

# NOTARIZED PROCESSING METHOD FORM FOR BLOOD PROCESSING FACILITIES

## Sample Form and Comments

Please find below a sample completed Appendix 2A. This form is required for all technical blood facility (non-equidae).

### A. General Purpose of Form:

The facility notes/verifies on this form:

1. The species of origin of the blood;
2. An understanding of the disease status of the region of origin of the blood as it relates to the requirements for export (APHIS or the Ministry of Animal Health of the Country of origin who actually verifies this disease status.);
3. If ruminant products are being exported to the EU that are required to be further processed at an approved establishment in the EU, identification of the approved processing facility in the EU; and
4. Criteria of required self-inspection programs if applicable.

### B. Disease status of Area of Origin of Raw Material (Blood collection)

The EU requires blood to originate from regions free from certain diseases (and not vaccinating from those diseases), or to process the materials in a certain way (unless the materials are being exported to an approved establishment in the EU for further treatment).

Ruminant origin blood must be collected from animals originating from regions: where no case of foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever and bluetongue has been recorded for 12 months and in which vaccination has not been carried out against those diseases for at least 12 months

Blood from species other than ruminants must be collect from animals from regions where no case of foot-and-mouth disease, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease or highly pathogenic avian influenza has been recorded for 12 months in the **susceptible species** and in which vaccination has not been carried out against those diseases for at least 12 months.

Blood from species (e.g. rabbits) other than ruminants that would not be susceptible to foot-and-mouth disease, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease or avian influenza is not subject to “area of origin-disease status” related requirements.

Due to the presence of bluetongue in the United States and the occasional presence of vesicular stomatitis ruminant origin blood originating in the US, must always be processed according to the required self-inspection program, or exported to an EU approved establishment for further processing (if being exported as technical blood).

The Area Office should always be diligent when reviewing this form to consider the recent history of the US for all diseases of concern.

### **C. Review of the Form**

#### **I. Species of origin**

In this section the facility selects for which products (by species of origin) they are seeking approval. In our example, the facility is seeking approval for blood from three species:

X ruminant origin blood or blood products (specify species): goat;

     porcine origin blood or blood products;

X avian origin blood or blood products;

X other species of blood products (specify species): bat.

When they select “ruminant” they must specify which ruminants. They have specified “goat.” They’ve also noted that they have selected “avian” materials, and checked “other” specifying “bat.” Bats fall under the “rodent” category that NCIE does not feel are generally covered under Regulation (EC) 1774/2002. However some EU member countries are believed to be requiring 1774 certification. Therefore, exporters seeking 1774 approval for these commodities may do so, if they meet all the requirements.

#### **II. Disease freedom or treatment**

In this section at least one item must be checked (out of the five possible options) for each livestock species of material noted in Roman numeral I above) (i.e., if they select ruminant origin blood and avian origin blood in roman numeral I above, they need to select item “c”, and either item “a” or one of the last two check spots of the first page of the form.

In our example, the first three parts of this section are completed as follows:

***EITHER*** the products are derived from areas free of the following diseases:

\_\_\_\_\_ a. ruminant origin blood or blood products from the following areas are free of foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever, and bluetongue for at least 12 months (list country of origin: \_\_\_\_\_);

\_\_\_\_\_ b. porcine origin blood or blood products from the following areas free of foot-and-mouth disease, swine vesicular disease, classical swine fever, and African swine fever (list country of origin: \_\_\_\_\_);

X c. avian materials from the following areas that have been free of exotic Newcastle disease and highly pathogenic avian influenza for the last 12 months: (list country/states of origin: US wide, and also Lambnovia (Certificate from government of Lambnovia attached) \_\_\_\_\_):

Option “a” may never be selected for US origin products because of the presence of ruminant products. In this case, the facility is noting in option c that the avian materials both originate from various facilities in the US and are imported from Lambnovia. When imported materials are sited, a copy of the certificate from the exporting country verifying that the materials meet the requirements must be attached. You will note that a certificate from the government of Lambnovia has been attached as page three of the form. The facility imports duck serum from Lambnovia. They may also receive various other avian origin blood materials from other US approved suppliers – those suppliers would have been specified on their Approved Supplier Form (Appendix One).

After reviewing the first three options in section two, you will note that the facility still has not accounted for the origin of the goat blood. They do not need to account in this section for the “bat” blood because it is an “other” species that is not subject to any “region disease freedom” requirements. NOTE- While “other” species blood is not subject to the “disease status” requirements, it is subject to collection under the other requirements of Regulation (EC) 1774/2002, and therefore imported blood must still be imported with certification of compliance with the regulation.

Looking at the last two options in this section in our example:

***AND / OR***

\_\_\_\_\_ Ruminant origin items are from regions not free of bluetongue and/or vesicular stomatitis but will only be exported for technical purposes, including pharmaceuticals, in vitro diagnosis, and laboratory reagents, and **will be exported directly to the following EU approved plants for further processing:**

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***AND/ OR***

X the products for export to the EU have been treated with the below noted parameters (check appropriate selection), and the processing facility has in place a self-inspection program with the critical limits referenced (check all that apply):

Our facility has not selected the second to last option. If the facility wished to export ruminant origin blood to the EU without first processing the blood under the required self-inspection program (including testing the product after the processing), they could have selected this box if they were going to export the products only directly to approved establishments in the EU for further processing. In this case, the facility would need to have identified the specific approved facilities in the EU.

Or the facility may select the last option, to treat and test the product in compliance with the required self inspection program- which is what our example facility has done.

Note that a facility could select both of the last two options if they had a program in place to identify which products would be eligible only for export to approved EU establishments and which products would be eligible for general export to the EU.

If the facility has selected the last option in this section, then they MUST select an option in the CCP and CL chart which follows on the second page of the form. In our example, the facility has selected to treat the material as follows.

<b>X</b>	Heat to 65 degrees C for 3 hours	Minimum temperature, AND	65 degrees C
		Minimum time at minimum temperature	3 hours

Note- Because imported materials requiring verification of the disease status of the country of are of origin are utilized, the facility is required to attach certification from the government of the country of origin. A copy of that certificate is acceptable. Note that the facility has changed the page numbers of the form to note the addition of the certificate, and initialed each change.

**Appendix 2A**

**NOTARIZED PROCESSING METHOD FORM FOR BLOOD PROCESSING FACILITIES**

(This form is required for processing/exporting facilities)

This serves to inform officials of the United States Department of Agriculture's Animal and Plant Health Inspection Service that Elvira's Palace (Plant's name), located at 66666 Transylvania Court, Puncture Lane, Scary, PA

\_\_\_\_\_  
(Plant's street address, including City, State, and Zip), handles for export to the EU (check all that apply):

**I. Species of origin**

ruminant origin blood or blood products (specify species): goat;

\_\_\_\_ porcine origin blood or blood products;

avian origin blood or blood products;

other species of blood products (specify species): bat.

**II. Disease freedom or treatment**

**EITHER** the products are derived from areas free of the following diseases:

\_\_\_\_ a. ruminant origin blood or blood products from the following areas are free of foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever, and bluetongue for at least 12 months (list country of origin: \_\_\_\_\_);

\_\_\_\_ b. porcine origin blood or blood products from the following areas free of foot-and-mouth disease, swine vesicular disease, classical swine fever, and African swine fever (list country of origin: \_\_\_\_\_);

c. avian materials from the following areas that have been free of exotic Newcastle disease and highly pathogenic avian influenza for the last 12 months: (list country/states of origin: US wide, and also Lambnovia (Certificate from government of Lambnovia attached)):

**AND / OR**

\_\_\_\_ Ruminant origin items are from regions not free of bluetongue and/or vesicular stomatitis but will only be exported for technical purposes, including pharmaceuticals, in vitro diagnosis, and laboratory reagents, and **will be exported directly to the following EU approved plants for further processing:**

\_\_\_\_\_  
**AND/ OR**

the products for export to the EU have been treated with the below noted parameters (check appropriate selection), and the processing facility has in place a self-inspection program with the critical limits referenced (check all that apply):

<b>Required CCPs and Critical Limits for Plants Processing <u>Ruminant</u> Blood or Blood Fractions</b>			
<b>Processing method (check one of the below)</b>		<b>Critical control points</b>	<b>Critical limits</b>
<b>X</b>	Heat to 65 degrees C for 3 hours	Minimum temperature, AND	65 degrees C
		Minimum time at minimum temperature	3 hours
	Irradiation	Minimum irradiation	2.5 megarads or by gamma rays
	pH altering	pH, AND	5
		Minimum time at pH of 5	2 hours
	Heat to 90 degrees C	Minimum internal temperature	90 degrees C
<b>Required CCPs and Critical Limits for Plants Processing <u>Avian or Porcine</u> Blood or Blood Fractions</b>			
<b>Processing method (check one of the below)</b>		<b>Critical control points</b>	<b>Critical limits</b>
	Heat to 65 degrees C for 3 hours	Minimum temperature, AND	65 degrees C
		Minimum time at minimum temperature	3 hours
	Irradiation	Minimum irradiation	2.5 megarads or by gamma rays
	Heat to 90 degrees C	Minimum internal temperature	90 degrees C

**The above referenced self-inspection program specifies that material will be safety-tested for the disease agent of concern after the treatment.**

I certify that the statements listed above are true to the best of my knowledge and belief.  
Signed by: Elvira LeState Date: 5-1-05

Printed name of signing official: Elvira LeState

Position of signing official: President

Company name and phone number:  
Elvira's Palace, 555-555-5555

Notary signature: \_\_\_\_\_

Health Certificate No. 02280599

**Veterinary Sanitary Certificate for the Export of Blood Products from Lambnovia**

Name and address of Consignor:

**Batty Battalion**  
666 Aerial Rodent Cove  
Funny Coincidence, Lambnovia

Name and address of Consignee:

**Elvira's Palace**  
66666 Transylvania Court  
Puncture Lane, Scary, PA

Method of shipment:

Plane

Date of shipment:

3-1-05

Description of products included in shipment:

12 containers, 25 ml each duck serum Lot number 5486,

Certified was produced from raw material of the following species: duck

The products described above originated from Lambnovian origin ducks that did not show at the time of collection clinical signs of any disease communicable to humans or animals.

No vaccination against, and no case of Newcastle disease or highly pathogenic avian influenza has been reported in Lambnovia for the last 12 months.

Done at Funny Coincidence Lambnovia Ministry of Animal Health Regional Office,  
(Place)

on February 27, 2005 by KJ Boshmuckulwitchz,  
DVM  
(Date) (Signature of the official veterinarian)

Stamp

KJ Boshmuckulwitchz, DVM, Regional Veterinarian In Charge  
(Name in capital letters, qualifications, and title of signatory)

Graphics note- in reality – this page would be sealed by the gov't of Lambnovia.

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