (3) a person who accepts any carcasses of poultry, eviscerated carcasses of poultry, or poultry parts in violation of the provisions of Paragraph 1 or 2, Article 18;
- (4) a person who fails to disinfect or dispose of any poultry, carcasses of poultry, eviscerated carcasses of poultry, or poultry parts, or to take other measures to prevent them from being supplied for food in violation of the provisions of Article 19;
- (5) a person who violates any prohibition made under the provisions of Paragraph 1, Article 20 or any order made under the provisions of Paragraph 2 thereof;
- (6) a person who refuses, obstructs, or evades the implementation of duties carried out by the prefectural personnel under the provisions of Paragraph 2 or 3, Article 20.

Article 47. Any executive or personnel of a designated inspection agency which acts contrary to the order to suspend its poultry inspection service under the provisions of Paragraph 2, Article 33 shall be punished by imprisonment of not more than one year or by a fine of not more than 1,000,000 yen.

Article 48. Any person who falls under any of the following categories shall be punished by a fine of not more than 500,000 yen:

- (1) a person who makes changes or modifications to the structure or facilities of a poultry slaughter plant without permission as under Paragraph 1, Article 6;
- (2) a person who fails to give notice or gives false notice under the provisions of Paragraph 6, Article 12;
- (3) a person who fails to make a report or make a false report under the provisions of Paragraph 1, Article 37; and

(4) a person who refuses, obstructs or evades any entrance, inspection or collection performed under the provisions of Paragraph 1, Article 38 or who fails to make a statement or makes a false statement to any inquiry made thereunder.

Article 49. Any executive or personnel of a designated inspection agency shall be punished by a fine of not more than 500,000 yen, if the designated inspection agency:

- (1) fails to prepare accounting books, fails to record necessary data thereon, records false data thereon, or fails to store them in place in violation of the provisions of Article 30;
- (2) wholly suspends its poultry inspection services without permission under the provisions of Paragraph 1, Article 32;
- (3) fails to make a report or makes a false report under the provisions of Paragraph 2, Article 37;
- (4) refuses, obstructs, or evades any entrance or inspection performed under the provisions of Paragraph 2, Article 38, or fails to make a statement or makes a false statement to any inquiry made thereunder.

Article 50. When any representative of a juridical person, or any agent, servant, or employee of a juridical person or a person commits any of the violation acts as prescribed in the following subparagraphs in the course of performing the duties related to any work or service carried out by that juridical person or person, that juridical person and individual shall, in addition to the violating representative, agent, servant, or employee, be punished by the fine in an amount specified in the applicable Subparagraphs and the respective Articles, respectively.

- (1) Article 45 A fine of not more than 100,000,000 yen
- (2) Article 46 or 48 A fine in an amount prescribed in the respective Articles

Annex 2

ENFORCEMENT ORDER FOR THE POULTRY SLAUGHTER BUSINESS CONTROL AND POULTRY INSPECTION ACT (Cabinet Order No. 52; March 25, 1991)

**Last amendment: Cabinet Order No. 128,
March 31, 2015**

(Registration of a Training Institution)

Article 1. The Minister of Health, Labour and Welfare shall register a training institution under Subparagraph (3), Paragraph 5, Article 12 of the Poultry Slaughter Business Control and Poultry Inspection Act (hereinafter referred to as 'the Act') according to criteria defined by the applicable Ministry of Health, Labour and Welfare Ordinance such as admission requirements, term of study, and subjects.

(Application for Registration)

Article 2. A person who intends to apply for registration of a training institution under Subparagraph (3) Paragraph 5, Article 12 of the Act shall submit an application to the Minister of Health, Labour and Welfare based on the provisions of the applicable Ministry of Health, Labour and Welfare Ordinance.

(Notification of Changes)

Article 3. A person who has established a training institution registered under Subparagraph (3), Paragraph 5, Article 12 of the Act (referred to as 'registered training institution' hereinafter) shall, when any change occurs pertaining to matters designated by the applicable Ministry of Health, Labour and Welfare Ordinance, give notice to the Minister of Health, Labour and Welfare within one month from the date of the change.

(Collection of Reports)

Article 4. The Minister of Health, Labour and Welfare may, if he/she deems necessary, ask a person who has established a training institution to report on said institution.

(Rescission of Registration)

Article 5. The Minister of Health, Labour and Welfare may, if he/she determines that a registered institution has not met the criteria designated by the applicable Ministry of Health, Labour and Welfare Ordinance under Article 1, or when an application is submitted under the next Article, cancel the registration.

(Application for Rescission of Registration)

Article 6. A person who has established a training institution shall, when he/she intends to apply for rescission of registration for the institution, submit an application to the Minister of Health, Labour and Welfare according to the applicable Ministry of Health, Labour and Welfare

Ordinance.

(Public Notice)

Article 7. The Minister of Health, Labour and Welfare shall put an announcement in their official gazette in any of the following cases:

- (1) When registration is made under Subparagraph (3), Paragraph 5, Article 12 of the Act;
- (2) When a notice is submitted under Article 3 (limited to those designated by the applicable Ministry of Health, Labour and Welfare Ordinance); and
- (3) When registration under Subparagraph (3), Paragraph 5, Article 12 of the Act is rescinded based on Article 5.

(Registration of a Training course)

Article 8. A person who intends to apply for the registration of a training course under Subparagraph (4), Paragraph 5, Article 12 of the Act shall submit an application to the Minister of Health, Labour and Welfare according to the applicable Ministry of Health, Labour and Welfare Ordinance.

(Disqualification Clause)

Article 9. A person who falls under any of the following conditions does not qualify for registration of a training course under Subparagraph (4), Paragraph 5, Article 12 of the Act:

- (1) A person who was punished by a fine or more severe penalty due to violation of Acts or disposition based on Acts within the past 2 years;
- (2) A person whose registration was rescinded under the provisions of Article 17 within the past 2 years; and
- (3) A juridical person any of whose executives responsible for the applicable operation falls under any of the preceding paragraphs.

(Criteria for Registration)

Article 10. The Minister of Health, Labour and Welfare shall register a training course, if the operator of the training course who applied for registration under Article 8 operates the course according to the Ministry of Health, Labour and Welfare Ordinance under Paragraph 7, Article 12 of the Act.

(Duty to Implement Training Course)

Article 11. An operator of a training course registered under Subparagraph (4), Paragraph 5, Article 12 of the Act (referred to as 'registered training course' hereinafter) shall make a plan for the implementation of a training course, and hold the registered training course in accordance with it; provided, however, that this shall not apply to cases with reasonable reasons for doing otherwise.

2. An operator of a registered training course shall implement said training course adequately and in a manner meeting the criteria designated by the applicable Ministry of Health, Labour and Welfare Ordinance.

3. An operator of a registered training course shall submit the plan created under Paragraph 1, prior to implementing said training course, to the Minister of Health, Labour and

Annex 2

Welfare. The same shall apply to intended changes.

(Notification of Changes)

Article 12. An operator of a training course shall, when intending to change matters designated by the applicable Ministry of Health, Labour and Welfare Ordinance, give notice to the Minister of Health, Labour and Welfare more than two weeks prior to the scheduled date of change.

(Suspension and Termination of Operations)

Article 13. An operator of a registered training course shall, when intending to suspend or terminate all or part of operations pertaining to the registered training course, give advance notice to the Minister of Health, Labour and Welfare according to the provisions of the applicable Ministry of Health, Labour and Welfare Ordinance.

(Availability of Financial Statements)

Article 14. An operator of a registered training course shall create general inventory, balance sheet, profit-and-loss statements or income and expenditure accounts, and operating reports or business reports (including electromagnetic records (those created in electronic, magnetic or any other formats unrecognized by human sensory perception intended for computer-based processing. Hereinafter the same shall apply in this Article.) created in lieu of the above-mentioned documents. Referred to as 'financial statements' in the following paragraph.), and make them available in its office.

2. A person who intends to participate in a registered training course or any other interested person may make the following requests at any time during the operation hours of an operator of the registered training course; provided, however, that he/she shall pay the amount designated by the operator of the registered training course for the request under Subparagraph (2) or (4):

- (1) Request for review or duplication of written financial statements, if applicable;
- (2) Request for transcript or extract transcript of documents mentioned in the preceding subparagraph;
- (3) Request for review or duplication of descriptions of electromagnetic records of financial statements indicated by devices designated by the applicable Ministry of Health, Labour and Welfare Ordinance, if applicable; and
- (4) Request for provision of descriptions of electromagnetic records by electromagnetic devices designated by the applicable Ministry of Health, Labour and Welfare Ordinance or supply of applicable descriptions in a written form.

(Order of Conformity)

Article 15. The Minister of Health, Labour and Welfare may, when he/she determines that an operator of a registered training course has not implemented a registered training course according to the Ministry of Health, Labour and Welfare Ordinance under Paragraph 7, Article 12 of the Act, ask said operator to take necessary measures for carrying out of the registered training course according to the Ministry of

Health, Labour and Welfare Ordinance under the Paragraph thereunder.

(Order of Improvement)

Article 16. The Minister of Health, Labour and Welfare may, when he/she determines that an operator of a registered training course violates the provisions of Article 11, ask said operator to implement a registered training course or to take necessary measures for improvement of operational methods such as implementation methods.

(Rescission of Registration)

Article 17. The Minister of Health, Labour and Welfare may rescind registration or order suspension of all or part of operations pertaining to a registered training course for a certain period, when an operator of a registered training course falls under any of the following cases;

- (1) Resulting in cases that fall under Paragraph 1 or 3, Article 9;
- (2) Violation of the provisions of Article 11-13, Paragraph 1, Article 14 or the next Article;
- (3) Rejection of requests based on the provisions of each Subparagraph, Paragraph 2, Article 14 without any reasonable basis;
- (4) Violation of orders under the provisions of the preceding 2 articles; and
- (5) Registration under Subparagraph (4), Paragraph 5, Article 12 by improper methods.

(Entry of Financial Records)

Article 18. An operator of a registered training course shall prepare financial records by entering descriptions according to the Ministry of Health, Labour and Welfare Ordinance and store them.

(Collection of Reports)

Article 19. The Minister of Health, Labour and Welfare may ask an operator of a registered training course to submit reports on operations or financial conditions pertaining to said training course as far as necessary for the implementation of Acts and this Cabinet Order.

(On-site Inspection)

Article 20. The Minister of Health, Labour and Welfare may ask personnel of the Ministry to enter offices of an operator of a registered training course and to inspect the situation of operations, financial records and other documents or items, as far as necessary for implementation of Acts and this Cabinet Order.

2. Personnel who conduct on-site inspection based on the preceding paragraph shall bring their identification card to present to interested person.

3. Authorities of on-site inspection under Paragraph 1 shall not be construed as those for criminal investigation.

(Public Notice)

Article 21. The Minister of Health, Labour and Welfare shall publish the following cases in the official gazette:

Annex 2

- (1) Registration under Subparagraph (4), Paragraph 5, Article 12 of the Act;
- (2) Notice under the provisions of Article 12 or 13; and
- (3) Rescission of registration of a registered training course or order of suspension of operations pertaining to a registered training course under the provisions of Article 17.

(Number as Prescribed by the Applicable Cabinet Order Referred to in Paragraph 1, Article 16 of the Act)

Article 22. The number as prescribed by the applicable Cabinet Order referred to in Paragraph 1, Article 16 of the Act shall be 300,000 for the year during which a poultry slaughterer (as defined in Paragraph 1, Article 6 of the Act; the same definition shall apply to the succeeding provisions herein) intends to obtain a certificate as prescribed in Paragraph 1, Article 16 of the Act (that is, between April 1 in that year and March 31 in the next year, or between April 1 in the preceding year and March 31 in that year if the poultry slaughterer intends to obtain said certificate on a date between January and March in that year); provided, however, that for the year during which a poultry slaughterer obtains a license under Article 3 of the Act, the number shall be a product of 25,000 multiplied by the number of months from the month during which the poultry slaughterer obtains said license to March in that year (the number of months shall be one if the poultry slaughterer obtains said license in March).

(Number as Prescribed by the Applicable Cabinet Order Referred to in Paragraph 4, Article 16 of the Act)

Article 23. The number as prescribed by the applicable Cabinet Order referred to in Paragraph 4, Article 16 of the Act shall be 300,000 for each year (that is, between April 1 in that year and March 31 in the next year) after the year during which a poultry slaughterer intends to obtain a certificate as prescribed in Paragraph 1 thereof (that is, between April 1 in that year and March 31 in the next year, or between April 1 in the preceding year and March 31 in

that year if the poultry slaughterer intends to obtain said certificate on a date between January and March in that year; hereafter referred to as “certification year” in this article); provided, however, that for the certification year during which a certified small scale poultry slaughterer (as defined in Paragraph 2, Article 16 of the Act) obtains a license under Article 3 of the Act, the number shall be a product of 25,000 multiplied by the number of months from the month during which the poultry slaughterer obtains said license to March in that certification year (the number of months shall be one if the poultry slaughterer obtains said license in March).

(Transportation as Prescribed by the Applicable Cabinet Order Referred to in Subparagraph (7), Paragraph 1, Article 17 of the Act)

Article 24. The transportation as prescribed by the applicable Cabinet Order referred to in Subparagraph (7), Paragraph 1, Article 17 of the Act shall include: transportation of a certain quantity of carcasses of poultry, eviscerated carcasses of poultry, or poultry parts (as defined in Subparagraphs (2) through (4), Article 2 of the Act; those definitions shall apply to the succeeding provisions herein) collected by Food Sanitation Inspectors under the provisions of Paragraph 1, Article 28 of the Food Sanitation Act (Act No. 233, 1947); and transportation of a certain quantity of carcasses of poultry, eviscerated carcasses of poultry, or poultry parts sampled or collected by Animal Quarantine Officers or Prefectural Veterinary Inspectors under the provisions of Paragraph 1, Article 51 of the Domestic Animal Infectious Diseases Control Act (Act No. 166, 1951).

(Qualification as Prescribed by the Applicable Cabinet Order Referred to in Article 39 of the Act)

Article 25. The qualification as prescribed by the applicable Cabinet Order referred to in Article 39 of the Act shall be a veterinarian’s license granted under the Veterinary License Act (Act No. 186, 1949).

Annex 3

ENFORCEMENT REGULATIONS FOR THE POULTRY SLAUGHTER BUSINESS CONTROL AND POULTRY INSPECTION ACT

(Ministry of Health and Welfare Ordinance No. 40,
June 29, 1990)

Last amendment: Ministry of Health, Labour and
Welfare Ordinance No. 93, April 13, 2015

CHAPTER 1. LICENSE FOR POULTRY SLAUGHTER BUSINESS

(Items to be Described in Drawings and Documents Accompanying an Application for License)

Article 1. The items as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 2, Article 4 of the Poultry Slaughter Business Control and Poultry Inspection Act (Act No. 70, 1990, hereinafter referred to as "Act") shall be listed below:

- (1) a plan view of the poultry slaughter plant;
- (2) a layout drawing of the machinery to be used for poultry slaughter;
- (3) summarized specifications for the machinery to be used for poultry slaughter;
- (4) the number of poultry to be handled;
- (5) a copy of documents certifying the results of a water quality test performed by the agency concerned of a local public entity or a person designated by the Minister of Health, Labour and Welfare under the provisions of Paragraph 3, Article 20 of the Water Works Act (Act No. 177, 1957), if the poultry slaughter plant intends to use any water other than that from public supply or private sources as prescribed by the Water Works Act (hereinafter referred to as "water from public supply or private sources"); and
- (6) a copy of the register for a juridical person.

(Standards for Structure and Facilities)

Article 2. The Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 2, Article 5 of the Act shall be as prescribed in Appendix 1 hereof.

2. The Standards for structure and facilities as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 2, Article 5 of the Act and applicable to a poultry slaughter plant for which an authorized small scale poultry slaughterer obtains a certificate (including a poultry slaughter plant for which a poultry slaughterer intends to obtain a certificate under Paragraph 1, Article 16 of the Act at the same time an application is filed for a license under Article 3 of the Act) shall be as prescribed in Appendix 2 hereof, regardless of the provisions of the preceding paragraph.

(Minor Changes or Modifications)

Article 3. The minor changes or modifications as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 1, Article 6 of the Act shall include:

- (1) any change or modification made to the machinery to be used for poultry slaughter;
- (2) any change or modification made to the lighting facilities; and
- (3) any change or modification made to the water supply piping in the poultry slaughter plant.

CHAPTER 2. OBLIGATIONS OF POULTRY SLAUGHTERER

(Sanitary Control Standards)

Article 4. The Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Article 11 of the Act shall be as prescribed in Appendix 3 or Appendix 4 hereof.

(Requirements for Appointment of Quality Controllers)

Article 5. The number of quality controllers to be appointed and stationed at each poultry slaughter plant under Paragraph 1, Article 12 of the Act shall be such that the poultry slaughter processes performed at the plant can be kept under sanitary conditions. If the poultry slaughter plant has overhead conveyers or other means installed to perform the poultry slaughter processes in continuously moving lines, two quality controllers for each line (one quality controller for each line in a poultry slaughter plant which is subject to the post feather-removal inspection simultaneously with the post-evisceration inspection under Paragraph 5, Article 15 of the Act (hereafter referred to as "poultry slaughter plant under Paragraph 5, Article 15 of the Act" in this article) plus one additional quality controller for every 20 carcasses per minute (every 35 carcasses per minute for a poultry slaughter plant under Paragraph 5, Article 15 of the Act) for each line.

(Qualifications Requirements for Quality Controllers)

Article 6. A person determined to be equal to or surpassing the person as prescribed in Article 47 of the School Education Act (Act No. 26, 1947) referred to in Subparagraph (4), Paragraph 5, Article 12 of the Act shall be any of the following:

- (1) a person who has finished a higher class at any national elementary school under the National Elementary School Order (Imperial Ordinance No. 148, 1941);
- (2) a person who has finished a two-year course at any middle school under the Middle School Order (Imperial Ordinance No. 36, 1943);
- (3) a person who has finished the second grade at any junior high school or girls' high school attached to a normal school under the Normal School Education Order (Imperial Ordinance No. 109, 1943);
- (4) a person who has the second grade of a middle class at

Annex 3

any school for the deaf and mute under the Blind School and Deaf-Mute School Order (Imperial Ordinance No. 375, 1923);

(5) a person who has finished the second grade of an ordinary class at any high school under the High School Order (Imperial Ordinance No. 389, 1918);

(6) a person who has finished an ordinary class at any boys' school under the Boys School Order (Imperial Ordinance No. 254, 1939);

(7) a person who has finished a higher class at any national elementary school, who has finished a two-year course at any middle school, or who has been determined as equivalent to that prescribed in Subparagraph (5) above, under the provisions of Articles 1 through 3 and Article 7 of the regulations for entrance or transfer of any student or pupil who has been learning at or any graduate who has graduated from a school located outside the main lands of Japan to another school (Ministry of Education Ordinance No. 63, 1943);

(8) a person who has finished the School for Seaman's Training under the Seaman's Training School Order (Imperial Ordinance No. 458, 1939); and

(9) a person who has been determined, for the purpose of qualifying a quality controller, by the Minister of Health, Labour and Welfare to be equal to or surpassing in scholastic achievement that person as prescribed in Article 47 of the School Education Act.

(Items to be Notified in Connection with Quality Controllers)

Article 7. The items as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 6, Article 12 of the Act shall be listed below:

(1) the notifier's name or title and address, and, in the case of a juridical person, the name of its representative;

(2) the title and location of the poultry slaughter plant;

(3) the name, address, and date of birth of each quality controller;

(4) a statement that the quality controller falls under one of the categories as listed in Paragraph 5, Article 12 of the Act; and

(5) the date when the quality controller was appointed or replaced.

2. The notice given under the preceding paragraph shall be accompanied with a document certifying that the quality controller falls under one of the categories as listed in Paragraph 5, Article 12 of the Act.

CHAPTER 3. REGISTRERED TRAINING INSPECTION AND REGISTERED TRAINING COURSE

(Criteria for Registration of a Training Institution)

Article 8. Criteria designated by the Ministry of Health, Labour and Welfare Ordinance under Article 1 of the Enforcement Order for the Poultry Slaughter Business Control and Poultry Inspection Act (Cabinet Order No. 52, 1991, referred to as 'the Order' hereinafter) shall be as

follows:

(1) University under the School Education Act or educational institution recognized as providing programs equivalent to those provided by a university or graduate university under the provisions of Subparagraph (2), Paragraph 4, Article 68-2 of the School Education Act;

(2) Providing programs containing one or more courses listed in the lower column of Appendix 5 for each subject listed in the upper column of said table, comprising 22 or more units in total;

(3) Providing programs containing courses mentioned in the preceding subparagraph and Appendix 6, comprising 40 or more units in total; and

(4) Providing lessons using machinery and equipment listed on the second column of the attached table of the Food Sanitation Act (Act No. 233, 1947), as a rule.

(Application Procedures for Registration)

Article 9. An application designated by Article 2 of the Order shall be accompanied by attachments describing the following items:

(1) Name and location of the training institution;

(2) Name and location of the person who established the training institution and date of establishment;

(3) Name and address of the head of the training institution;

(4) Name, personal record and course of teachers and their positions as full-time or part-time;

(5) Program plan for each grade, number of units, and classification of compulsory or selective subjects;

(6) Number of students for enrollment;

(7) Admission requirements and timing;

(8) Term of study;

(9) List of machinery and equipment and books for instruction and practices;

(10) Plat and layout drawing of school site and buildings;

(11) Rules and regulations; and

(12) Other items to be referred

(Recording on Registry)

Article 10. A training institution under Subparagraph (3), Paragraph 5, Article 12 of the Act shall be registered by entering the following items on the registry;

(1) Date and number of registration; and

(2) Name and location of a registered training institution (as designated by Article 3 of the Order. The same shall apply hereinafter), and name of head.

(Items for Notification of Changes)

Article 11. Items designated by the Ministry of Health, Labour and Welfare Ordinance under Article 3 of the Order shall mean those listed in Paragraph 1-3, 5-8, 9 (only those pertaining to machinery and equipment listed on the second column of the attached table of the Food Sanitation Act), 10 and 11, Article 9.

(Attachments)

Article 12. An application under Article 6 of the Order

Annex 3

shall be accompanied by attachments describing the following item:

- (1) Reasons for requesting rescission of registration;
- (2) Scheduled day of rescission of registration; and
- (3) Handling of existing students, if applicable.

(Public Notice)

Article 13. Descriptions designated by the Ministry of Health, Labour and Welfare Ordinance under Paragraph 2, Article 7 of the Order shall mean those listed on Paragraph 1, Article 9.

(Program of Training Course)

Article 14. The program of a training course under Paragraph 7, Article 12 of the Act shall meet all of the following requirements:

(1) Covering all courses listed on a to f and meeting the listed criteria for unit number:

- a. Introduction to Public Health, 4 hours
- b. Poultry inspection-related Acts and regulations, 4 hours
- c. Poultry anatomy and physiology, 2 hours
- d. Poultry pathology, 6 hours
- e. Poultry meat sanitation, 6 hours; and
- f. Relevant Acts, 2 hours

(2) A teacher shall be responsible for any courses equivalent to those listed in a to f in university based on the School Education Act, shall engage in food sanitary administration or food sanitary-related inspection in the national government, prefecture or city, or city or special ward establishing health centers, or shall be qualified as having knowledge and experience equivalent to those thereunder;

(3) Admission requirements shall include graduation from junior high school based on the School Education Act or equivalent, completion of the first half of a middle school program, or any of the conditions listed on each paragraph, Article 6 and work experience of not less than 3 years in poultry slaughter; and

(4) Completion of programs shall be appropriately authorized by examination or any other methods at the end of training course.

(Application Procedures for Registration)

Article 15. A person who intends to apply for registration under the provisions of Article 8 of the Order shall submit an application accompanied by a copy of his/her residence certificate (for a juridical person, transcript of corporation charter, donation or register book) and documents describing the following items to the Minister of Health, Labour and Welfare:

- (1) Name and address of an operator of a training course (for a juridical person, its name, location of its principle office and name of a representative);
- (2) Existence of facts falling under any of paragraphs, Article 9 of the Order;
- (3) For a juridical person, name, address and brief personal history of executives;
- (4) Name and location of a training course site;
- (5) Name and location of a place for practical training;

(6) Duration and schedule of a training course;

(7) Scheduled number of students;

(8) Subjects and number of hours; and

(9) Name and occupation of teachers, courses for which they are responsible and number of hours for each course.

(Entry on Registry)

Article 16. Registration under Article 8 of the Order shall be made by entering the following items on the registry:

(1) Date and number of registration;

(2) Name and address of an operator of a registered training course (for a juridical person, its name, location of its principle office and name of a representative); and

(3) Duration of the registered training course.

(Criteria for Registration of a Training course)

Article 17. Criteria stipulated by the Ministry of Health, Labour and Welfare Ordinance under Article 10 of the Order shall be as follows:

(1) Qualification of students shall be confirmed by their curriculum vitae, employee certificate issued by relevant operators and other documents;

(2) A certificate for completion of training course shall be issued to those who have successfully completed the relevant program; and

(3) A registered training course shall be conducted according to the provisions of Article 19.

(Items for Notification of Changes)

Article 18. Items designated by the Ministry of Health, Labour and Welfare Ordinance under Article 12 of the Order shall be as follows:

(1) Name and address of an operator of a registered training course (for a juridical person, its name and location of its principle office); and

(2) Duration of a registered training course.

(Notification of Suspension or Termination of Operations)

Article 19. An operator of a registered training course, when intends to suspend or terminate operations of a registered training course under the provisions of Article 13 of the Order, shall give a notice of the following items to the Minister of Health, Labour and Welfare:

(1) Reasons and scheduled period of suspension or termination; and

(2) Duration of suspension, if applicable.

(Availability of Financial Statements)

Article 20. An operator of a registered training course shall create financial statements of the previous fiscal year (Financial statements designated in Paragraph 1, Article 14 of the Order. Hereinafter the same shall apply in this Article.)(When less than 3 months have passed since the end of the previous fiscal year, financial statements of the previous fiscal year may replace them.), and make them available between acquisition of registration and the completion of a registered training course.

Annex 3

(Indication Methods of Electromagnetic Records)

Article 21. Devices designated by the Ministry of Health, Labour and Welfare Ordinance under Subparagraph (3), Paragraph 2, Article 14 of the Order shall be hardcopy or indication on a monitor of output devices of descriptions stored in the relevant electromagnetic records.

(Methods of Provision of Electromagnetic Records)

Article 22. Electromagnetic devices designated by the Ministry of Health, Labour and Welfare Ordinance under Subparagraph (4) Paragraph 2, Article 14 of the Order shall be the one designated by an operator of a registered training course out of those listed in the following paragraphs:

- (1) Devices using electronic data processing system which connect sender's computers (including input-output devices. Hereinafter the same shall apply in this paragraph) and receiver's computers by electronic communication lines, in which information is sent through the relevant electronic communication lines, and recorded in files stored in the computers of a receiver; and
- (2) Provision of media containing files created by devices ensuring the recording of certain information using magnetic or other methods.

(Descriptions of Registry)

Article 23. Items designated by the Ministry of Health, Labour and Welfare Ordinance under Article 18 of the Order shall be as follows:

- (1) Name and personal history of students;
 - (2) Number of students; and
 - (3) Name, birth date, and address of a person who received a certificate for the completion of the training course, and name and location of his/her work place;
- 2.** Financial records under Article 18 of the Order shall be stored for 3 years from the last entry.

(Identification for On-site Inspection etc.)

Article 24. Personnel's identification cards under the provisions of Paragraph 2, Article 20 of the Order shall be based on Form 1.

CHAPTER 4. POULTRY INSPECTION

(Scope of Diseases or Unusual Conditions subject to Inspection)

Article 25. Diseases and unusual conditions designated by the Ministry of Health, Labour and Welfare Ordinance under Subparagraph (2) or (3), Paragraph 4, Article 15 of the Act shall be those listed in Appendix 7.

(Requirements for Exceptional Inspection)

Article 26. The requirements as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 5, Article 15 of the Act shall be listed below:

- (1) One or more overhead conveyers shall be installed with a trolley-to-trolley spacing of not less than 15 cm.
- (2) Mirrors shall be provided at an appropriate location in the inspection area in order to allow the poultry inspectors to visually examine the back of each eviscerated carcass of poultry without turning it over or moving themselves.

(Methods and Procedures for Poultry Inspection)

Article 27. The methods as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 6, Article 15 of the Act shall be listed below:

- (1) Any poultry inspection shall be performed under adequate natural light or proper artificial light.
 - (2) Any ante-mortem inspection (as prescribed in Paragraph 1, Article 15 of the Act; this term shall apply to the succeeding provisions herein) shall be performed by visually examining the conditions of live poultry before slaughter and, if as a result of the visual examination, any one of the live poultry is suspected to suffer from one or more of the diseases or unusual conditions as prescribed in Paragraph 4, Article 15 of the Act, by further examining all the live poultry one by one for judgment.
 - (3) Any post feather-removal inspection shall be performed by visually and tactually examining all the defeathered (or feather-removed) carcasses of poultry one by one for surface conditions and, if as a result of the visual and tactual examinations, any one of the carcasses of poultry is suspected to suffer from one or more of the diseases or unusual conditions as prescribed in Paragraph 4, Article 15 of the Act, by further examining the suspected carcass of poultry for judgment.
 - (4) Any post-evisceration inspection shall be performed by visually and tactually examining all the eviscerated carcasses of poultry one by one for inner surface conditions and all the viscera related to those carcasses for visceral conditions and, if as a result of the visual and tactual examinations, any of the eviscerated carcasses of poultry or the viscera is suspected to suffer from one or more of the diseases or unusual conditions as prescribed in Paragraph 4, Article 15 of the Act, by further examining the suspected viscera or eviscerated carcass of poultry for judgment.
 - (5) The kind, breed, number, and growing district of the poultry inspected and the inspection results shall be recorded.
- 2.** The procedures as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 6, Article 15 of the Act shall consist of submission of an application form for each poultry slaughter plant by a poultry slaughterer who wishes to undergo the poultry inspections, to the governor of the prefecture where the plant is located or the mayor of the city where the plant is located if that city is required to establish an appropriate number of health centers by the applicable Cabinet Order referred to in Article 1 of the Health Center Act (Act No. 101, 1947) (hereinafter referred to as "city establishing health centers") (this alternative shall apply to the succeeding provisions herein, if applicable) and the application form shall state:
- (1) the applicant's name or title and address, and, in the case

Annex 3

- of a juridical person, the name of its representative;
- (2) the date on which the applicant intends to slaughter any number of poultry; and
- (3) the kind, breed, number, and growing district of poultry for which the applicant intends to undergo the poultry inspections.

(Verification Methods, Verification Standards, and Simplified Methods for Poultry Inspection)

Article 28. For the purpose of verifying that any carcasses of poultry comply with the Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 7, Article 15 of the Act, any quality controller shall examine visually, tactually, and olfactorily the following conditions under the supervision of poultry inspectors (as defined in Article 49 hereof; this definition shall also apply to the succeeding provisions herein) or other inspectors (as defined in Paragraph 2, Article 25 of the Act; this definition shall also apply to the succeeding provisions herein) who are performing any poultry inspection for the poultry slaughter plant at that point of time:

(1) for verification in connection with a post feather-removal inspection, the surface conditions of each one of the defeathered carcasses of poultry; or

(2) for verification in connection with a post-evisceration inspection, the inner surface conditions of each one of the eviscerated carcasses of poultry and the conditions of the viscera related to that carcass.

2. The Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 7, Article 15 of the Act shall be as listed in Appendix 8 hereof.

3. The simplified methods for the post feather-removal inspection and the post-evisceration inspection referred to in Paragraph 7, Article 15 of the Act shall be performed by omitting part of visual and tactual examinations on each carcass of poultry for surface conditions or part of visual and tactual examinations on each eviscerated carcass of poultry and the viscera related thereto for inner surface conditions and visceral conditions.

(Items to be Described in Verification Plans and Regulations and Standards therefor)

Article 29. The items as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 1, Article 16 of the Act shall be listed below:

(1) the verification methods referred to in Paragraph 5, Article 16 of the Act;

(2) the verification procedures referred to in Paragraph 5, Article 16 of the Act (including information concerning their relation to the methods and procedures for poultry inspection);

(3) information concerning how to record the results of any verification performed under Paragraph 5, Article 16 of the Act and how to keep the records; and

(4) information concerning the participation of quality controllers.

2. The Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 1, Article 16 of the Act shall be listed below:

(1) The verification performed under Paragraph 5, Article 16 of the Act shall be such that the conditions of live poultry can be properly checked for compliance with each of the requirements as listed in Appendix 9 hereof or the surface conditions of carcasses of poultry or the inner surface conditions of eviscerated carcasses of poultry or the conditions of the viscera related thereto can be properly checked for compliance with each of those listed in Appendix 8 hereof.

(2) The verification methods and procedures referred to in Paragraph 5, Article 16 of the Act shall be appropriate for the kind and number of poultry to be handled by the poultry slaughterer, for the type of poultry slaughter processes as listed in Subparagraph (5), Article 2 of the Act, and for the poultry slaughter methods and other operational conditions.

(3) The results of the verification performed under Paragraph 5, Article 16 of the Act shall be properly recorded and those records shall be properly kept.

(4) The verification referred to in Paragraph 5, Article 16 of the Act shall be properly performed by quality controllers.

(Verification Methods and Judgment)

Article 30. The verification referred to in Paragraph 5, Article 16 of the Act shall be accomplished as listed below:

(1) for the conditions of live poultry, by performing proper visual and tactual examinations; and

(2) for the surface conditions of carcasses of poultry and for the inner surface conditions of eviscerated carcasses of poultry and the conditions of the viscera related thereto, by performing proper visual, tactual, and olfactory examinations on each carcass.

2. The Standards as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 5, Article 16 of the Act shall be as listed in Appendix 9 hereof for the conditions of live poultry and in Appendix 8 hereof for the surface conditions of carcasses of poultry and for the inner surface conditions of eviscerated carcasses of poultry and the conditions of the viscera related thereto.

(Reporting)

Article 31. Any report required under Paragraph 7, Article 16 of the Act shall be made for each poultry slaughter plant by the end of every month, stating the following items concerning any verification performed in the previous month under Paragraph 5 thereof:

(1) the date when any poultry were slaughtered or eviscerated;

(2) the kind and number of the poultry handled;

(3) the kind and number of such poultry as determined compliant with the Standards referred to in Paragraph 2 of the preceding article;

(4) the kind and number of such poultry as determined non-compliant with the Standards referred to in Paragraph 2 of the preceding article and the reasons for non-compliance; and

Annex 3

(5) a description of any measure taken under Article 19 of the Act.

(Registration of Registered Meat Sellers)

Article 32. Any person who intends to make a registration under Subparagraph (4), Paragraph 1, Article 17 of the Act shall submit a registration form stating the following items and a copy of the document certifying that the person has been granted a license for meat selling business under Subparagraph (12), Article 35 of the Enforcement Order for the Food Sanitation Act (Cabinet Order No. 229, 1953):

- (1) the person's name or title and address, and, in the case of a juridical person, the name of its representative; and
- (2) major suppliers and customers for carcasses of poultry.

(Measures)

Article 33. The measures to be taken by a poultry slaughterer (but not an authorized small scale poultry slaughterer) under Article 19 of the Act shall be listed below:

(1) Measures to be taken based on the results of the antemortem inspection

a. For any live poultry determined to suffer from one or more of the diseases or unusual conditions as listed in Appendix 10 hereof (excluding excessive scalding and insufficient bleeding), the poultry slaughterer shall prohibit said live poultry from being slaughtered and dispose of them or take other measures to prevent them from being supplied for food (hereinafter referred to as "disposal or other measures").

b. For any poultry determined to suffer from one or more of the diseases or unusual conditions as prescribed in Paragraph 4, Article 15 of the Act (excluding those diseases and unusual conditions as listed in Appendix 10), the poultry slaughterer shall slaughter said poultry after all of the acceptable poultry have been slaughtered, and take one of the measures listed in the subparagraphs (2) a., (2) b. and (2) c. of this paragraph based on the results of the post feather-removal inspection (or one of the measures listed in the subparagraphs (3) a., (3) b. and (3) c. of this paragraph based on the results of the post feather-removal inspection and the post-evisceration inspection, if those inspections are performed simultaneously under Paragraph 5, Article 15 of the Act; this alternate shall also apply to the provision of the subparagraph (1) c. of this paragraph).

c. For any poultry suspected to suffer from one or more of the diseases or unusual conditions as prescribed in Paragraph 4, Article 15 of the Act (excluding excessive scalding and insufficient bleeding), the poultry slaughterer shall slaughter said poultry after all of the acceptable poultry have been slaughtered, and take one of the measures listed in the Subparagraphs (2) a., (2) b. and (2) c. of this paragraph based on the results of the post feather-removal inspection, or the poultry slaughterer shall defer any measure until further inspection determines whether said live poultry can pass the ante-mortem inspection.

(2) Measures to be taken based on the results of the post feather-removal inspection (except for the case where the post feather-removal inspection is performed simultaneously

with the post-evisceration inspection under Paragraph 5, Article 15 of the Act)

a. For any carcass of poultry determined to suffer from one or more of the diseases or unusual conditions as listed in Appendix 10 hereof, the poultry slaughterer shall prohibit said carcass of poultry from being eviscerated and take disposal or other measures against it.

b. For any carcass of poultry determined to suffer from one or more of the diseases or unusual conditions as prescribed in Paragraph 4, Article 15 of the Act (excluding those diseases and unusual conditions as listed in Appendix 10), the poultry slaughterer shall eviscerate said carcass of poultry after all of the acceptable carcasses have been eviscerated, and take one of the measures listed in the Subparagraphs (3) a., (3) b. and (3) c. of this paragraph based on the results of the post-evisceration inspection.

c. For any carcass of poultry suspected to suffer from one or more of the diseases or unusual conditions as prescribed in Paragraph 4, Article 15 of the Act, the poultry slaughterer shall eviscerate said carcass of poultry after all of the acceptable carcasses have been eviscerated, and take one of the measures listed in the Subparagraphs (3) a., (3) b. and (3) c. of this paragraph based on the results of the post-evisceration inspection, or the poultry slaughterer shall defer any measure until further inspection determines whether said carcass of poultry can pass the post feather-removal inspection.

(3) Measures to be taken based on the results of the post-evisceration inspection (including the case where the post feather-removal inspection is performed simultaneously with the post-evisceration inspection under Paragraph 5, Article 15 of the Act)

a. For any parts of poultry determined to suffer from one or more of the diseases or unusual conditions as listed in Appendix 10 hereof, the poultry slaughterer shall take disposal or other measures against all of them.

b. For any parts of poultry determined to suffer from one or more of the diseases or unusual conditions as listed in the left columns of Appendix 11 hereof, the poultry slaughterer shall take disposal or other measures against the parts listed in the appropriate right column thereof.

c. For any parts of poultry suspected to suffer from one or more of the diseases or unusual conditions as prescribed in Paragraph 4, Article 15 of the Act, the poultry slaughterer shall defer any measure until further inspection determines whether said parts of poultry can pass the post feather-removal inspection (only for the case where the post feather-removal inspection is performed simultaneously with the post-evisceration inspection under Paragraph 5, Article 15 of the Act) and the post-evisceration inspection.

(4) Disinfection

For any live poultry, carcass of poultry, eviscerated carcass of poultry, or poultry parts determined to suffer from one or more of the diseases or unusual conditions prescribed in Paragraph 4, Article 15 of the Act and thereby to be likely to a source or medium of infection, the poultry slaughterer shall isolate said live poultry or disinfect said carcass of poultry, eviscerated carcass of poultry, or poultry parts, and disinfect

Annex 3

the facilities and equipment of the poultry slaughter plant which are contaminated or suspected to be contaminated with any pathogen or take other measures necessary to prevent the pathogen from spreading.

2. The measures to be taken by an authorized small scale poultry slaughterer under Article 19 of the Act shall be listed below:

(1) Measures to be taken based on the results of the verification for the conditions of any live poultry For any live poultry which does not comply with the Standards listed in Appendix 9 hereof, the authorized small scale poultry slaughterer shall prohibit said live poultry from being slaughtered and take disposal or other measures against it.

(2) Measures to be taken on the results of the verification for the surface conditions of any carcass of poultry or for the inner surface conditions of any eviscerated carcass of poultry and the conditions of the viscera related thereto

a. For any carcass of poultry which does not comply with the Standards listed in Subparagraph (1) a. of Appendix 8 hereof or any eviscerated carcass of poultry which does not comply with the Standards listed in Subparagraph (2) thereof, the authorized small scale poultry slaughterer shall take disposal or other measures against said carcass of poultry or all of the parts related to said eviscerated carcass of poultry.

b. For any carcass of poultry which does not comply with the Standards listed in Subparagraph (1) b. of Appendix 8 hereof, the authorized small scale poultry slaughterer shall take disposal or other measures against any part of said carcass of poultry that is determined to suffer from one or more of the unusual conditions listed in that subparagraph.

c. For any viscera which do not comply with the Standards listed in Subparagraph (3) of Appendix 8 hereof, the authorized small scale poultry slaughterer shall take one of the following measures:

(i) if a single viscus is incompliant with the Standards listed in that subparagraph, disposal or other measures against said viscus; and

(ii) if two or more viscera are incompliant with the Standards listed in that subparagraph, disposal or other measures against all of the viscera related to the same carcass of poultry.

(3) Disinfection

The authorized small scale poultry slaughterer shall isolate any live poultry or disinfect any carcass of poultry, eviscerated carcass of poultry, or poultry parts and the facilities and equipment of the poultry slaughter plant, as required.

CHAPTER 5. DESIGNATED INSPECTION AGENCY

(Application for Designation)

Article 34. Any person who wishes to apply for designation under the provisions of Paragraph 2, Article 21 of the Act shall submit to the Minister of Health, Labour and Welfare an application (Form No. 2) with the following documents attached thereto:

(1) a copy of the register;

(2) an inventory of property and a balance sheet prepared for the business year immediately before the current business year in which such application is submitted (or an inventory of property prepared at the time of establishment if the applicant agency was established in the current business year);

(3) business plans (including those for any service other than the poultry inspection service if the applicant agency is engaged therein) and accompanying fiscal budgets prepared for the current business year in which such application is submitted and for the next business year;

(4) a document enough to prove the applicant agency's decision made on such application;

(5) the following documents on the applicant agency's executives:

a. a document stating the name, address, and summary of personal career of each executive;

b. a document declaring that none of the executives falls under the category referred to in Subparagraph (4) a. or (4) b., Paragraph 2, Article 22 of the Act;

(6) for an incorporated association, a document stating the name of each employee or the association;

(7) a document stating a summary of the service currently performed by the applicant agency;

(8) a poultry inspection program including the following:

a. business hours for the poultry inspection service and holidays;

b. for each of the poultry inspection offices,

(i) the name and address of that office;

(ii) a summary of the poultry inspection service to be conducted therein;

(iii) the number of inspectors to be appointed;

c. the way to receive inspection fees;

d. methods to conduct the poultry inspections;

e. procedures to conduct the poultry inspections;

f. the kinds of books for recording the poultry inspection service and the way to manage them;

g. records on the appointment and dismissal of inspectors;

h. training of inspectors;

i. other items necessary for conducting the poultry inspection service;

(9) a document stating the name and summary of personal career of each inspector and a document certifying that such inspector has the qualification as referred to in Paragraph 3, Article 37 hereof;

(10) for each of the poultry inspection offices, a document stating the machinery and equipment used for the poultry inspections and a provision schedule for them; and

(11) other documents for reference.

(Notice of Changes)

Article 35. Any designated inspection agency shall, when intending to notify any change under the provisions of Paragraph 2, Article 23 of the Act, submit a notification (Form No. 3) to the Minister of Health, Labour and Welfare.

Article 36. Any designated inspection agency shall, when intending to notify any change under the provisions of

Annex 3

Paragraph 2, Article 24 of the Act, submit a notification stating:

- (1) the name, the principal place of business, or the location of a poultry inspection office to be changed;
- (2) the date when the change becomes effective; and
- (3) the reasons for the change.

(Methods and Procedures for Poultry Inspection and Qualification for Inspectors)

Article 37. The methods as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 2, Article 25 of the Act shall be as prescribed in Paragraph 1, Article 27 hereof.

2. The provisions of Paragraph 2, Article 27 hereof shall apply to the poultry inspections referred to in Paragraph 2, Article 25 of the Act; provided, however, that the wording “to the governor of the prefecture” in Paragraph 2, Article 27 hereof shall be interpreted as the wording “to a designated inspection agency authorized by the governor of the prefecture”.

3. The qualification as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 2, Article 25 of the Act shall be a veterinarian’s license granted under the Veterinary License Act (Act No. 186, 1949).

(Reporting Procedures and Contents of Reports)

Article 38. Any report made under Paragraph 3, Article 25 of the Act shall be prepared by the end of each month and describe the poultry inspection service conducted during the previous month for each poultry slaughter plant inspected.

2. The items as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 3, Article 25 of the Act shall be listed below:

- (1) the date when the poultry inspections were conducted;
- (2) the kind, breed, number, and growing district of the poultry inspected;
- (3) the kind, breed, and number of such poultry as determined compliant;
- (4) the kind, breed, and number of such poultry as determined non-compliant and the reasons for non-compliance;
- (5) a description of any measure taken under Article 19 of the Act.

(Application for Approval on Appointment and Dismissal of Executives)

Article 39. Any designated inspection agency shall, when intending to receive an approval on the appointment or dismissal of an executive under the provisions of Paragraph 1, Article 26 of the Act, submit an application (Form No. 4) to the Minister of Health, Labour and Welfare.

2. An application for appointment as referred to in the preceding paragraph shall be accompanied with a document stating a summary of personal career of an executive to be appointed and a document proving that the executive does not fall under the category prescribed in Subparagraph (4) a. or (4) b., Paragraph 2, Article 22 of the Act.

(Notification of Appointment and Dismissal of Inspectors)

Article 40. Any designated inspection agency shall, when intending to notify the appointment or dismissal of an inspector under the provisions of Paragraph 2, Article 26 of the Act, submit a notification (Form No. 5) to the Minister of Health, Labour and Welfare.

2. A notification of appointment as referred to in the preceding paragraph shall be accompanied with a document stating a summary of personal career of an inspector to be appointed and a document proving that the inspector has the qualification as prescribed in Paragraph 3, Article 37 hereof

(Inspection Service Plans and Regulations)

Article 41. The items for the poultry inspection service as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Paragraph 1, Article 28 of the Act shall be as listed in Paragraph 8, Article 34 hereof.

2. Any designated inspection agency shall, when receiving an approval on its inspection service plans and regulations under the provisions of Paragraph 1, Article 28 of the Act, submit to the Minister of Health, Labour and Welfare an application (Form No. 6) accompanied with such inspection service plans and regulations.

3. Any designated inspection agency shall, when receiving an approval on any revision of its inspection service plans and regulations under the provisions of Paragraph 1, Article 28 of the Act, submit to the Minister of Health, Labour and Welfare an application (Form No. 7) accompanied with a document stating the authorizing Governor’s view as prescribed in Paragraph 2 of the same article.

(Application for Approval on Business Plans)

Article 42. Any designated inspection agency shall, when receiving an approval on its business plan and operating budget under the provisions of Paragraph 1, Article 29 of the Act, submit to the Minister of Health, Labour and Welfare an application (Form No. 8) accompanied with such business plan and operating budget and a document stating the authorizing Governor’s view as prescribed in Paragraph 2 of the same article.

2. Any designated inspection agency shall, when receiving an approval on any revision of its business plan and operating budget under the provisions of Paragraph 1, Article 29 of the Act, submit to the Minister of Health, Labour and Welfare an application (Form No. 9) accompanied with a document stating the authorizing Governor’s view as prescribed in Paragraph 2 of the same article.

(Accounting Books)

Article 43. The accounting books as prescribed in Article 30 of the Act shall be prepared for each poultry slaughter plant where the poultry inspection service is conducted, be provided in each poultry inspection office of the designated inspection agency, and be stored in place for a period of ten years after recording data in them.

2. The items as prescribed by the applicable Ministry of

Annex 3

Health, Labour and Welfare Ordinance referred to in Article 30 of the Act shall be listed below:

- (1) the requesting poultry slaughterer's name or title and address, and in the case of a juridical person, the name of its representative;
- (2) the date when the request for poultry inspection was received;
- (3) the date when the poultry inspections were conducted;
- (4) the kind, breed, number, and growing district of the poultry inspected;
- (5) the name of each inspector who conducted the poultry inspections;
- (6) a description and results of the poultry inspections;
- (7) a description of any measure taken under Article 19 of the Act and the reasons thereof;
- (8) other items necessary for the poultry inspections.

(Application for Approval on Cessation or Suspension of Poultry Inspection Service)

Article 44. Any designated inspection agency shall, when receiving a permission under the provisions of Paragraph 1, Article 32 of the Act, submit an application (Form No. 10) to the Minister of Health, Labour and Welfare.

(Transfer of Poultry Inspection Service)

Article 45. In the case as prescribed in Paragraph 4, Article 35 of the Act, any designated inspection agency (including any designated inspection agency whose designation was revoked by the Minister of Health, Labour and Welfare under the provisions of Paragraph 1 or 2, Article 33 of the Act) shall:

- (1) transfer the portion of its poultry inspection service that the authorizing Governor will take over, to the authorizing Governor;
- (2) deliver appropriate accounting books and documents for the portion of its poultry inspection service that the authorizing Governor will take over, to the authorizing Governor; and
- (3) take such other measures as deemed necessary by the Minister of Health, Labour and Welfare or the authorizing Governor.

CHAPTER 6. MISCELLANEOUS

(Reporting Obligations)

Article 46. The Governor shall, before requesting any poultry slaughterer to make a report under Paragraph 1, Article 37 of the Act, notify to that poultry slaughterer of the matter requiring such report, the reasons therefore, and the time limit thereof.

(Collection Certificates and Identification Cards)

Article 47. The personnel of a prefecture (or the personnel of a city, if that city is a city establishing health centers) shall, when performing any collection under Paragraph 1, Article 38 of the Act, issue a collection certificate (Form No. 11) to the collectee.

2. The personnel who conducts an onsite inspection in accordance with Paragraph 1, Article 38 of the Act shall bear a certificate for identification (Form No. 12).

3. The personnel who conducts an onsite inspection in accordance with Paragraph 2, Article 38 of the Act shall bear a certificate for identification (Form No. 13).

(Personnel as Prescribed by the Applicable Ministry of Health, Labour and Welfare Ordinance Referred to in Article 39 of the Act)

Article 48. The personnel as prescribed by the applicable Ministry of Health, Labour and Welfare Ordinance referred to in Article 39 of the Act shall be rabies control officers or environmental sanitation inspectors.

(Poultry Inspector)

Article 49. The personnel designated by the Governor under Article 39 of the Act shall be called "poultry inspectors".

(Delegation of Authority)

Article 50. The following authorities of the Minister of Health, Labour and Welfare shall be delegated to a Director of Local Health Office under the provisions of Paragraph 1, Article 42-3 of the Act:

- (1) Authorities under Subparagraph (3), Paragraph 5, Article 12 of the Act (limited to those pertaining to collection of reports);
- (2) Authorities under Subparagraph (4), Paragraph 5, Article 12 of the Act (limited to those pertaining to orders for conformity and improvement, collection of reports and on-site inspection);
- (3) Authorities designated by Paragraph 1, Article 31 of the Act;
- (4) Authorities designated by Paragraph 2, Article 37 of the Act; and
- (5) Authorities designated by Paragraph 2, Article 38 of the Act.

2. Authorities listed in Subparagraph (1) of the preceding paragraph shall be delegated to a Director of Local Health Bureau under the provisions of Paragraph 2, Article 42-3 of the Act; provided, however, that it shall not preclude a Director of Local Health Office from executing the relevant authority.

Annex 3

Appendix 1 (related to Article 2)

1. A poultry-processing site shall be established in a place free of contamination risks.

2. The ground surface around the buildings of a poultry-processing site shall be paved or otherwise enable easy cleaning, with effective drainage.

3. Facilities of a poultry-processing site and layout of the facilities

A A poultry-processing site shall be equipped with a facility for receiving live birds, facility for processing poultry, room for storing products, room for packaging materials, inspection room, changing room, toilets, and wastewater processing facility, marked from each other and established in appropriate locations. It is acceptable that a poultry-processing site that directly discharges blood and wastewater to a sewer equipped with a terminal processing plant does not have a wastewater processing facility.

B A facility for receiving live birds shall be equipped with a yard for storing live birds and a yard for quarantine, laid out in adequate locations.

C A facility for processing poultry shall be equipped with a room for slaughtering and bleeding, room for hot water steeping and plucking, room for evisceration (i.e. room with equipment for evisceration; the same applies hereafter in this Appendix), and areas for post-plucking inspection and for post-evisceration inspection, marked from each other and located in adequate locations. It is acceptable that a poultry-processing site where no operations listed in B, Item 5, Article 2 of the Act are undertaken does not have a room for evisceration and an area for post-evisceration inspection.

D A facility for receiving live birds; a shipping yard for poultry carcasses after processing, eviscerated poultry carcasses, and poultry meat; and a shipping yard for poultry carcasses, eviscerated poultry carcasses, and poultry meat that have been rated as non-conforming in inspection, shall be separated from each other.

4. Structure and equipment of a poultry-processing site (common matters)

A The site shall have adequate space for sanitary packaging and storage of received live birds, processed poultry, poultry carcasses, eviscerated poultry carcasses, and/or poultry meat.

B The floor, inner walls and ceiling shall use materials and structure as described below.

(1) The floor of a facility for receiving live birds and of a facility for processing poultry shall be made of impermeable materials (i.e. impermeable by blood or wastewater; the same applies to hereafter in this Appendix, in Appendix 2 and in Appendix 3), without cracks or unevenness, and have appropriate inclination for effective drainage.

(2) The inner walls of a facility for poultry processing shall be smooth and easy to clean, without gaps, and shall be skirted with impermeable materials up to the height of at least 1.2 meters from the floor surface, above which height

the walls shall be made of water-proof materials. The inner walls of facilities other than a facility for poultry processing shall be smooth and easy to clean.

(3) The interface between the inner walls and the floor in a facility for poultry processing shall be easy to clean and wash, by rounding for example.

(4) The ceiling of a facility for poultry processing shall be smooth and easy to clean, and use materials and structure that prevent mold and falling dust, and minimize dew condensation. The ceiling of facilities other than a facility for poultry processing shall be smooth and easy to clean.

C The facilities shall have a structure or equipment that provides the following illuminance.

(1) Illuminance of at least 540 lux over surfaces on which inspection is conducted in inspection areas

(2) On parts other than surfaces indicated in (1), illuminance that does not interfere with operations

(3) Lighting that does not alter the natural colors of poultry, poultry carcasses, eviscerated poultry carcasses, and organs

D The facilities shall have the following (hot) water supply systems, etc.

(1) Water supply system capable of sufficiently providing water supplied by the water utility service or potable water

(2) Hot water supply system capable of sufficiently providing hot water of 60°C or higher temperature

(3) In places where heat or steam is generated, ventilation system with sufficient capacity in appropriate locations

E The wastewater system shall have smooth inner walls and appropriate inclination for effective drainage, and be equipped with drainage grooves connected to a wastewater processing facility or public sewer. The drainage grooves shall be equipped with traps to prevent the backflow of wastewater and odor, as well as devices to prevent the entry of pest.

F The facilities shall be equipped with cleansing/disinfection tools and cleaning tools for different purposes, and storage equipment for such tools, in appropriate locations.

5. Facility for receiving live birds

A A yard for storing live birds shall have adequate space for storing poultry and conducting ante-mortem inspection before slaughtering, in accordance with the quantity of poultry processing, and shall be equipped with a cleansing/disinfection equipment for live bird transportation containers, and a hand washing equipment using running water where employees engaged in poultry processing (referred to as “employees” hereafter in this Appendix, in Appendix 2 and in Appendix 3) can cleanse/disinfect their hands and fingers (simply referred to as “hand washing equipment” hereafter in this Appendix, in Appendix 2 and in Appendix 3).

B A yard for quarantine shall be equipped with a required number of containers for poultry to be disposed of (i.e. containers for keeping poultry that requires disposal or other actions based on the results of poultry inspection; the same applies hereafter in this Appendix), hand washing equipment for poultry inspectors or other inspectors (collectively

Annex 3

referred to as “poultry inspectors” hereafter in this Appendix), and equipment for cleansing/disinfecting poultry waste and wastewater that requires disposal or other actions.

6. Facility for poultry processing

A A facility for poultry processing shall be marked with partitions from living quarters, offices and other areas that are not directly related to poultry processing, and the entrance/exit doors shall be sealable. Openings to outside (e.g. windows, vents) shall be equipped with devices to prevent the entry of insects, etc.

B The facility shall be equipped with equipment for storing containers of inedible parts (referred to as “containers of inedible parts” hereafter in this Appendix, in Appendix 2, and in Appendix 3) in appropriate locations inside, and such equipment shall have a structure that is easy to clean.

C The room for slaughtering and bleeding shall satisfy the following requirements.

(1) Have a bleeding trough or bleeding groove of the size matching the poultry processing quantity, that is made of impermeable materials, is easy to cleanse, and has a structure that prevents the scattering of blood

(2) Equipped with machinery and instruments used for slaughtering and bleeding, and cleansing/disinfection equipment for those machinery and instruments

(3) Equipped with hand washing equipment that matches the number of employees

D The room for hot water steeping and plucking shall satisfy the following requirements.

(1) Equipped with a hot water steeping machine that has adequate capacity matching the quantity of poultry processing, plucking machine, washing machine for poultry carcasses, and cleansing/disinfection equipment for those machinery

(2) Equipped with hand washing equipment that matches the number of employees

E The room for evisceration shall satisfy the following requirements.

(1) Equipped with an overhead conveyor, belt conveyor, bat or other types of equipment with a structure that enables confirmation that an eviscerated poultry carcass and the relevant organs come from the same bird, and prevents contamination of other eviscerated poultry carcasses and/or organs

(2) Equipped with machinery and instruments, with adequate capacity matching the quantity of poultry processing, for cloaca section, abdominal opening, evisceration, cleansing inside and outside eviscerated poultry carcasses, and cooling eviscerated poultry carcasses, and cleansing/disinfection equipment for those machinery and instruments

(3) Equipped with cleansing/disinfection equipment for an overhead conveyor, belt conveyor, bat, table, cutting boards and other machinery and instruments used for poultry processing

(4) Equipped with hand washing equipment that matches the number of employees

F The areas for inspection shall satisfy the following requirements.

(1) Equipped with a dedicated inspection table or rack for conducting post-plucking inspection or post-evisceration inspection for the whole or part of poultry carcasses, eviscerated poultry carcasses, and poultry meat

(2) Equipped with dedicated hand washing equipment for poultry inspectors and poultry processing sanitation managers, and equipment capable of supplying hot water of 83°C or higher temperature for steeping and disinfecting instruments used for poultry inspection

(3) Equipped with a required number of containers for keeping the whole or part of poultry carcasses, eviscerated poultry carcasses, and poultry meat that require disposal or other actions based on the results of post-plucking or post-evisceration inspection, with the relevant labeling indication (referred to as “containers for disposal” hereafter in this Appendix)

7. Room for storing products

A Equipped with refrigeration and chilling equipment

B Equipped with lockable storage equipment dedicated to poultry carcasses, eviscerated poultry carcasses, and poultry meat that are withheld based on the results of post-plucking or post-evisceration inspection

8. The inspection room shall be lockable, and be equipped with an inspection table and hand washing equipment.

9. The changing room shall have adequate space that matches the number of employees, and be equipped with storage equipment dedicated to the boots, aprons and work clothes for employees.

10. Toilets

A Completely segregated from other parts of the site with partitions, and have no direct entry from / exit to the facility for poultry processing or otherwise have no influence on the facility for poultry processing

B Equipped with hand washing equipment

C Openings to outside (e.g. windows, vents) shall be equipped with devices to prevent the entry of insects, etc.

11. The wastewater processing facility shall be equipped with wastewater processing equipment that has adequate capacity that matches the quantity of wastewater to be processed.

12. Structure and materials of machinery and instruments

A Machinery and instruments shall have a structure that is easy to cleanse/disinfect.

B Machinery and instruments that are fixated or difficult to move shall be installed in locations that are convenient for operation, and easy to clean/cleanse/disinfect.

C Live bird transportation containers shall be made of non-corrosive materials, and have a structure that is easy to cleanse/disinfect.

D Containers for keeping poultry carcasses, eviscerated

Annex 3

poultry carcasses, or edible organs that have been rated as conforming in poultry inspection, shall be made of non-corrosive materials, have a structure that prevents contamination from other substances, and have a structure that is easy to cleanse/disinfect.

E Containers for poultry processing, containers for disposal, and containers for inedible parts shall be made from impermeable materials, have lids, be easy to cleanse/disinfect, and have a structure that precludes the leak of wastewater and odor.

F When an overhead conveyor is installed, it shall be made of non-corrosive materials, and be equipped with cleansing/disinfection equipment for the shackles.

G The plucking machine shall have a structure that precludes the scattering of feathers, and be capable of spraying cleansing water.

H When an automatic cloaca section machine, automatic abdominal opening machine, and/or automatic evisceration machine are used, they shall have automatic cleansing/disinfection functions.

I Machinery and instruments that come into direct contact with poultry, poultry carcasses, eviscerated poultry carcasses, and/or poultry meat, such as a belt conveyor, bat, table and cutting board used for poultry processing, shall be made of non-corrosive materials, and have a structure that is easy to cleanse/disinfect.

Appendix 2 (related to Article 2)

1. A poultry-processing site shall be established in a place free of contamination risks.

2. The ground surface around the buildings of a poultry-processing site shall be paved or otherwise enable easy cleaning, with effective drainage.

3. Facilities of a poultry-processing site and layout of the facilities

A A poultry-processing site shall be equipped with an area for receiving live birds, facility for processing poultry, toilets, and wastewater processing facility, established in appropriate locations. It is acceptable that a poultry-processing site where no operations listed in A, Item 5, Article 2 of the Act are undertaken does not have an area for receiving live birds, and that a poultry-processing site that directly discharges blood and wastewater to a sewer equipped with a terminal processing plant does not have a wastewater processing facility.

B A room for processing poultry shall be equipped with an area for slaughtering and bleeding, area for hot water steeping and plucking, and area for evisceration (i.e. area with equipment for evisceration; the same applies hereafter in this Appendix) laid out in adequate locations. It is acceptable that a poultry-processing site where no operations listed in A, Item 5, Article 2 of the Act are undertaken does not have an area for slaughtering and bleeding or area for hot water steeping and plucking, and that a poultry-processing

site where no operations listed in B of the same item are undertaken does not have an area for evisceration.

C An area for receiving live birds and a shipping area for poultry carcasses after processing, eviscerated poultry carcasses and poultry meat shall be separated from each other.

4. Structure and equipment of a poultry-processing site (common matters)

A The site shall have adequate space for sanitary packaging and storage of processed poultry, poultry carcasses, eviscerated poultry carcasses, and/or poultry meat.

B The site shall have refrigeration or chilling equipment for poultry carcasses, eviscerated poultry carcasses or poultry meat, and adequate storage equipment for packaging materials.

C The site shall have a structure or equipment that provides illuminance that does not interfere with operations.

D The site shall have the following (hot) water supply systems.

(1) Water supply system capable of sufficiently providing water supplied by the water utility service or potable water

(2) Hot water supply system capable of sufficiently providing hot water

E The wastewater system shall have smooth inner walls and appropriate inclination for effective drainage, and be equipped with drainage grooves connected to a wastewater processing facility or public sewer. The drainage grooves shall be equipped with traps to prevent the backflow of wastewater and odor, as well as devices to prevent the entry of pests.

5. Area for receiving live birds

A The floor shall be made of impermeable materials, without cracks or unevenness, and have appropriate inclination for effective drainage.

B The area shall have adequate space for checking the conditions of live birds for conformity to the standards established by the Ordinance of the Ministry of Health, Labour and Welfare (MHLW) mentioned in Paragraph 5, Article 16 of the Act (referred to as “Check of conformance to the standards” hereafter in this Appendix and in Appendix 3).

C The area shall be equipped with containers for keeping poultry that requires disposal or other actions (referred to as “containers for poultry processing” hereafter in this Appendix) based on the results of checking the conditions of live birds for non-conformance to the standards established by the Ordinance of the MHLW mentioned in Paragraph 5, Article 16 of the Act (referred to as “Check of non-conformance to the standards” hereafter in this Appendix and in Appendix 3).

D The area shall have hand washing equipment.

6. Room for poultry processing

A A room for poultry processing shall be marked with partitions from living quarters, offices and other areas that are not directly related to poultry processing, and the

Annex 3

entrance/exit doors shall be sealable. Openings to outside (e.g. windows, vents) shall be equipped with devices to prevent the entry of insects, etc.

B The floor shall be made of impermeable materials, without cracks or unevenness, and have appropriate inclination for effective drainage.

C The inner walls shall be smooth and easy to clean, without gaps, and shall be skirted with impermeable materials up to the height of at least one meter from the floor surface, above which height the walls shall be made of water-proof materials.

D The ceiling shall be smooth and easy to clean, and use materials and structure that prevent mold and falling dust, and minimize dew condensation.

E The room shall have a structure or equipment that provides adequate sunlight/lighting and ventilation.

F The facility shall be equipped with equipment for storing containers of inedible parts in appropriate locations inside, and such equipment shall have a structure that is easy to clean.

G The area for slaughtering and bleeding shall be equipped with machinery and instruments used for slaughtering and bleeding, and cleansing/disinfection equipment for those machinery and instruments.

H The area for hot water steeping and plucking shall be equipped with a hot water steeping machine that has adequate capacity matching the quantity of poultry processing, machinery and instruments for plucking and cleansing poultry carcasses, and cleansing/disinfection equipment for those machinery and instruments.

I The area for evisceration shall satisfy the following requirements.

(1) Equipped with equipment that enables confirmation that an eviscerated poultry carcass and the relevant organs come from the same bird, and prevents contamination of other eviscerated poultry carcasses and/or organs

(2) Equipped with cleansing/disinfection equipment for a bat, table, cutting boards and other machinery/instruments and containers used for poultry processing

J Equipped with a required number of containers for keeping the whole or part of poultry carcasses, eviscerated poultry carcasses, and poultry meat that require disposal or other actions (referred to as “containers for disposal” hereafter in this Appendix), due to rating as non-conforming based on the results of checking conditions on the surface of poultry carcasses or on organs from eviscerated poultry carcasses and their inner body sidewalls, with the relevant labeling indication.

K Equipped with hand washing equipment that matches the number of employees

7. The wastewater processing facility shall be equipped with wastewater processing equipment that has adequate capacity that matches the quantity of wastewater to be processed.

8. Structure and materials of machinery and instruments

A Machinery and instruments that come into direct

contact with poultry carcasses, eviscerated poultry carcasses, and/or poultry meat, such as a table and cutting board used for poultry processing, shall be made of non-corrosive materials, and have a structure that is easy to cleanse/disinfect.

B Machinery and instruments that are fixated or difficult to move shall be installed in locations that are convenient for operation, and easy to cleanse/disinfect.

C Containers for poultry processing, containers for disposal, and containers for inedible parts shall be made from impermeable materials, have lids, be easy to cleanse/disinfect, and have a structure that precludes the leak of wastewater and odor.

Appendix 3 (related to Article 4)

1. Sanitation control of a poultry-processing site

A Undertake appropriate cleaning, and maintain a status that causes no sanitation problems.

B Put the site in order and refrain from leaving unnecessary objects around.

C When there is a damage or failure in the floor, inner walls, ceiling, window or door, it shall be rapidly fixed or repaired.

D Ensure adequate ventilation to remove odor and excessive humidity.

E Guarantee necessary illuminance with sunlight or lighting equipment.

F Sanitation control of water supply systems shall be as described below.

(1) When water not supplied by the water utility service is used, water quality shall be inspected at least once a year (and whenever water quality may have been altered due to contamination of the water source due to disaster, etc.), and documented inspection certificates shall be retained for at least one year. When water is rated as inedible in the inspection, the site shall immediately consult the governor of the prefecture for instructions, and take appropriate actions.

(2) When a disinfection device and/or water purification device is installed, check every day that these devices are normally operating.

(3) When a water storage tank is used, it should be inspected and cleaned on a periodic basis.

(4) A hot water supply system shall be adequately controlled to ensure that water temperature that matches its purpose should be maintained.

G Drainage grooves shall be cleaned to prevent the outflow of solid substances and to ensure effective drainage. Any damage shall be rapidly repaired.

H Sanitation control of machinery and instruments shall be performed as follows.

(1) Use machinery and instruments that match the purpose.

(2) The faces of machinery and instruments that come into direct contact with poultry carcasses, eviscerated poultry carcasses, or poultry meat, must be cleansed/disinfected before use.

(3) Every time a bird with a (suspected) disease or

Annex 3

abnormality has been processed, with the risk of contamination to other birds/objects, the machinery and instruments used for such processing shall be cleansed/disinfected.

(4) Machinery and instruments shall be cleansed/disinfected after the end of operation.

(5) Machinery and instruments and their disassembled parts shall be stored in specified locations in a sanitary status.

(6) Machinery and instruments shall be periodically inspected. Any damage or failure shall be rapidly repaired or fixed, so that the machinery and instruments are always ready to be used effectively.

(7) Thermometers, manometers, flow meters, and other meters shall be periodically checked for precision. Any failure or abnormality shall be rapidly repaired.

I To prevent the entry of pests, insects, etc. into the facility for poultry processing, room for storing products, and room for packaging materials (read as "room for poultry processing, equipment for storing products, and equipment for packaging materials" for a poultry-processing site that pertains to the certification of a small-sized poultry processing service provider; the same applies hereinafter), any damage or failure in pest/insect control equipment shall be rapidly repaired or fixed. At the same time, windows and exists/entrances without pest/insect control equipment may not be left open. Extermination shall be conducted on a periodic basis, and the records of extermination shall be retained for at least one year.

J Pesticide, insecticide and other agents shall be stored in specified locations outside the facility for poultry processing or the room for storing products.

K The refrigeration/chilling equipment in the room for storing products shall be maintained at or lower than 10°C for refrigeration, and at or lower than -15°C for chilling.

L Sanitation control of inedible parts, etc. shall be performed in accordance with the standards specified below.

(1) Inedible parts shall be appropriately put and transported in containers for inedible parts, thereby precluding interference with sanitation control in the poultry-processing site. The containers for inedible parts shall be emptied and cleansed after the end of operation.

(2) Containers for poultry processing as stipulated in Appendix 1 or Appendix 2, or containers for disposal as stipulated in Appendix 1 or in Appendix 2 (collectively referred to as "containers for disposal" hereinafter) shall be taken out of the facility for poultry processing in an appropriate manner, precluding the leak of wastewater or odor. The containers shall be emptied and cleansed after the end of operation.

(3) Poultry, poultry carcasses, eviscerated poultry carcasses or poultry meat, as well as inedible parts that require disposal or other actions shall be adequately handled to preclude sanitation problems.

M Toilets shall be kept clean, and periodically disinfected.

N Cleansing and disinfection shall be performed as stipulated below.

(1) When agents are used, those that match the purpose shall be used in a proper manner.

(2) When hot water is used for disinfection, hot water of 83°C or higher temperature shall be used.

O Hand washing equipment shall be continuously equipped with detergent for hand washing.

P Cleaning tools shall be stored in specified locations.

2. Sanitary handling of poultry, poultry carcasses, eviscerated poultry carcasses, and poultry meat

A Receiving live birds

(1) In the collection of poultry to be processed, make efforts to remove abnormal birds, and take care of maintaining the health of live birds during transportation.

(2) Use clean containers for transporting live birds, and adequately cleanse/disinfect them after use.

(3) Birds that have passed the ante-mortem inspection or otherwise rated as conforming to standards based on their live conditions shall be rapidly slaughtered and bled. For birds that have failed the inspection or otherwise rated as non-conforming to standards, take actions stipulated in Article 33.

B Bleeding

(1) Birds shall be adequately bled.

(2) Take care to avoid contamination of live or slaughtered birds by blood that has been discharged.

(3) In the collection of blood, collect it in containers made of impermeable materials, and take it out as appropriate.

C Hot water steeping

(1) Hot water steeping shall be performed rapidly after bleeding.

(2) Sufficient water shall be used for hot water steeping.

(3) Also take care to remove contaminants to the possible highest degree in hot water steeping.

D Plucking

(1) In the plucking process, take measures to prevent feathers from scattering during sprayed washing with water. Feathers that have come off shall be kept in containers for inedible parts, and be frequently taken out of the facility for poultry processing even during operation.

(2) Residual feathers shall be removed through singeing. Refrain from evisceration in the case of inadequate plucking.

(3) Complete the plucking of poultry carcasses prior to post-plucking inspection or checking of the bird surface conditions for conformance to standards.

(4) Inedible parts, as well as the whole or part of poultry carcasses that require disposal or other actions based on failure in the post-plucking inspection or the rating of poultry surface conditions as non-conformant to standards, shall be handled to preclude contamination to other birds/objects, and respectively kept in containers for inedible parts and in containers for disposal.

E Evisceration

(1) Care shall be taken of the following points in the post-evisceration inspection, or while checking conditions on organs from eviscerated poultry carcasses and their inner body sidewalls for conformance to standards.

(i) The bird/carcass/meat shall be inspected or checked in such a manner that enables confirmation that an eviscerated poultry carcass and the relevant organs come from the same

Annex 3

bird.

(ii) Abdominal opening for inspection or confirmation shall be made only to the minimum extent that enables the inspection or confirmation.

(iii) Adequately pull out the heart, liver, spleen, gizzard, etc. for confirmation.

(2) Take care of the following points to avoid contamination of eviscerated poultry carcasses and poultry meat by substances leaked out from the digestive tract.

(i) Abdominal opening shall be made with care to avoid damage to the digestive tract. Avoid making unnecessary opening.

(ii) The section of cloaca shall be performed with care to avoid the content from leaking out.

(iii) Eviscerated poultry carcasses that have passed the post-evisceration inspection, or rated as conforming to standards based on their inner body sidewalls, shall be adequately cleansed inside and outside with a proper amount of water.

(iv) Organs that have passed the post-evisceration inspection, or rated as conforming to standards, shall be divided to edible parts and inedible parts, and the former shall be adequately cleansed.

(v) Inedible parts and parts that require disposal or other actions shall be handled in such a manner that precludes contamination to edible parts, and be respectively kept in containers for inedible parts and in containers for disposal.

F Cooling

(1) Cleansed poultry carcasses, eviscerated poultry carcasses, and poultry meat shall be rapidly cooled down to below 10°C.

(2) When poultry carcasses, eviscerated poultry carcasses, and poultry meat are refrigerated with cool water, the refrigeration shall be performed while sufficiently renewing refrigeration water with water cooled down by a cooling machine, or with water and an appropriate amount of crushed ice, thereby minimizing the absorption and remainder of water.

(3) The cooling tank shall be emptied and cleansed/disinfected after the end of operation.

G Poultry carcasses, eviscerated poultry carcasses, and poultry meat shall be handled in a clean and sanitary manner, and preclude contamination by filth, toxin, hazardous substance, or pathogenic microorganism.

3. Sanitation control by employees

A The poultry processing service provider or the poultry processing sanitation manager shall implement continuous sanitation training to ensure sanitary poultry processing.

B The poultry processing service provider or the poultry processing sanitation manager shall ensure sanitation control of employees as specified below.

(1) Make efforts to identify health conditions of employees, and urge them to undergo health checkups as necessary.

(2) Prevent employees who have been infected by a purulent disease or other diseases that may cause food poisoning, or a disease that may be transferred via poultry meat, from working for poultry processing.

(3) Ensure that employees put on dedicated clean work

clothes and a cap in light bright colors on a poultry-processing site, together with dedicated shoes, and prevent them from putting on unnecessary objects.

(4) Prohibit employees from entering toilets with their aprons, etc. on.

(5) Ensure that employees always keep their hands and fingers clean, and direct them to carefully cleanse/disinfect their hands and fingers before operation, after going to the toilet, or after coming into contact with poultry, poultry carcass, eviscerated poultry carcass, or other objects that may contaminate poultry meat.

(6) Prohibit employees from changing, smoking, spitting or eating in places other than the designated areas in a poultry-processing site.

4. Others

The poultry processing service provider or the poultry processing sanitation manager shall restrict access to inside the poultry-processing site by persons other than employees.

Appendix 4 (related to Article 4)

1. Sanitation control of poultry slaughtering plants
Same as Appendix Section 3 Subparagraph (1).

2. Sanitary handling of poultry, carcass of poultry, eviscerated carcass of poultry, and poultry parts.

a. Poultry slaughtering businesses conducting sanitary control using the hazard analysis and critical control point method (a method of sanitary control in which the substances which may cause hazards important in securing food safety and the processes in which the relevant hazards may occur are identified, evaluated, and managed) shall organize a team consisting of a quality controller and other persons possessing specialized knowledge regarding the sanitary handling of poultry, carcass of poultry, eviscerated carcass of poultry, and poultry parts, and take the following measures from (1) to (7).

(1) Product manuals describing the name, type, raw materials, and other necessary items of the products shall be prepared.

(2) A chart describing the flow of the receiving, slaughtering, dressing, butchering, storing, shipping of the poultry and other processes shall be prepared in accordance with the actual processes and layout of the facility equipment at the poultry slaughtering plant.

(3) A document describing the following items shall be prepared.

(i) Measures to prevent the substances which may cause food sanitation hazards and the relevant hazards which may occur in the relevant processes from occurring (hereinafter referred to as “control measures”) for each process including the acceptance of the living body, bleeding, scalding, feather removal, evisceration, and cooling (when no relevant substance which may cause hazards can be found, the reason is to be stated).

(ii) The processes of (i) in which the implementation status

Annex 3

of the control measures associated with the relevant process need to be checked continuously or at a fair frequency (hereinafter referred to as “critical control point”) in order to prevent food sanitation hazards associated with the products (when a critical control point is not determined, the reason is to be stated).

(iii) Criteria of the control measures for each of all of the critical control points in order to reduce to an acceptable range or eliminate the substances which may cause food sanitation hazards which may occur at the relevant critical control point.

(iv) Method to confirm (ii)

(4) A document describing the method of the improvement measures which shall be taken when the control measures associated with the critical control points are not found to be taken properly upon the confirmation of (3) (ii) shall be prepared.

(5) A document describing the method to verify that the testing method of the products is properly preventing food sanitation hazards shall be prepared.

(6) A document describing the recording method and the method and duration of storage of the relevant records shall be prepared for the following items.

(i) Items regarding the confirmation of (3) (ii)

(ii) Items regarding the improvement measures of (4)

(iii) Items regarding the verification of (5)

(7) According to the documents prepared based on the provisions of (3) to (6), measures necessary for public health shall be taken in order to prevent food sanitation hazards associated with poultry, carcass of poultry, eviscerated carcass of poultry, and poultry parts.

b. Other than those specified in a., the following measures shall be taken.

(1) Prior to post feather-removal inspections and confirmation of the compatibility with the standards regarding the body surface conditions in the carcass of poultry, the feather removal of the carcass of poultry shall be finished.

(2) The following items shall be considered for the handling of the post-evisceration inspection or the confirmation of the compatibility with the standards regarding the viscera and the conditions of the inside of the body wall associated with the eviscerated carcass of poultry.

(i) The eviscerated carcass of poultry and the relevant organs associated with the eviscerated carcass of poultry shall be used for inspection and confirmation in a condition where they can be confirmed to viscera from the same poultry.

(ii) Dissection of the abdominal region for inspection or confirmation shall be kept to a minimal degree in which the inspection or confirmation can be performed.

(iii) The heart, liver, spleen, and gizzard shall be adequately pulled out for the inspection or confirmation.

3. Sanitary control of the personnel

Same as Appendix Section 3 Subparagraph (3).

4. Others

a. Poultry slaughtering businesses and quality controllers at poultry slaughtering plants shall not permit persons other than the personnel to enter the poultry slaughtering plant without reason.

b. Poultry slaughtering businesses shall manage in the following ways in order for the measures prescribed in Subparagraph (1) and Subparagraph (2) a. and b. are properly conducted.

(1) A document describing necessary items in order to conduct in an appropriate and well-planned manner shall be prepared.

(2) The quality controllers at poultry slaughtering plants shall confirm that the relevant measures are conducted appropriately based on the document in (1).

Appendix 5 (related to Article 8)

Department	Subjects
Chemistry	Analytical chemistry, organic chemistry, inorganic chemistry
Biochemistry	Biochemistry, food chemistry, physiology, food analytics, toxicology
Microbiology	Microbiology, food microbiology, food preservation science, food production science
Public health science	Public health science, food hygienic science, environmental hygienic science, public health administration, epidemiology

Appendix 6 (related to Article 8)

Fisheries chemistry, animal husbandry chemistry, radiation chemistry, emulsification chemistry, meat chemistry, polymer chemistry, bioorganic chemistry, environmental pollutant analytics, enzyme chemistry, food physics and chemistry, fisheries physiology, livestock physiology, plant physiology, environmental biology, applied microbiology, dairy farming microbiology, pathology, introduction to medicine, anatomy, medical chemistry, industrial medicine, hematology, serology, genetics, parasitology, veterinary medicine, nutrition chemistry, biostatistics, nutritional science, environmental health science, hygiene management science, fisheries production science, livestock product production science, agricultural product production science, brewed and seasoned food production science, dairy product production science, distilled liquor production science, canned food engineering, food engineering, food preservation science, chilling and refrigeration science, quality control science, and other subjects related to food health equivalent to the above

Annex 3

Appendix 7 (related to Articles 25, 27 and 33)

Rabies, inclusion body hepatitis, psittacosis, colibacillosis, infectious coryza, swine erysipelas, salmonellosis, staphylococcosis, listeriosis, toxemia, pyemia, sepsis, mycosis, protozoan diseases (except toxoplasmosis), toxoplasmosis, parasitic diseases, degeneration, urate deposition, edema, ascites, bleeding, inflammation, atrophy, tumors (except Marek's disease and avian leukosis), abnormal shape, size, hardness, color or smell of organs, abnormal body temperature (only cases of remarkable high fever (43°C or higher) or low temperature (lower than 40°C), including cases of sunstroke and heat stroke), jaundice, trauma, toxicoses (only cases with potential health injury), emaciation and poor development (only remarkable cases), state of remarkable reaction to the administration of biological products, contamination by lubricant, inflammatory product, etc., poor bleeding, excessive hot water steeping (state with appearance similar to boiled meat caused by hot water steeping)

Appendix 8 (related to Articles 28, 29, 30 and 33)

1. Poultry carcasses

A None of the following abnormalities shall be observed.

- (1) Remarkable darkening in the skin or muscle
- (2) Remarkable paleness in the skin or muscle
- (3) Development of dehydration symptoms
- (4) Presence of tumor
- (5) Remarkable emaciation
- (6) Abnormal abdominal swelling
- (7) Extensive scabbing, wound, abscess, or inflammation on the skin
- (8) Remarkable swelling of wing and leg bones
- (9) Remarkable abnormal odor or general abnormal odor

B None of the following abnormalities shall be observed in any part of poultry carcasses.

- (1) Blue, red or blue-green colored part of skin
- (2) Overhydrated part of skin or muscle
- (3) Scabbing, wound, abscess, or inflammation on a part of skin
- (4) Swollen bone or joint
- (5) Abnormal odor

2. Eviscerated poultry carcasses

None of the following abnormalities shall be observed.

A Yellow cheesy solid or semi-solid substance of accumulated pus, ascites, a large amount of blood or abnormal odor in a body cavity or air sac

B Presence of tumor

C Inflammation or thickening on inner body sidewalls or serous membranes

D Excessive adhesion between inner body sidewalls and organs or between organs

3. Organs

A Liver

None of the following abnormalities shall be observed.

- (1) Coverage by gelatin or cheesy exudate
- (2) Irregular unevenness on the surface
- (3) Webbed surface
- (4) Green, blue, pink or other colors that differ from normal ones
- (5) Remarkable swelling
- (6) Remarkable fragility
- (7) Hardened parts
- (8) Hematoma or numerous bloody spots
- (9) Presence of a white or yellow focus of disease

Note) A normal liver has an even color (reddish brown) and hardness, and the size in proportion to body weight is mostly at the same level.

B Spleen

None of the following abnormalities shall be observed.

- (1) Presence of thickened coating
- (2) Presence of a white or yellow focus of disease or remarkable swelling
- (3) Fragility
- (4) Remarkable atrophy

Note) A normal spleen is in dark reddish brown, sometimes in deep red or pink, of variable size, and is relatively hard.

C Heart

None of the following abnormalities shall be observed.

- (1) Remarkably thickened pericardium
- (2) Adhesion between the heart and the pericardium
- (3) Cellulose or cheesy substance in pericardial effusion
- (4) Remarkably increased pericardial effusion
- (5) Remarkably enlarged or expanded heart
- (6) Blood spots in adipose tissue
- (7) Presence of a white or yellow focus of disease

Note) A normal heart is placed in the pericardium. Its base is rich in fat, with adipose tissue in the coronary part and apical part of the base.

D Kidney

None of the following abnormalities shall be observed.

- (1) Remarkable swelling
- (2) Large and/or multiple cysts
- (3) Presence of a white focus of disease
- (4) Dense presence of white minute deposits

Note) A normal kidney is in deep red. When it is completely bled, a kidney may be in pink or ocher.

E No abnormalities shall be observed in other organs.

Appendix 9 (related to Articles 29, 30 and 33)

None of the following abnormalities shall be observed.

A Moribund state

B Slow movements or enfeebled appearance

C Emaciation

D A large amount of excretion from eyes or nostrils

E A large amount of excrement attached to feather around the anus

Annex 3

Appendix 10 (related to Article 33)

Fowl cholera, highly-pathogenic avian influenza, lowly-pathogenic avian influenza, Newcastle disease, poultry salmonella infection, avian influenza, lowly-pathogenic Newcastle disease, fowlpox, Marek's disease, infectious bronchitis, infectious laryngotracheitis, infectious bursa Fabricius, avian leukosis, avian tuberculosis, avian mycoplasma, leucocytozoonosis, duck hepatitis, duck viral gastroenteritis, rabies, inclusion body hepatitis, psittacosis, colibacillosis, infectious coryza (only cases with systemic symptoms), swine erysipelas, salmonellosis, staphylococcosis, listeriosis, toxemia, pyemia, sepsis, mycosis, protozoan diseases except toxoplasmosis (only cases with systemic spreading), toxoplasmosis, parasitic diseases (only cases with systemic spreading), degeneration (only systemic cases), urate deposition (only cases with systemic symptoms), edema (only advanced cases), ascites, bleeding (only systemic cases), inflammation (only systemic cases), atrophy (only systemic cases), tumors except Marek's disease and avian leukosis (except localized cases in a part of meat, organs, bones or skin), abnormal shape, size, hardness, color or smell of organs (except localized cases in a part of organs), abnormal body temperature (only cases of remarkable high fever (43°C or higher) or low temperature (lower than 40°C), including cases of sunstroke and heat stroke), jaundice, trauma (only systemic cases), toxicoses (only cases with potential health injury), emaciation and poor development (only remarkable cases), state of remarkable reaction to the administration of biological products, contamination by lubricant, inflammatory product, etc. (only cases of systemic contamination), poor bleeding, excessive hot water steeping (state with appearance similar to boiled meat caused by hot water steeping)

Edema (except advanced cases)	Meat, organs, bones and skin of the relevant lesions
Bleeding (except systemic cases)	Meat, organs, bones and skin of the relevant lesions
Inflammation (except systemic cases)	Meat, organs, bones and skin of the relevant lesions
Atrophy (except systemic cases)	Meat, organs, bones and skin of the relevant lesions
Tumors except Marek's disease and avian leukosis (only localized cases in a part of meat, organs, bones or skin)	Meat, organs, bones and skin of the relevant lesions
Abnormal shape, size, hardness, color or smell of organs (only localized cases in a part of organs)	Organ with the relevant abnormality
Trauma (except systemic cases)	Meat, organs, bones and skin of the relevant lesions
Contamination by lubricant, inflammatory product, etc. (except cases of systemic contamination)	Meat, organs, bones and skin of the relevant lesions

Appendix 11 (related to Article 33)

Disease or abnormality	Parts
Infectious coryza (except cases with systemic symptoms)	Meat, organs, bones and skin of the relevant lesions
Protozoan diseases except toxoplasmosis (except cases with systemic spreading)	Meat, organs, bones and skin of the relevant lesions
Parasitic diseases (except cases with systemic spreading)	Meat, organs, bones and skin with parasites and the lesions of parasitic diseases
Degeneration (except systemic cases)	Meat, organs, bones and skin of the relevant lesions
Urate deposition (except cases with systemic symptoms)	Meat, organs, bones and skin of the relevant lesions