Under Article 34.2 of the *Act on the Prevention of Contagious Animal Disease*, Ministry of Agriculture, Food and Rural Affairs (MAFRA) enacts the *Import Health Requirements for Collagen and Gelatin* as follows.

Import Health Requirements for Collagen and Gelatin (Draft)

Month Day, 2017

Minister of Agriculture, Food and Rural Affairs

Article 1 (Objective) The objective of this notice is to stipulate necessary conditions such as quarantine and animal disease-free situation in the exporting country with regard to collagen and gelatin that are exported to the Republic of Korea in accordance with Article 34.2 of *Act on the Prevention of C* Animal Diseases.

Article 2 (Definitions) The terms used in this notice shall be defined as follows.

- 1. "Collagen" means protein collected from connective tissues of raw hide, skin or bones of animals.
- 2. "Gelatin" means partially hydrolysis product made by protein which had been collected from connective tissues of raw hide, skin or bones of animals.
- 3. "Specified Risk Material (SRM)" means brain, eyes, spinal cord, skull, and spinal column of cattle aged 30 months or older, and tonsils and distal ileum from cattle of any age.
- 4. "The veterinary officer of the exporting country" means the person who belongs to "the government of the exporting country" and who is granted the authority to carry out inspection or quarantine for livestock products.

Article 3 (Conditions for collagen and gelatin) ① Collagen and gelatin must be produced from animals that are deemed healthy based on the ante-mortem and post-mortem inspections conducted by the government of the exporting country.

- ② SRMs should be removed during the slaughtering process when producing collagen and gelatin by using bones of cattle from a country with reported case of BSE. Collagen and gelatin should be collected, transported, and handled in a manner that prevents cross contamination with SRMs during the manufacturing process of collagen and gelatin.
- ③ When collagen and gelatin are produced by using bones of cattle from a country with reported case of BSE, they shall be produced through processes including degreasing, acid demineralization, acid or alkali treatment, filtration and sterilization (for a minimum of four seconds at $138\,\%$).

Article 4 (Conditions for manufacturing facility) ① Manufacturing facility shall be dedicated to collagen and gelatin exclusively and be registered in accordance with relevant regulations of the exporting country and be inspected by the government of the exporting country.

- ② Manufacturing facility and ucing collagen and gelatin by using bones of cattle from a country with reporter ase of BS I must have been notified from the government of the exporting country to the Expublic of Korea and must have been approved by the Korean government through an on-site audit or other means.
- ③ When the manufacturing facility producing collagen and gelatin by using bones of cattle from a country with reported case of BSE suspends production of goods for export due to bankruptcy or closure, etc. the government of the exporting country must cancel the registration of the given manufacturing facility and immediately notify the government of the Republic of Korea.
- ④ The government of the Republic of Korea may cancel the approval of the manufacturing facility if there is no record of export of collagen and gelatin to the Republic of Korea for 3 years or more from the date it is approved as a manufacturing facility to produce collagen and gelatin by using bones of cattle from a country with reported case of BSE or from the date of the last export. The government of the Republic of Korea must notify this to the government of exporting country and hold consultations before making a decision to cancel the approval.

Article 5 (Information to be provided in the quarantine certificate) ① The veterinary officer

of the exporting country must issue a quarantine certificate that has been consulted with the government of the Republic of Korea before the shipment of collagen and gelatin.

② The government of the exporting country should consult the quarantine certificate of collagen and gelatin in accordance with the quarantine certificate (draft) of the Appendix with the government of the Republic of Korea.

Article 6 (Review deadline) The Minister of Agriculture, Food and Rural Affairs must take actions on this notice such as making improvements by reviewing the validity at the time marking an interval of three years starting July 1, 2017 (meaning until June 30 in the third year).

Addendum <MAFRA Notice. 2017-00, Month, Date, 2017>

Article 1 (Effective date) This notice shall be enacted on the day marking three months from the day of announcement of this notice.

Ministry of Trade,

Article 2 (Interim m. Collagen and getatin imported in accordance with "Quarantine method and standard of designated quarantine" (Animal and Plant Quarantine Agency Notice. 2017-3) prior to the enact of this notice shall be considered to have been imported according to this notice.

② The Health Certificate for collagen or gelatin that has been used before the enact of this notice shall be deemed effective up to three years from the effective date of this notice.

[별표] 콜라겐 및 젤라틴 검역증명서 서식(안)

[Appendix] Draft of Quarantine Certificate for Collagen and Gelatin

I. 제품 정보 Product information
품명 Product :
축종 Species :
포장형태 Type of packaging :
포장수량 Number of packaging :
총중량 Gross weight :
순중량 Net weight :
제조시설의 명칭 및 주소 Name and address of the manufacturing plant(s)
승인 제조시설의 승인 전호(소해난 상노용(ESE) 발생국전 소 뼈 유리 콜라겐과 젤라틴에 한함) Approval number of the apparation of the appar
수입자의 주소와 성명(업체명) Name and address of consignee :
선적일자 Date of shipment :
선적지 Place of shipment:
선박명 또는 항공기명 Name of means of transport :
컨테이너 번호 <i>Container No.</i> :
봉인 번호 Seal No. :

II. 위생 증명 사항 Health information

수출국 정부 검역관은 다음사항을 증명한다.

The undersigned quarantine official of the exporting country certifies the following:

□ BSE 발생국산 소 뼈 유래 콜라겐 및 젤라틴

For collagen and gelatin derived from bones of cattle from countries with reported case of BSE^{1} (Delete as appropriate)

1. 콜라겐과 젤라틴을 생산하기 위한 소는 수출국 정부에서 실시한 생체 및 해 체검사 결과 이상이 없다.

The cattle from which collagen and gelatin had been derived were subject to ante-mortem and post-mortem inspections conducted by the government of exporting country, and were found to be healthy.

2. BSE 발생국산 소의 제 그래 콜라겐과 젤라틴을 생산하기 위한 소는 도축 과정에서 특정위험물질 되었다. 클라겐과 젤라틴 제조 과정 중에 이러한 특정위험물질과 교차오염이 이루어지지 않도록 수집, 운반, 처리되었다.

Specified risk materials (SRMs) have been removed during the slaughter of cattle from which collagen and gelatin were derived. Collagen and gelatin were collected, transported, and handled in such a manner as to prevent cross-contamination with SRMs.

3. BSE 발생국산 소의 뼈에서 유래된 콜라겐과 젤라틴의 제조공정은 다음과 같다. 다음을 포함한다.

The collagen and gelatin derived from bones of cattle have been processed by the following manufacture method.

(제조공정 예, example of manufacture method)

I)

I degreasing

- ii) 산성 탈염 acid deminerlaisation
- iii) 산 또는 알칼리 처리 acid or alkaline treatment
- iv) 여과 filtration,
- v) 살군((138 \mathbb{C} 에서 최소 4초간) sterilisation at \geq 138 \mathbb{C} for a minimum of 4 seconds
- 4. 제조시설은 콜라겐과 젤라틴만 전용으로 취급하는 곳이어야 하며, 수출국의 관련 규정에 의거하여 등록된 곳으로 수출국 정부에서 점검을 실시하여야 한다.

The manufacturing plant should be dedicated to handling collagen and gelatin only, and registered according to related regulations of the exporting country, and inspected by the government of exporting country.

□ 상기 항목에 해당되지 않은 모든 동물 유래 콜라겐 및 젤라틴

For collagen and ge in ot^k th in those derived from bones of cattle from countries with reported case of BSE (ι as appropriate)

1. 콜라겐과 젤라틴을 생산하기 위한 동물은 수출국 정부에서 실시한 생체 및 해체검사 결과 이상이 없었다.

The animal from which collagen and gelatin had been derived was subject to ante-mortem and post-mortem inspections conducted by the government of exporting country, and was found to be healthy.

2. 제조시설은 콜라겐과 젤라틴만 전용으로 취급하는 곳이어야 하며, 수출국의 관련 규정에 의거하여 등록된 곳으로 수출국 정부에서 점검을 실시하여야 한다.

The manufacturing plant should be dedicated to handling collagen and gelatin only, and registered according to related regulations of the exporting country, and inspected by the government of exporting country.

3. 콜라겐 및 젤라틴 제조공정(수출국 선택사항)

발급장소 Place: 발급일자 Date:

수출국 정부 검역관의 소속 및 직책

Competent authorities and qualification of the issuer:

수출국 정부 검역관 성명

Name of the quarantine officer:

수출국 정부 검역관 서명

Signature of the quarantine officer:

수출검역 도장

Official Stamp

