## Blood Products (Other than those Originating from Birds) for Technical Purposes

At this time, blood products for animal feeding are prohibited import into Japan. The only exceptions are:

- Spray dried porcine blood produced under the Porcine Origin Verification Program-Japan (POVP-J). For more information on the POVP-J, please go back to the general Japan page and see the separate article.
- Certain finished pet foods. For more information, please go back to the general Japan page and see information under "Pet food, chews, and treats."

Certification is not required for blood products derived from animals <u>other than</u> cattle, pigs, sheep, goats, equines, dogs, poultry, and rabbits.\*

For information on blood products derived from poultry, please go back to the general Japan page and see information under "Blood products (originating from birds)."

# Blood Products Derived from Cattle, Pigs, Sheep, Goats, Equines\* (see special additional CITES-related requirements for equidae blood at the end of this document), Dogs, Poultry, and Rabbits

The requirements for blood products derived from cattle, pigs, sheep, goats, equines, dogs, poultry, and rabbits are divided into 4 categories.

#### 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.** Highly purified blood products:

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.

#### **C.** "Unremovable blood products":

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. Blood-origin products intended for technical/research purposes where none 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. [The "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" sentence should only appear once on the VS Form 16-4 (it was preprinted on versions preceding the JUL 2022 version). If the JUL 2022 version of the VS Form 16-4 is utilized, it should be the first sentence in the ADDITIONAL DECLARATION area.]

Beginning of ADDITIONAL DECLARATIONS =>>>

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 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 products were derived from clinically healthy animals."

<== 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 from blood collected from clinically healthy animals.
- If the blood product producer is not the same entity that collects the blood from the source animals: Affidavit verifying the procedures used to ensure materials from each collection facility (and any other entities that handle the blood/blood products between collection and the exporting facility) meet the pertinent requirements (e.g. only sourced from animals verified to be clinically healthy at the time of collection).
- If additional entities handle the blood/blood products between the collection of the blood, equivalent affidavits must be included from each of those entities.

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. If not, certification from the government of the country of origin that the source blood was derived from clinically healthy animals (and/or animals that passed ante-mortem inspection for slaughter human consumption) must also be provided.

#### When there is doubt whether a product falls under A, B, C, or D above:

\*Exporters should always have their Japanese importers confirm prior to shipment 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)

Name	Airport (Seaport)	Telephone number	Fax number	E-mail address
Yokohama Head Office	Keihin	+81(0)45-751-	+81(0)45-751-	y-dobutu@aqs.maff.go.jp
(Animal Quarantine	Seaport	5921	5951	<del> </del>
Division)				
Hokkaido Sub-branch	Tomakomai	+81(0)123-24-	+81(0)123-24-	chitose@aqs.maff.go.jp
	Seaport,	6080	6091	
	Shin			
	Chitose			
Navita Buarda Occaration	Airport	.04/0)476 22 6664	.04/0\476.20.2044	
Narita Branch Quarantine  1st Division	Narita Internation	+81(0)476-32-6664	+81(0)476-30-3011	na-k1@aqs.maff.go.jp
13 DIVISION	al			
	Airport			
Narita Branch Quarantine	Narita	+81(0)476-34-2342	+81(0)476-34-2338	na-k2@aqs.maff.go.jp
2 <sup>nd</sup> Division	Internation al	. ,	· ,	<u></u>
	Airport			
(Cargo inspection)	Narita	+81(0)476-32-6655	+81(0)476-30-3012	n-kamotu@aqs.maff.go.jp
	Internation			
	al			
	Airport	.04/0\0 5757 0750	.04/0\0 5757.0750	
Haneda Airport Branch	Tokyo Internation	+81(0)3-5757-9752	+81(0)3-5757-9758	haneda@aqs.maff.go.jp
	al			
	Airport			
(Cargo inspection)	Tokyo	+81(0)3-5757-	+81(0)3-5757-	h-kamotu@aqs.maff.go.jp
(3. 6. 3)	Internation al	9755	9760	<u> </u>
	Airport			
Chubu Airport branch	Chubu	+81(0)569-38-8577	+81(0)569-38-8585	meiku@aqs.maff.go.jp
	Internation			
	al			
Nagoya Sub-branch	Airport Nagoya	+81(0)52-651-0334	+81(0)52-661-0203	ng-ken@aqs.maff.go.jp
Nagoya Sub-branch	Seaport	181(0)32-031-0334	181(0)32-001-0203	ng-ken@aqs.man.go.jp
Kansai Airport Branch	Kansai	+81(0)72-455-1956	+81(0)72-455-1957	ka-ken@ags.maff.go.jp
Quarantine Division	Internation	01(0)/1 100 1000	101(0)/12 100 200/	na none adominanipolip
	al			
	Airport			
(Cargo inspection)	Kansai	+81(0)72-455-1958	+81(0)72-455-1959	k-kamotu@aqs.maff.go.jp
	Internation al			
	Airport	/->		
Kobe Branch	Kobe	+81(0)78-222-8990	+81(0)78-222-8994	ko-ken@aqs.maff.go.jp
Osaka Sub branch	Seaport Osaka	+81(0)6-6575-3466	+81(0)6-6575-0977	osaka@ags maff go in
Osaka Sub-branch	Seaport	+61(0)0-0373-3400	+01(0)0-03/3-09//	osaka@aqs.maff.go.jp
Moji Branch	Kanmon	+81(0)93-321-1116	+81(0)93-332-5858	mo-ken@aqs.maff.go.jp
	Seaport,	01(0)00 011 1110	01(0)00 001 0000	o non Cagamamgerjp
	Kitakyusyu			
	Airport			
Hakata Sub-branch	Hakata	+81(0)92-262-5285	+81(0)92-562-5283	hakata@aqs.maff.go.jp
	Seaport			
Fukuoka Airport Sub-	Fukuoka	+81(0)92-477-0080	+81(0)92-477-7580	fukuoka@aqs.maff.go.jp
branch	Airport			

Kagoshima Airport	Kagoshima	+81(0)955-43-9061	+81(0)995-43-9066	kagosima@aqs.maff.go.jp
Sub-branch	Airport			
Okinawa Branch	Naha	+81(0)98-861-4370	+81(0)98-862-0093	oki-ken@aqs.maff.go.jp
	Seaport			
Naha Airport Sub-branch	Naha	+81(0)98-857-4468	+81(0)98-859-1646	naha@aqs.maff.go.jp
	Airport			

#### \*Special CITES Requirements for Equidae Blood Products

The government of Japan"s Ministry of Economy, Trade and Industry (METI) requires special CITES documentation in addition to the above noted requirements for equidae blood products.

For equidae products covered by CITES, METI requires a USFWS permit. The U.S. Fish & Wildlife Service is the Agency responsible for providing CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora) certification. If CITES documentation is required, exporters should contact the U.S. Fish & Wildlife Service.

For equidae products NOT protected by CITES, METI requires a **manufacturer's declaration** (e.g. Products derived from donkeys were produced from the sera of domestic donkeys of a genus and species not protected by CITES).

To determine whether METI (government of Japan) considers a particular equidae blood product to be protected by CITES, the Japanese importer should contact METI:

CITES Team
Trade Licensing Division
Trade Control Department
Trade and Economic Cooperation Bureau
Ministry of Economy, Trade and Industry

Tel: +81-3-3501-1723 (dial-in)

Fax: +81-3-3501-0997

Online contact form:

https://wwws.meti.go.jp/honsho/comment form/comments send.htm#form