

ASF Response Plan

Spray Dried Blood/Plasma Facility

July 17, 2023

Note: This ASF Response Plan is for a Spray Dried Blood / Plasma Facility and is intended to serve as a guide. This template is specific to Spray Dry Blood / Plasma Facilities that are dedicated to blood / plasma. It can be amended as necessary to be specific to the single Spray Dry Blood / Plasma Facility identified below. Attach any supplemental materials necessary and reference in each section as applicable.

Date: _____

Spray Dried Plasma/Blood Facility Information Needed	
Facility Type	<input type="checkbox"/> Federally Inspected <input type="checkbox"/> State Inspected <input type="checkbox"/> Custom Exempt
Species of blood processed <input type="checkbox"/> Porcine <input type="checkbox"/> Bovine	Processed type: <input type="checkbox"/> Whole blood <input type="checkbox"/> Plasma <input type="checkbox"/> Red Cell <input type="checkbox"/> Other species (specify): _____
Premises ID # (not FSIS Establishment #)	
Special ID (<i>assigned by the Incident Management Team</i>) <input type="checkbox"/> check if not applicable	
State abbreviation, county, and site #	
Spray Dry Blood / Plasma facility owner/manager	
Name of facility	
Address and contact information	
Corporate Office information (if applicable)	
Name	
Address and contact information	

ASF EMERGENCY RESPONSE DESIGNATIONS FOR SPRAY DRIED BLOOD/PLASMA FACILITY

The status of the Spray Dried Blood/Plasma Facility will be determined by its geographic location (e.g., located within a Control Area) **AND** the status of the associated Meat Harvest Facility that is the source of raw material, when the material is received within an established epidemiological trace period. A Spray Dried Blood/Plasma Facility may receive raw material from more than one Meat Harvest Facility that have different statuses; in such cases, the Spray Dried Blood/Plasma Facility will have the most restrictive status of the associated Meat Harvest Facility. For example, if the Spray Dried Blood/Plasma Facility received raw materials from an Infected Meat Harvest Facility and a Meat Harvest Facility that is a Contact Premises, then the Spray Dried Blood/Plasma Facility will take on the status of the Infected Meat Harvest Facility and implement the biosecurity requirements for that status classification.

CLASSIFICATION OF Source of Raw Material	Definition	Facility Area or Zone
<p>Harvest Facility and Spray Dried Blood/Plasma Facility in a Free Area Product is harvested from animals passed antemortem inspection and found free of disease symptoms.</p>	<p>Meat Harvest Facility and Spray Dried Blood/Plasma Facility outside of a Control Area and not a Contact Premises (CP) or Suspect Premises (SP).</p> <p>The status of the Spray Dried Blood/Plasma Facility is determined by geographical location and the status of the associated Meat Harvest Facility (infected premises, contact premises, control area premises).</p>	Free Area
<p>Harvest Facility and/or Spray Dried Blood/Plasma Facility in a Control Area Product is harvested from animals passed antemortem inspection and found free of disease symptoms.</p>	<p>Meat Harvest Facility and/or Spray Dried Blood/Plasma Facility objectively demonstrates that it is not an IP or Suspect Premises (SP). Facility meets a set of defined biosecurity criteria to receive susceptible animals or products from inside or outside of the Control Area.</p> <p>The status of the Spray Dried Blood/Plasma Facility is determined by geographical location and the status of the associated Meat Harvest Facility (infected premises, contact premises, control area premises).</p>	Control Area
<p>Harvest Facility and/or Spray Dried Blood/Plasma Facility identified as a Contact Premises Product is harvested from animals passed antemortem inspection and found free of disease symptoms.</p>	<p>Meat Harvest Facility that received swine epidemiologically traced from an Infected Premises (IP) within the established contact trace period. Traced pigs may not be available for testing; if available, traced pigs tested negative for ASFV. A Spray Dried Blood/Plasma Facility that received blood/plasma from a Meat Harvest Facility that received pigs from an IP within the established contact trace period.</p> <p>The status of the Spray Dried Blood/Plasma Facility is determined by geographical location and the status of the associated Meat Harvest Facility (infected premises, contact premises, control area premises).</p>	Control Area / Free Area

Harvest Facility identified as a Suspect Premises (SP) Product is harvested from animals passed antemortem inspection and found free of disease symptoms.	Slaughter establishment under investigation due to the presence of swine on premises reported to have clinical signs compatible with ASF. This is intended to be a short-term premises designation; after diagnostic testing, a SP will become either an IP (ASF detected), a FP (ASF not detected, facility not a CP or a Control Area premises), a CP (ASF not detected but swine were received from an IP), or a Control Area premises (ASF not detected, facility is in a Control Area).	Control Area / Free Area
Harvest Facility and/or Spray Dried Blood/Plasma Facility identified as an Infected Premises (IP) Product is harvested from animals passed antemortem inspection and found free of disease symptoms.	Meat Harvest Facility where a presumptive positive case or confirmed positive case exists based on laboratory results, compatible clinical signs, ASF case definition, and international standards. A Spray Dried Blood/Plasma Facility that received blood/plasma from Meat Harvest Facility determined to be an IP. The status of the Spray Dried Blood/Plasma Facility is determined by geographical location and the status of the associated Meat Harvest Facility (infected premises, contact premises, control area premises).	Infected Zone/ Control Area

ASF ZONE AND AREA DESIGNATIONS

Zone/Area	Definition
Infected Zone	Zone that immediately surrounds an Infected Premises.
Buffer Zone	Zone that immediately surrounds an Infected Zone or a Contact Premises.
Control Area	Consists of an Infected Zone and a Buffer Zone. For an infected meat harvest facility, the Control Area may be the perimeter of the facility. Swine premises in a Control Area are under quarantine.
Surveillance Zone	Zone outside and along the border of a Control Area. The Surveillance Zone is part of the Free Area.
Free Area	Area not included in any Control Area. Includes the Surveillance Zone.

MANAGED MOVEMENTS AND REQUIRED BIOSECURITY IN AN ASF OUTBREAK

Managed movements and required biosecurity are emergency regulatory interventions to manage swine movements. The following authority applies:

- State Authority and/or
- USDA Authority: existing USDA authorities or USDA Extraordinary Declaration.

A Spray Dried Blood/Plasma Facility that is located within a Free Area or Control Area will continue to process swine blood/plasma if biosecurity and traceability requirements are in place.

A Spray Dry Blood / Plasma Facility that is located within a Control Area, or associated with a Meat Harvest Facility that has an Infected Premises or Contact Premises status will be required to implement all biosecurity and traceability requirements in these guidelines to continue processing and business operations.

THE MAIN TENETS OF THIS PLAN INCLUDE:

- ◆ Biosecurity,
- ◆ Epidemiological investigation and traceability,
- ◆ Managed movements, and
- ◆ Regaining Free Premises status.

BIOSECURITY

REDUCING THE RISK OF INFECTION

A site-specific biosecurity protocol to be implemented as a condition of processing porcine blood / plasma will be developed, if needed, and approved by regulatory FDA, State and USDA personnel. **Minimum biosecurity criteria** that should be implemented include the procedures outlined on pages 6 through 8 and are based on the premises status of the Spray Dried Blood/Plasma Facility as determined by the associated Meat Harvest Facility.

If the Spray Dry Blood / Plasma Facility is located within a Control Area, the facility may be subject to additional biosecurity protocols as specified for the Control Area and implemented by regulatory State or VS personnel.

EPIDEMIOLOGICAL INVESTIGATION AND TRACEABILITY

The Spray Dry Blood / Plasma Facility may be requested to share its manufacturing records, receiving log and shipping log that includes records of blood / plasma movements on and off the facility as part of an Epidemiological Investigation if the Spray Dried Blood/Plasma Facility is associated with a Meat Harvest Facility that has an Infected Premises and/or Contact Premises status.

MANAGED MOVEMENTS

- A. **If the minimum biosecurity criteria (see next section) are implemented or can be implemented by date:_____ time:_____ AM/PM (specify the date and time) that is within 24 hours OR by close of business the following day¹ after the Spray Dry Blood / Plasma Facility confirms (verbally or in writing) receiving notification of its Premises Status to regulatory State or VS personnel**, then the biosecurity criteria will be verified by regulatory State or VS personnel and the facility will be allowed to continue receiving blood / plasma for processing.
- B. **If the minimum biosecurity criteria (see next section) are not implemented or cannot be implemented by date:_____ time:_____ AM/PM (specify the date and time) that is within 24 hours OR by close of business the following day after the Spray Dry Blood / Plasma Facility confirms (verbally or in writing) receiving notification of its Premises Status to regulatory State or VS personnel**, the facility should process remaining blood / plasma onsite. Any product in transit to the Spray Dry Blood / Plasma Facility when the facility is notified of its Premises Status may continue to the Spray Dry Blood / Plasma Facility and allowed to be processed. No additional scheduling of movements of blood / plasma to the facility should be allowed until the minimum biosecurity criteria are implemented, unless allowed by the SAHO.

REGAINING FREE PREMISES STATUS

1. **Spray Dried Blood / Plasma in a Control Area**
 - a. The Control Area release will be based on requirements for all Infected Premises. For swine production sites, the minimum time a Control Area is released is two WOAHP incubation periods (30 days) after virus elimination is completed on the last Infected Premises.
 - b. Once the Control Area is released, the Spray Dried Blood / Plasma Facility will regain a Free Premises status.
2. **Spray Dried Blood/Plasma Facility not in a Control Area**
 - a. A Spray Dried Blood/Plasma Facility that is not located in a Control Area will regain a Free Premises status after the **minimum biosecurity criteria** on pages 6 through 8

are implemented and checked by regulatory State or VS personnel, based on the premises status of the Spray Dried Blood/Plasma Facility as determined by the associated Meat Harvest Facility.

OWNER/FACILITY MANAGEMENT:

Signature: _____ *Date:* _____

VS INCIDENT COMMANDER OR **VS DISTRICT DIRECTOR/AREA VETERINARIAN IN CHARGE:**

Signature: _____ *Date:* _____

STATE INCIDENT COMMANDER OR **STATE VETERINARIAN:**

Signature: _____ *Date:* _____

Spray Dry Blood/Plasma Facility Biosecurity Levels

The goal of enhanced biosecurity plan is to prevent lateral spread of ASFV, facilitate continuity of business.

Sanitation will be conducted in accordance with the existing protocols and defined under the facility's compliance with 21 CFR 507 FSMA.

Unique features of a Spray Dry Blood/Plasma Facility:

- All blood/plasma is collected from pigs that have passed anti-mortem inspection and have been found fit for slaughter for human consumption.
- Trucks and trailers do not come in contact with live pigs.
- Spray dried blood/plasma is delivered to a feed manufacturing facility and is not delivered to a pig farm.
- ASF risk is independent of the location of the spray dry blood/plasma facility, i.e. inside or outside of a Control Area.
- Harvest Facilities may be designated:
 - Free Zone
 - Control Area
 - Contact Premises
 - Suspect Premises
 - Infected Premises
- Spray dry blood/plasma facilities collect from multiple Harvest Facilities.

ASFV Risk level for SDBF

Level 1	ASFV not reported in the US, normal biosecurity practices.
Level 2	ASFV reported in the US, enhanced biosecurity practices. Includes if a Harvest Facility is a Contact Premises or if a Spray Dried Blood/Plasma Facility is in a Control Area.
Level 3	During the 72 hour National Movement Standstill or if the Spray Dried Blood/Plasma Facility is associated with an Infected Meat Harvest Facility.

Biosecurity Procedures at a Spray Dry Blood/Plasma Facility

People other than employees	Level 1	Level 2	Level 3
Facility zoning and traffic control is implemented where possible.	X	X	X
All visitors shall be informed of the current biosecurity level prior to visiting the manufacturing facility.		X	X
All visitors must be approved by the Plant Manager.		X	X
Personnel	Level 1	Level 2	Level 3
Employees shall be informed of the current biosecurity Level at the manufacturing facility.	X	X	X

Employees shall work in dedicated areas and follow procedures to help enforce facility zoning and traffic control.		X	X
Employee uniforms and shoes shall be kept on site.	X	X	X
Employee personal belongs (including clothing) shall be stored appropriately in locker rooms.	X	X	X
Personnel traveling to Harvest Facility must not return to the plant until clothes and shoes are changed or cleaned and sanitized.		X	X
Cleaning and Sanitation	Level 1	Level 2	Level 3
Sanitary barriers (handwash and boot wash stations) shall be maintained insuring wet/dry separation.	X	X	X
Tanker wheels are disinfected while entering the unloading bay.	X	X	X
The tanker shall be cleaned and disinfected around the area where the hose is coupled prior to attachment of the hose.		X	X
Office, breakrooms, locker rooms, rest rooms and walk zones are cleaned and disinfected daily.			X
QA samples or raw material will be treated in inactivate potential virus before disposal.		X	X
Implement sanitation procedures for a Biosecurity Alert.			X

Plant Cleaning and Disinfection for Biosecurity Alert

1	Once all raw blood/plasma has been received, processed, and package the “wet” side of the facilities will be cleaned and disinfected.
2	Clean and disinfect all liquid tanks/silo’s/balance tanks with normal CIP processes and the approved Sanitizer at the strength recommended to inactivate ASFV (ie., Quaternary ammonium 0.003% or equivalently effective sanitizer to inactivate ASFV).
3	CIP UV system including the normal CIP process and warm-up procedure.
4	CIP membrane system (NANO or RO) following normal procedures and ensuring that the final step includes a sanitizer approved to inactivate ASFV.
5	Clean and disinfect the exterior surface of wet area equipment
6	Clean and disinfect wet area walls, floors including the truck bay.
7	Clean and disinfect Sanitary Barriers, including replacement of cleaning solution in the boot wash.
8	Clean and disinfect welfare and office areas.
9	Isolate and schedule for pick-up all used uniforms.
10	Clean and disinfect mops, rags, scrub brushes and other cleaning equipment.
11	Sampling equipment used on the “wet” area should be cleaned and disinfected.
12	Forklifts used in the “wet” area should be cleaned and disinfected with special attention to the wheels.
13	Commonly used tools used in the “wet” area should be cleaned and disinfected.
14	Laboratory and sample preparation area(s) shall be cleaned and disinfected