Requirements for Beef and Beef Products to be Exported to Japan from the United States of America

January 25, 2013

Requirements for beef and beef products to be exported to Japan from the United States of America (United States) are as follows:

- 1. General Requirements
 - a) Beef and beef products mean all edible parts of cattle and products derived from such parts of cattle¹ that are derived from cattle that are less than 30 months of age and produced in a manner that ensures the hygienic removal of the specified risk materials (SRMs) comprising tonsils and distal ileum of the small intestine. To be eligible to export beef and beef products to Japan, a U.S. meat establishment must implement a U.S. Department of Agriculture (USDA) Less Than 30 Months Age Verification Quality System Assessment Program (QSA Program GVD1035A) (hereinafter "QSA LT-30 Program") that is approved by USDA's Agricultural Marketing Service (AMS). Only upon completion of a successful on-site audit by AMS of a meat establishment to ensure compliance with the QSA LT-30 program requirements will that U.S. meat establishment be approved as eligible to export beef and beef products to Japan, as described in Section 4 of this document.
 - b) Beef and beef products from the United States (the fifty states, the District of Columbia and Guam) for export to Japan must be products which Japan and the United States recognize as eligible to export to Japan.
 - c) Cattle must be domesticated bovine animals (*Bos taurus* and *Bos indicus*) born and raised in the United States or legally imported into the United States from a country deemed eligible by Japan to export beef or beef products to Japan.
 - d) The United States meets or exceeds World Organization for Animal Health (OIE) guidelines to be considered controlled risk for bovine spongiform encephalopathy (BSE).

¹ As defined in the U.S. Federal Meat Inspection Act (21 U.S.C. Sec. 601 et seq. (2012)).

- e) The United States, consistent with its World Trade Organization (WTO) obligations, provides notice to all trading partners, including Japan, regarding the repeal or modification of any BSE-related measure.
- f) In the event of (an) additional case(s) of BSE, the current requirements set out in this document will not be modified.
- 2. Requirements for U.S. Meat Establishments²
 - a) Any U.S. meat establishment may be certified as eligible to export to Japan. The meat establishment will be certified as eligible to export beef and beef products to Japan upon the U.S. government notification to the Japanese government of the meat establishment's name, address, and establishment number as listed in the FSIS Meat and Poultry Inspection (MPI) Directory.³ FSIS will provide to the Government of Japan on an annual basis a list of U.S. meat establishments eligible to export to Japan.
 - b) Only U.S. meat establishments that have an approved AMS approved Less Than 30 Months Age Verification Quality System Assessment Program (QSA Program GVD1035A), which meets the specified product requirements for Japan, will be listed on the Official Listing of Eligible Establishments for the QSA LT-30 Program. The QSA LT-30 Program ensures that the requirements are supported by a documented quality management system.
 - c) The Japanese government may conduct on-site audits of the U.S. inspection system through representative samples of the meat establishments that export beef or beef product to Japan to ensure they comply with the relevant requirements detailed in this document and U.S. regulations. In the event a non-compliance with the requirements detailed in this document is found as a result of the on-site audit, the Japanese government will inform the U.S. government on-site of the finding. FSIS would issue a Non-compliance Record (NR) and would immediately control the non-compliant product.

² "U.S. Meat establishment" includes any slaughtering or processing establishment for beef and beef products that operates under USDA inspection.

³ At such time that facilities subject to U.S. State Meat and Poultry Inspection Programs operating under the federal cooperative agreement program seek to export beef and beef products to Japan, FSIS and the Ministry of Health, Labor, and Welfare (MHLW) will hold consultations to facilitate the participation of such facilities in exports of beef and beef products to Japan under these requirements.

If the process that resulted in the non-compliant product is on-going, FSIS would immediately stop the process until it determines that appropriate corrective and preventative measures have been taken. Only when FSIS determines that corrective actions are adequate will it permit production to resume. The U.S. government will inform the Japanese government if a U.S. meat establishment is suspended as a result of an NR, as well as when said establishment is determined by FSIS to be eligible for production and export after corrective and preventative action has been taken by the establishment.

- d) The Government of the United States will verify that the U.S. meat establishment in question has determined and implemented appropriate corrective and preventative measures to address the non-compliances. The Government of the United States will inform the Government of Japan of the corrective and preventative measures the meat establishment has taken and of the date that FSIS lifts the suspension of the affected process.
- 3. Requirements for Beef and Beef Products
 - a) The beef or beef products were derived from cattle that passed ante- and post-mortem inspections consistent with FSIS regulations.
 - b) For the purpose of age determination of the cattle and for SRM removal, the age of cattle at the time of slaughter was determined by the establishment and was verified through either (1) documentation which identifies the age, or (2) dentition.
 - c) The beef or beef products were produced and handled in a manner to prevent contamination from SRMs in accordance with FSIS regulations.
 - d) All carcasses from cattle less than 30 months of age must be recognizable as such.
 - e) Beef and beef products that are eligible for export to Japan as listed on the FSIS website must be processed using the procedures as incorporated into the facility's hazard analysis critical control points (HACCP), sanitation standard operating procedures (SSOP), or prerequisite program, and must be produced in a manner that ensures the hygienic removal of the SRM.
 - f) Sanitary packaging material was used to package the beef or beef products.

- g) In the case where the beef or beef products are transported to Japan by way of third countries, the beef or beef products must be stored in an enclosed ocean/air vessel container.
- 4. Export Certificate
 - a) Beef and beef products qualify for import quarantine inspection if accompanied by the Export Certificate of Wholesomeness and the Certificate for Export of Beef and Beef Products to Japan issued by authorized personnel under the U.S. Federal Meat Inspection Act, which include the following information, in English, to be submitted to the quarantine authority of the Japanese government, as required by the Food Safety Act of Japan:
 - Name, address, and establishment number of each meat establishment where a relevant procedure, such as slaughtering or processing, occurred;
 - 2) Slaughtering and/or processing period (dd/mm/yy-dd/mm/yy).
 - Date, authorities' name, and place of issue of the inspection certificate, and name and title of signer.
 - 4) Required condition of item 4(b) below.
- b) Eligible products produced by eligible U.S. meat establishments and identified as meeting the requirements of the QSA LT-30 Program must receive a FSIS export certificate with a statement indicating that the eligible products fulfilled all of the requirements of the QSA LT-30 Program.
- 5. Other Issues
 - a) The beef and beef products must be subject to the standard, random quarantine import inspection process, including rates of inspection, that is applied to all countries eligible to export beef and beef products to Japan.
 - b) The Government of Japan and the Government of the United States will cooperate to resolve as expeditiously as possible cases of import suspensions by the Government of Japan, with introduction of a customary turnaround time, which has been determined by both governments as aiming for the resolution of such cases within one month and, in any event, as early as practicable.

- c) After a reasonable period of time from the date of implementation of these requirements, taking into account: (a) the actual record of compliance as determined by the Japanese authorities based on their import inspection, (b) the actual record of compliance as determined by the U.S. authorities based on U.S. regulations, and (c) the result of the onsite audit after implementation of QSA LT-30 program with respect to Japan, the Government of Japan will further review its import quarantine inspection and regulatory measures and consider modifications to these same measures in the event that the compliance record is satisfactory.
- d) The Government of Japan will promptly notify the Government of the United States of any changes to its quarantine inspection process and rates and the reason for such changes.
- e) The Government of Japan and the Government of the United States will hold consultations at least annually, unless otherwise decided, to review in a comprehensive manner the interpretation and implementation of the requirements detailed in this document as well as any measures related to trade in beef and beef products. In addition, both governments will hold *ad hoc* consultations at any given time at the request of either government. Such *ad hoc* consultations will be held, to the extent practicable for both sides, within seven (7) calendar days from the date of the request, or at the earliest possible date that is mutually acceptable, on any of the matters mentioned above in this paragraph.

6. Commencement Date

The application of these requirements for beef and beef products to be exported to Japan from the United States will commence on February 1, 2013.