Certification for Export to Korea:
Processed Animal Protein Products for Laboratory or Research Purposes

These requirements pertain to processed animal protein products (as described in this paragraph) which are intended for laboratory or research purposes ONLY. Included are blood products (whole blood, blood plasma, blood serum, antibodies, antiserum, blood clotting factors, red blood cells, white blood cells, albumin), cell lines, hybridoma, monoclonal antibodies, tissue cultures, ascitic fluid, extracts, feces, fluids, hormones, peptides, tissues, urine, and processed animal protein contained in diagnostic kits.

These requirements do NOT pertain to fetal bovine serum (FBS), products derived from primates, and products to be used in manufacturing biological pharmaceuticals such as vaccines. Current requirements for the export of fetal bovine serum (for non-feeding purposes) to Korea are posted separately on the International Animal Product Regulations (IREGs) Korea home page under "Blood: Fetal bovine serum." Requirements for products other than those listed above will be determined by the Director General of Korea's National Veterinary Research and Quarantine Service (NVRQS). For non-listed products, interested exporters should work with their Korean importers to determine the entry requirements.

Media including a small amount of blood (for example mouse cells with a small amount of FBS added for nutrition) will be subject to entry requirements but exempt from quarantine inspection. Note that the determination of what constitutes a "small amount of blood" will be made by NVRQS.

I. Entry requirements for processed animal protein products (as listed in the first paragraph above) derived from NON-ruminant animals (e.g. mice, rats, rabbits, other NON-primate laboratory animals, horses, swine poultry):

1. An import permit is not required for processed animal protein products derived from U.S. origin NON-ruminant animals when the products are intended for laboratory or research purposes only. NOTE: It is advisable for exporters to confirm with their Korean importers that an import permit will not be required. IF exporters intend to export products to Korea that were legally imported into the United States, they need to work with their Korean importers to verify that this is acceptable to Korea (NVRQS). Since the determination as to whether an import permit is needed or not is based on the eligibility of the country of origin to export the live animals from which the product was derived, an import permit may be needed.

2. A use (distribution) plan must be submitted by the importer when applying for inspection.

3. Products must be accompanied by an official veterinary export certificate (VS 16-4) endorsed by the government agency – the Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS); OR a physio-chemical treatment certificate or manufacturing process document verified or issued by a government agency (APHIS or a local government agency); OR a notarized certificate issued by the manufacturer and signed by a knowledgeable representative (including personnel at universities or other types of research institutes). NOTE: If NVRQS

determines that an import permit is needed, the only certification option is an official VS 16-4 endorsed by APHIS/VS.

4. The accompanying document (using one of the three options noted above) must include the following statements. If the VS 16-4 option is used, it will be endorsed by APHIS/VS on the basis of a notarized affidavit provided by the exporter/manufacturer.

   This is to certify that rinderpest, foot-and-mouth disease, classical swine fever, swine vesicular disease, African swine fever, and contagious bovine pleuropneumonia do not exist in the United States of America.

   This office has on file a notarized affidavit from [insert name of exporter/manufacturer] verifying the accuracy of the statements below.

   1) The materials described herein or below* were derived from [*insert animal species of origin*].
   2) The products are U.S. origin or (alternatively) 2) the products were legally imported from [*insert country of origin*]. **
   3) The products are intended for laboratory or research purposes only.
   4) The products were manufactured, processed, and handled in such a manner as to prevent the transmission of communicable disease pathogens.
   5) The products were manufactured, processed, and handled in such a manner as to prevent cross-contamination with BSE-related materials (e.g., SRMs*** or any materials contaminated with SRMs).

*If an official VS 16-4 is used, the name/description of the materials (blood, plasma, etc.), as well as the species of origin, should be included in the Product Section of the VS 16-4. If other types of documents are used, the name/description of the materials should be included in the body of the document.

**If the products for export to Korea were legally imported into the United States from a third country, the certification statements for Korea must be supported by the documentation (export certificate) provided by the country of origin.

***SRMs or specified risk materials, as used here, means the skull, brain, eyes, trigeminal ganglia, spinal cord, dorsal root ganglia, and vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age or older; and the tonsils and distal ileum from cattle of all ages. NOTE: Although materials such as brain or spinal cord are NOT considered SRMs if derived from cattle less than 30 months of age, it is likely that Korea will not permit the entry of these materials. If products are composed of tissues or tissue cultures containing these types of materials, exporters are advised to work with their Korean importers to determine if the products will be allowed entry.

[Neither the asterisks nor the explanatory information should appear on a VS 16-4.]

II. Entry requirements for processed animal protein products (as listed in the first paragraph of this document) derived from ruminant animals (e.g. cattle, sheep, goats, bison, cervidae such as deer or elk, exotic ruminants):

1. An import permit is required for processed animal protein products derived from ruminant animals where the products are intended for laboratory or research purposes only. NOTE: Processed animal protein products derived from ruminants are prohibited entry for any other intended use, including animal feeding. NOTE: IF exporters intend to export products to Korea that were legally imported into the United States, they need to work with their Korean importers to verify that this is acceptable to Korea (NVRQS).

2. A use (distribution) plan must be submitted by the importer when applying for inspection.

3. Products must be accompanied by an official VS 16-4 endorsed by APHIS/VS.

4. Endorsement of the VS 16-4 will be based on a notarized affidavit provided by the exporter/manufacturer.

   This is to certify that rinderpest, foot-and-mouth disease, classical swine fever, swine vesicular disease, African swine fever, and contagious bovine pleuropneumonia do not exist in the United States of America.

   This office has on file a notarized affidavit from [insert name of exporter/manufacturer] verifying the accuracy of the statements below."

   1) The materials described below* were derived from [*insert animal species of origin*].
   2) The products are U.S. origin or (alternatively) 2) the products were legally imported from [*insert country of origin*]. **
   3) The products are intended for laboratory or research purposes only.
   4) The products were manufactured, processed, and handled in such a manner as to prevent the transmission of communicable disease pathogens.
   5) The products were manufactured, processed, and handled in such a manner as to prevent cross-contamination with BSE-related materials (e.g., SRMs*** or any materials contaminated with SRMs).

*The name/description of the materials (blood, plasma, etc.), as well as the species of origin, should be included in the Product Section of the VS 16-4.

**If the products for export to Korea were legally imported into the United States from a third country, the certification statements for Korea must be supported by the documentation (export certificate) provided by the country of origin. NOTE: Products imported into the U.S. from Australia or New Zealand (negligible BSE risk countries from which Korea allows the importation of live ruminants) are considered eligible for re-export with country of origin verification.

***SRMs or specified risk materials, as used here, means the skull, brain, eyes, trigeminal ganglia, spinal cord, dorsal root ganglia, and vertebral column (excluding the vertebrae of the tail, the

transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age or older; and the tonsils and distal ileum from cattle of all ages. NOTE: Although materials such as brain or spinal cord are NOT considered SRMs if derived from cattle less than 30 months of age, it is likely that Korea will not permit the entry of these materials. If products are composed of tissues or tissue cultures containing these types of materials, exporters are advised to work with their Korean importers to determine if the products will be allowed entry.

[Neither the asterisks nor the explanatory information should appear on a VS 16-4.]