Poultry Origin Blood Products intended for Technical/Research Purposes

NOTE: The import of poultry-origin blood products for animal consumption is prohibited. [There are some exceptions for finished pet foods. For more information, please go back to the general Japan page and see information under "Blood products (originating from birds)" for more information on pet foods.]

A. "Sterilized" Blood Products:

Blood products that have been treated in one of the following ways do not require certification. The only documentation that should be included with the consignment is a manufacturer's declaration of the treatment:

- Boiling for one hour; or
- Impregnation with propiolactone, glutaraldehyde, or formaldehyde. [Impregnation with other substances may also be acceptable. The Japanese importer should confirm^{*} with the Japanese Animal Quarantine Service officials at the port through which the consignment enters Japan.]

B. <u>Highly purified blood products:</u>

Blood products that result from a fractionation, purification, or extraction process do not require certification. The only documentation that should be included with the consignment should be a manufacturer's declaration detailing the fractionation, extraction, or purification process.

Examples of fractionation, purification, and extraction processes include salt precipitation, or column chromatography.

Examples of products that can be produced through these processes include albumin, globulin, prothrombin, fibrinogen, monoclonal antibodies, IgG, IgM, and IgE.

In cases where an exporter believes (but is not certain) that their blood product may qualify as having been produced through a "fractionation, purification, and extraction process," they should provide a processing description (not a certificate) to their importer for confirmation^{*} with the Japanese Animal Quarantine Service officials at the port through which the consignment enters Japan.

<u>C. "Unremovable blood products":</u>

These are blood products where the derivative of the blood has been made into another product- from which the blood component cannot be removed. An example is a microplate coated with a blood derivative.

For these products, no documentation is required.

In cases where an exporter believes (but is not certain) that their blood product may qualify as an "unremovable blood product," they should provide a processing description (not a certificate) to their importer for confirmation^{*} with the Japanese Animal Quarantine Service officials at the port through which the consignment enters Japan.

D. <u>Blood-origin products intended for technical/research purposes where none</u> of the above apply (products are not covered by A, B, or C above)

This is the only category for which APHIS may endorse certificates.

This option is required for blood products where the Japanese importer **has** <u>not</u> verified that officials at the port of entry into Japan have agreed that the product falls under A, B, or C above.

A VS Form 16-4 is required with the following exact text in the "ADDITIONAL DECLARATIONS". No additional text may be included.

Beginning of ADDITIONAL DECLARATIONS =>>>

This office has on file a notarized affidavit from [insert name of company here] verifying the accuracy of the statements below. I, the endorsing official listed below, have read the notarized affidavit referenced above, and to the best of my knowledge and belief these statements are true. The exporter has in place procedures to ensure that:

The live poultry used for the product originated in and transited before being carried into collection facilities only the following State(s): [Insert names of State(s) in which live poultry originated and which live poultry transited (if applicable). Also insert "dates" for each State if State was ever banned by Japan for LPAI or HPAI.]

The product has been produced under sanitary conditions.

The products were derived from clinically healthy animals.

Products are stored in clean and sanitary wrappings and/or containers and handled in a way to prevent being exposed to any pathogens or any animal infectious diseases prior to shipment.

<<= End of ADDITIONAL DECLARATIONS.

Exporters must email to the APHIS office scans of the following documentation with the prepared VS Form 16-4:

- Affidavit from the blood product producer verifying:
 - The blood products were produced under sanitary conditions.
 - The blood products are stored in clean and sanitary wrappings and/or containers and handled in a way to prevent being exposed to any pathogens or any animal infectious diseases prior to shipment.

- The blood products were produced from blood collected from clinically healthy animals.
- The names, addresses, and (if slaughter facilities) FSIS establishment numbers of the collection facility or facilities (facility where the blood was taken from the chicken). [These are usually either slaughter facilities or live animal facilities.]
- Affidavit verifying the procedures used to ensure materials from each collection facility listed above (and any other entities that handle the blood/blood products between the flock of origin of the source birds and the exporting facility) meet the pertinent requirements (e.g. only sourced from birds verified to be clinically healthy at the time of collection).
- If any source flocks are located in the "Avian Influenza Bans" table located at: [*ALERT* Important information regarding trade bans on various products] then additional documentation verifying the date (or date range) of blood collection must also be provided. The blood must not be sourced during the "dates" banned.

The affidavits do not become part of the VS Form 16-4 and are not sent to Japan with the shipment.

All affidavits must meet certain formatting criteria. Exporters should contact their local APHIS office for details.

The above assumes the blood products are from blood collected in the United States.

^{*}When there is doubt whether a product falls under A, B, C, or D above:

Exporters should always have their Japanese importers confirm <u>prior to shipment</u> that the consignment will be allowed entry with only the documentation that will accompany the consignment. If a Japanese importer is not sure whether a product falls under A, B, C, or D above, they should contact the pertinent Animal Quarantine Station (AQS) over the port of entry into Japan. A list of contact information for these AQS offices is available below. The U.S. exporter should not contact these offices directly. If Japanese importers send an email directly to these offices, Japanese animal health authorities have verified that an email response will be sent back. The Japanese importer can then provide that email, and an English translation to the U.S. exporter.

Japan Animal Quarantine Stations: Contact Information

List of Animal Quarantine Stations with jurisdiction over airports (seaports)(as of October 2010)

Animal Quarantine Stations with jurisdiction over the main airports (seaports) are as follows.

Name	Airport (Seaport)	Telephone number	Fax number	E-mail address
Yokohama Head Office (Animal Quarantine	Keihin Seaport	+81(0)45-751- 5921	+81(0)45-751- 5951	<u>y-dobutu@aqs.maff.go.jp</u>
Division) Hokkaido Sub-branch	Tomakomai Seaport, Shin Chitose	+81(0)123-24- 6080	+81(0)123-24- 6091	<u>chitose@aqs.maff.go.jp</u>
Narita Branch Quarantine 1 st Division	Airport Narita Internation al	+81(0)476-32-6664	+81(0)476-30-3011	<u>na-k1@aqs.maff.go.jp</u>
Narita Branch Quarantine 2 nd Division	Airport Narita Internation al	+81(0)476-34-2342	+81(0)476-34-2338	na-k2@aqs.maff.go.jp
(Cargo inspection)	Airport Narita Internation al	+81(0)476-32-6655	+81(0)476-30-3012	<u>n-kamotu@aqs.maff.go.jp</u>
Haneda Airport Branch	Airport Tokyo Internation al	+81(0)3-5757-9752	+81(0)3-5757-9758	haneda@aqs.maff.go.jp
(Cargo inspection)	Airport Tokyo Internation al	+81(0)3-5757- 9755	+81(0)3-5757- 9760	<u>h-kamotu@aqs.maff.go.jp</u>
Chubu Airport branch	Airport Chubu Internation al	+81(0)569-38-8577	+81(0)569-38-8585	<u>meiku@aqs.maff.go.jp</u>
Nagoya Sub-branch	Airport Nagoya Seaport	+81(0)52-651-0334	+81(0)52-661-0203	ng-ken@aqs.maff.go.jp
Kansai Airport Branch Quarantine Division	Kansai Internation al	+81(0)72-455-1956	+81(0)72-455-1957	<u>ka-ken@aqs.maff.go.jp</u>
(Cargo inspection)	Airport Kansai Internation al	+81(0)72-455-1958	+81(0)72-455-1959	<u>k-kamotu@aqs.maff.go.jp</u>
Kobe Branch	Airport Kobe Seaport	+81(0)78-222-8990	+81(0)78-222-8994	ko-ken@aqs.maff.go.jp
Osaka Sub-branch	Osaka Seaport	+81(0)6-6575-3466	+81(0)6-6575-0977	<u>osaka@aqs.maff.go.jp</u>
Moji Branch	Kanmon Seaport, Kitakyusyu Airport	+81(0)93-321-1116	+81(0)93-332-5858	<u>mo-ken@aqs.maff.go.jp</u>

Hakata Sub-branch	Hakata Seaport	+81(0)92-262-5285	+81(0)92-562-5283	hakata@aqs.maff.go.jp
Fukuoka Airport Sub- branch	Fukuoka Airport	+81(0)92-477-0080	+81(0)92-477-7580	fukuoka@aqs.maff.go.jp
Kagoshima Airport Sub-branch	Kagoshima Airport	+81(0)955-43-9061	+81(0)995-43-9066	<u>kagosima@aqs.maff.go.jp</u>
Okinawa Branch	Naha Seaport	+81(0)98-861-4370	+81(0)98-862-0093	oki-ken@aqs.maff.go.jp
Naha Airport Sub-branch	Naha Airport	+81(0)98-857-4468	+81(0)98-859-1646	<u>naha@aqs.maff.go.jp</u>