(Unofficial Translation)

Notification of the Ministry of Public Health

(No. 377) B.E. 2559 (2016)

Re: Designation of Requirements and Conditions for Import Food with Risk from Bovine Spongiform Encephalopathy

It deems appropriate to revise the regulatory measures with regard to the foods with risk from Bovine Spongiform Encephalopathy (BSE) in order to optimize protection of consumer safety and to comply with guideline of the World Organisation for Animal Health or Office International des Épizooties (OIE), which has classified the BSE risk status and including amendment the requirements and conditions associated to the risk of BSE.

By virtue of the provision of Section 5 in the first phase, and Section 6 (7), (8) and (9) of the Food Act B.E. 2522 (1979), the Minister of Public Health hereby issues the notification as the followings:

Clause 1 The following Notifications shall be repealed

(1) The Notification of the Ministry of Public Health (No. 269) B.E. 2549 (2006) Re: Foods with Risk from Bovine Spongiform Encephalopathy, dated 13th January B.E. 2549 (2006),

(2) The Notification of the Ministry of Public Health (No. 375) B.E. 2559 (2016) Re: Import Requirement for Food with Risk from Bovine Spongiform Encephalopathy, dated 1st April B.E. 2559 (2016).

Clause 2 In this notification

"BSE risk status" means the risk of Bovine Spongiform Encephalopathy (BSE) or mad cow disease prevalent to bovine population within the particular country or region; which classified into three categories, as follows:

Category 1 Country or region posing a negligible BSE risk;

Category 2 Country or region posing a controlled BSE risk;

Category 3 Country or region posing an undetermined BSE risk;

The list of the countries or regions prescribed in the list annexed to this Notification.

"Meat" means all edible parts of cattle such as meat, hides and skins, fat, offal, bone, milk, blood, bile, or tonsils.

"Fresh Meat" means "Meat" that has not been subjected to any treatment irreversibly modifying its organoleptic and physicochemical characteristics. This also includes frozen meat, chilled meat, or minced meat.

"Meat Products" means "Meat" that has been subjected to a treatment irreversibly modifying its organoleptic and physicochemical characteristics such as fresh meat marinated with sauce, brined offal, sausage, gelatin or collagen, and also includes food products prepared from or containing "Meat Products" such as dietary supplement capsule that made of cattle gelatine, beverages containing collagen, sweets containing gelatin or jelly.

Clause 3 The following "Fresh Meat" and "Meat Products" shall be imported without the condition of the BSE risk status categorization:

(1) Milk, Milk Products, Hides and Skins;

(2) Gelatine and Collagen prepared exclusively from hides and skins;

(3) Tallow with maximum level of insoluble impurities of 0.15% in weight and derivatives made from this tallow;

(4) Dicalcium phosphate (with no trace of protein or fat);

(5) Deboned skeletal muscle meat (excluding mechanically separated meat) from cattle which were slaughtered and dissected through the following processes:

(a) Passed ante- and post-mortem inspections without detection or suspicion of BSE, the cattle shall not be subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process or any other process that damaged brain and spinal cord;

(b) Shall not be contained and contaminated with:

1) Tonsils and distal ileum from cattle of any age; brains, eyes, spinal cord, skull and vertebral column from cattle over 30 months of age originating from BSE risk status in Category 2;

2) Tonsils and distal ileum from cattle of any age; brains, eyes, spinal cord, skull and vertebral column from cattle over 12 months of age originating from BSE risk status in Category 3;

(6) Blood and blood by-products: the cattle shall not be subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process or any other process that damaged brain and spinal cord;

(7) "Meat Products" which contained (1) (2) (3) (4) (5) or (6) as ingradients.

Clause 4 The following "Fresh Meat" and "Meat Products" shall be imported with the conditions of the BSE risk status categorization, depending on the following case:

(1) "Fresh Meat" and "Meat Products" other than those listed in Clause 3, shall be subjected to the following conditions:

(a) Category 1

1) Derived from cattle that were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal or greaves derived from ruminants had been effectively enforced;

2) Such cattle shall be passed ante- and post-mortem inspections to determine uninfected with BSE or without suspicion of BSE.

(b) Category 2

(1) Conditions are the same as (a), the cattle shall not be subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process or any other process that damaged brain and spinal cord;

(2) Shall not be contained and contaminated with:

a) Tonsils and distal ileum from cattle of any age;

b) Brains, eyes, spinal cord, skull and vertebral column from cattle over 30 months of age;

c) Mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

(c) Category 3

1) Derived from the cattle which have not been fed with meat-andbone meal or greaves derived from ruminants;

2) Such cattle shall be passed ante- and post-mortem inspections to determine uninfected with BSE or without suspicion of BSE, the cattle shall not be subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process or any other process that damaged brain and spinal cord;

3) Shall not be contained and contaminated with:

a) Tonsils and distal ileum from cattle of any age;

b) Brains, eyes, spinal cord, skull and vertebral column from cattle that were at the time of slaughter over 12 months of age;

c) Mechanically separated meat from the skull and vertebral column from cattle over 12 months of age;

d) Nervous and lymphatic tissues exposed during the deboning process.

(2) Gelatine and Collagen prepared from bones, shall be subjected to the following conditions:

(a) Category 1 Derived from the cattle which originated in the country or region having category 1 of the BSE risk status.

(b) Category 2 and 3

1) Derived from the cattle which shall be passed ante- and post-mortem inspections to determine uninfected with BSE or without suspicion of BSE;

2) None of vertebral columns from cattle over 30 months of age and skulls from cattle of any age;

3) Bones shall be subjected to a process which includes all of the following steps:

- a) Degreasing;
- b) Acid demineralization;
- c) Acid or alkaline treatment;
- d) Filtration;

e) Elimination of infective agents by sterilization at 138°C or greater

for a minimum of 4 seconds;

Operating under 3), any other process that be equivalent or better to reduce BSE infectivity may be used such as high pressure heating.

(3) Tallow (other than those listed in Clause 3 (3)), shall be subjected to the following conditions:

(a) Category 1 Derived from the cattle which originated in the country or region having category 1 of the BSE risk status.

(b) Category 2 Derived from the cattle which were passed ante- and postmortem inspections without detection or suspicion of BSE; and has not been prepared by using the "Fresh Meat" as specified in Clause 5 (1) (a) (b) (c) or (d).

(4) Tallow derivatives (other than those listed in Clause 3 (3)), shall be subjected to the following conditions:

(a) Category 1 Derived from the cattle which originated in the country or region having category 1 of the BSE risk status.

(b) Category 2 Derived or produced under either of the following conditions:

1) Derived from tallow complied the conditions as specified in Clause (3) (b);

2) Produced by hydrolysis, saponification or transesterification using high temperature and pressure.

(c) Category 3 Produced by hydrolysis, saponification or transesterification using high temperature and pressure.

(5) Dicalcium phosphate (other than those listed in Clause 3 (4)), shall be subjected to the following conditions:

(a) Category 1 Derived from the cattle which originated in the country, zone or compartment having category 1 of the BSE risk status.

(b) Category 2 and 3 the dicalcium phosphate is a by-product of bone gelatine produced as specified in Clause (2) (b).

(6) "Meat Products" which contain (1) (2) (3) (4) or (5) as ingredients, shall be subject to the conditions according to their BSE risk status categorization.

Import of any "Fresh Meat" and "Meat Products" according to the first paragraph, in the case of the reporting case of animal infected with BSE occurred in the country or region, the importers shall provide documents or evidence indicated that they have complied with the requirements and conditions set forth by the Department of Livestock Development presented to the officer at import check point of the Food and Drug Administration every time of entry. Clause 5 The following "Fresh Meat" and "Meat Products" are prohibited to be imported:

(1) Category 2

- (a) Tonsils, distal ileum from cattle of any age;
- (b) Brains, eyes, spinal cord, skull, vertebral column from cattle over 30 months

of age;

(c) Mechanically separated meat from the skull and vertebral column from cattle over 30 months of age;

- (d) "Fresh Meat" which contaminated with (a) (b) or (c);
- (e) "Meat Products" which contained (a) (b) (c) or (d) as ingredients.

(2) Category 3

- (a) Tonsils, distal ileum from cattle of any age;
- (b) Brains, eyes, spinal cord, skull, vertebral column from cattle over 12 months

of age;

(c) Mechanically separated meat from the skull and vertebral column from cattle over 12 months of age;

- (d) Nervous and lymphatic tissues exposed during the deboning process;
- (e) "Fresh Meat" which contaminated with (a) (b) (c) or (d);
- (f) Tallow, other than as defined in Clause 3 (3);
- (g) "Meat Products" which contained (a) (b) (c) (d) (e) or (f) as ingredients.

Clause 6 Import of "Meat Products" according to Clause 3 (2) (3) or (4) and also includes foods containing such products as ingredients, the importer shall have the evidence or certificate which certified by the responsible government agency from producing country or other agencies recognized by the responsible government agency of country as such, to present to the officer at import check point of the Food and Drug Administration for every time of entry and of which shall specified at least as follows:

- (1) Derived from Hides and Skins for food according to Clause 3 (2)
- (2) Insoluble impurities not exceed 0.15 percent in weight, for food according to Clause 3 (3)
- (3) No trace of protein or fat, for food according to Clause 3 (4)

Clause 7 Import of "Fresh Meat" according to Clause 3 (5) or (6) or Clause 4 (1), the origin of animals or carcasses shall be inspected and certified by the Department of Livestock Development (DLD) and the importer shall have the evidence or certificate to present to the officer at import check point of the Food and Drug Administration for every time of entry, as follows:

(1) Evidence or certificate of inspection and certification of origin of animals or carcasses, or evidence of permission to import the carcasses from the Department of Livestock Development (DLD);

(2) Copy of the Health Certificate of carcasses from responsible government agency of producing country or other agencies recognized by responsible government agency of producing country as such, indicating the details complied with requirements and conditions as specified in Clause 3 (5) or (6) or Clause 4 (1), as the case may be.

Clause 8 Import of "Meat Products" according to clause 3 (5) or (6) or Clause 4, the importer shall have the following evidence or certificate to present to the officer at import check point of Food and Drug Administration for every time of entry, as follows:

(1) Evidence or certificate of inspection of raw materials or ingredients derived from cattle as the case maybe, as the following:

(a) Raw materials or ingredients are "Fresh Meat", the evidence or certificate of inspection and certification of origin of animals or carcasses, or evidence of permission to import the carcasses from the Department of Livestock Development (DLD) shall be used. **Unless** such agency issue an evidence or certificate, the evidence or certificate issued by the responsible government agency or other agencies recognized by the responsible government agency and signed by an authorized veterinarian of the producing country of raw materials or ingredients shall be used that indicating the raw materials or ingredients complied with requirements and conditions as specified in this notification.

(b) Raw materials or ingredients are "Meat Products", the evidence or certificate of inspection and certification from responsible government agency or other agencies recognized by responsible government agency of producing country of raw materials or ingredients shall be used that indicating the raw materials or ingredients complied with requirements and conditions as specified in this notification. **Unless** such agency issue the evidence or certificate, the following evidence or certificate shall be used:

1) Evidence or certificate of inspection and certification from responsible government agency or other agencies recognized by responsible government agency of producing country of raw materials or ingredients, or Certification Body (CB) which is accredited by the Accreditation Body (AB) that are members and have been recognized by the International Accreditation Forum (IAF), which is still valid, indicating either of the following quality assurance system of the manufacturing premise of raw materials or ingredients:

a) Hazard Analysis and Critical Control Point (HACCP) System as designated by the Codex Alimentarius Commission;

b) Food Safety Management Systems-Requirements for any Organization in the Food Chain (ISO 22000 : 2005);

c) Other criteria or other international systems equivalent to a) or b), as approved by the Food Committee.

2) HACCP plan contained hazard analysis of BSE by manufacturer of the raw materials or ingredients, accompanied with the Quality Assurance System certificate as 1)

(2) Evidence or health certificate of the "Meat Products" from responsible government agency of producing country of the "Meat Products", or other agencies recognized by the responsible government agency of which at least the following substances shall be specified:

(a) The origin of the raw materials or ingredients derived from cattle used to produce "Meat Products", depending on the following case:

1) Raw materials or ingredients are "Fresh Meat", the slaughterhouse and/or cutting plant and country of origin of the "Fresh Meat" shall be indicated that complied with (1) (a);

2) Raw materials or ingredients are "Meat Products", the manufacturing premise and country of origin of the "Meat Products" shall be indicated that complied with (1) (b);

(b) Details of the requirements and conditions of raw materials or ingredients derived from cattle used to produce "Meat Products", the procedure shall be complied with the terms and conditions specified in this notification, as the case may be;

(c) No contamination with the BSE agent during storage of raw materials, food processing and storage of food products.

Unless the agencies in (2) issue the evidence or certificate, the importer shall have the following evidence or certificate:

(1) Evidence or certificate of inspection and certification from responsible government agency or other agencies recognized by responsible government agency of producing country of raw materials or ingredients, or Certification Body (CB) which is accredited by the Accreditation Body (AB) that are members and have been recognized by the International Accreditation Forum (IAF), which is still valid, indicating either of the following quality assurance system of the manufacturing premise of raw materials or ingredients:

(a) Hazard Analysis and Critical Control Point (HACCP) System as designated by the Codex Alimentarius Commission;

(b) Food Safety Management Systems-Requirements for any Organization in the Food Chain (ISO 22000 : 2005);

(c) Other criteria or other international systems equivalent to (a) or (b), as approved by the Food Committee.

(2) HACCP plan contained hazard analysis of BSE by manufacturer of the "Meat Products", accompanied with the Quality Assurance System certificate as (1)

Clause 9 This Notification shall come into force on 21st July 2016 onwards.

Notified on 11st July 2016

Signed Piyasakol Sakolsatayadorn

(Mr. Piyasakol Sakolsatayadorn)

Minister of Public Health

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This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the original Thai version shall prevail.

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List of the countries or regions based on BSE risk status

Attachment of Notification of the Ministry of Public Health (No. 377) B.E 2559 (2016) Re: Designation of Requirements and Conditions for Import Food with Risk from Bovine Spongiform Encephalopathy

1. Category 1 Countries or regions posing a negligible BSE risk:

- (1) Argentina (26) Lithuania (2) Australia (27) Luxembourg (3) Austria (28) Malta (4) Belgium (29) Mexico (5) Brazil (30) Namibia (31) Netherlands (6) Bulgaria (32) New Zealand (7) Chile (8) Colombia (33) Norway (9) Costa Rica (34) Panama (10) Croatia (35) Paraguay (11) Cyprus (36) Peru (12) Czech Republic (37) Portugal (13) Denmark (38) Romania (14) Estonia (39) Singapore (15) Finland (40) Slovakia (16) Germany (41) Slovenia (42) Spain (17) Hungary (18) Iceland (43) Sweden (19) India (44) Switzerland (45) United States of America (20) Israel (21) Italy (46) Uruguay (22) Japan
 - (47) People's Republic of China with the exclusion of Hong Kong and Macau

- (24) Latvia
- (25) Liechtenstein

(23) Korea (Rep. Of)

2. Category 2 Countries or regions posing a Controlled BSE risk:

- (1) Canada
 - (2) Chinese Taipei
 - (3) France
 - (4) Greece
 - (5) Ireland
 - (6) Nicaragua
 - (7) Poland
- (8) United Kingdom
- 3. Category 3 Countries or regions posing a Undetermined BSE risk: the countries or regions are not in Category 1 or 2