# Proposal for an industry-standard outbreak investigation

## Introduction

To protect the United States swine industry from substantial economic losses caused by an emerging, or transboundary disease outbreak, producers and veterinarians need to rapidly identify, control, and eliminate the pathogen. In response to events following the introduction of the porcine epidemic diarrhea virus (PEDV), the Swine Health Information Center (SHIC) funded Iowa State University to develop the Rapid Response to Emerging Disease Program (RRP) in August of 2016. The program now includes a nationwide network of veterinarians, state animal health officials or representatives, epidemiologists, and, when appropriate, federal animal health officials (Rapid Response Team) who are trained, prepared, and committed to moving within 24 hours of contact to conduct epidemiological investigations when a new transboundary or emerging disease threat occurs. The investigation form and reporting instrument used by the Rapid Response Team to conduct a rapid response outbreak investigation are now available for download on the SHIC website (https://www.swinehealth.org/rrc-resources/, accessed March 24, 2021).

While the RRT members and other veterinarians are using the investigation form and reporting instrument to conduct outbreak investigations of endemic diseases (e.g., PRRS and PED), the pork industry has not adopted it as an industry-standard. Individual veterinarians continue to use a wide variety of approaches when conducting outbreak investigations.

A well designed industry-standard outbreak investigation instrument with input from industry experts would facilitate learning from outbreaks faster and increase the likelihood that useful information would be gained from every outbreak investigation to reduce the frequency of future outbreaks. All disease outbreaks in swine herds are the result of mistakes. While mistakes are opportunities to learn, learning is not guaranteed. Outbreak investigations are opportunities to discover the mistakes and learn from them over time; however, they have traditionally been done in an inconsistent and unsystematic manner. Rarely are they done comprehensively, investigating all areas where mistakes may be made. The value of an industry-standard outbreak investigation instrument derives from the collective experience of the industry to conduct comprehensive, systematic, and consistent outbreak investigations. In short, to learn from our collective mistakes.

To this end, SHIC funded a project to obtain input from an industry working group and develop an industry-standard investigation and reporting instrument to conduct epidemiological investigations of endemic and transboundary or emerging disease outbreaks. The aim of the working group was to create the industry-standard form and reporting instrument to; 1) assure that the most relevant information is being gathered, 2) enable the logging of data from the investigations in a database that can be analyzed quickly for associations and patterns, and 3) generate buy-in and increase the likelihood of adoption by the entire industry.

This white paper describes the components of the industry-standard outbreak investigation proposed by the industry working group. Input was also obtained from the AASV PRRS Task Force and Transboundary and Emerging Disease Committee. Following the August 4$^{th}$ meeting of the PRRS Task Force, the committee was asked to vote on the following statement: “The AASV PRRS Task Force has reviewed the proposed industry-standard outbreak investigation instrument developed by the SHIC-funded working

group of swine veterinarians with input from the Task Force. The Task Force recommends that the AASV Board of Directors approve the request from this committee to adopt (endorse) it as the standard for conducting disease (including PRRS) outbreak investigations." The result of the vote was Yes:19; No:0; No vote:4. The members of the PRRS Task Force now ask that AASV BOD endorse the industry-standard outbreak investigation instrument.

N*ote: Terms defined in the Terminology section are italicized throughout the white paper.*

## Working group

A veterinary peer group of 14 veterinarians was formed to gather input on the industry-standard outbreak investigation instrument. The investigation form and reporting instrument used by the Rapid Response Team was used as the basis or starting point for the industry-standard instrument.

### Members of the working group

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## Scope

The *industry-standard outbreak investigation* was developed for the breed-to-wean phase of production only. The approach described applies to all phases of production, but the list of *entry events* is different for each phase of production. The *industry-standard outbreak investigation* was developed to be pathogen non-specific, with some exceptions. The investigation period may vary according to the pathogen, and some minor modifications to the form may be required for some pathogens.

## Methodology

The *industry-standard outbreak investigation* is conducted as a *biosecurity hazard analysis*.

Hazard analysis applied to biosecurity on swine farms is a method of collecting and evaluating the information on *biosecurity hazards* associated with the introduction of pathogens into a susceptible herd.

The industry-standard outbreak investigation conducted as a *biosecurity hazard analysis* consists of a review of *production processes* connected with each *entry event*. A description of the circumstances, activities, and steps for the *production processes* connected to each entry event must include all

relevant details to assess *biosecurity hazards*. All of the relevant *pathogen-carrying agents* associated with each *production process* must be evaluated.

The relevant details include all of the following for all *production processes* connected with each entry event:

- People (who)
- Swine, equipment, tools supplies, other animals, etc. (what)
- Locations (where)
- Timing of activities (when)
- Procedures (how)

A *biosecurity hazard analysis* may be conducted prospectively or retrospectively. A *retrospective biosecurity hazard analysis* is done immediately after an outbreak caused by the introduction of a pathogen. Retrospective *biosecurity hazard analyses* are aided by the availability of epidemiological information that can be incorporated with the hazard analysis to conduct an *integrated biosecurity hazard analysis* and *epidemiological investigation*. The *industry-standard outbreak investigation* describes an integrated *biosecurity hazard analysis* and *epidemiological investigation*. A prospective *biosecurity hazard analysis* is done any time and is done strictly as a hazard analysis. It is intended that the *industry-standard outbreak investigation* may be used to conduct prospective hazard analyses.

A critical concept for identifying *biosecurity hazards* is the 3 *failures* (see Terminology). **This concept is foundational for the industry-standard outbreak investigation conducted as a biosecurity hazard analysis.** For a pathogen to be transmitted to a herd, 3 *failures* must occur. All 3 *failures* are necessary for transmission to occur. For each *entry event*, the *production processes*, and the p*athogen-carrying agents* associated with them, are investigated to identify the *biosecurity hazards* that may result in any of the 3 *failures*.

## Outbreak investigation interview

The outbreak investigation interview is conducted as an open-ended discussion. Minimum parameters for the industry-standard investigation are outlined below.

- Use the industry-standard investigation form
- Location: On the farm where the outbreak occurred.
- People present:
    - Farm manager
    - Herd veterinarian
    - Investigation facilitator
        - A third party that is relatively unfamiliar with the site where the outbreak occurred is recommended
        - A veterinarian is recommended but not required
        - The herd veterinarian  cannot also be the investigation facilitator
    - Assistant facilitator
        - Optional but highly recommended
        - Takes notes and helps draft the outbreak investigation report
    - Others

        - Optional

**The scope of the *industry-standard outbreak investigation* is limited to the *outbreak investigation interview*.** It is expected that other avenues of investigation (e.g., investigation or audits of feed mills, truck washes or additional interviews with other personnel) will be motivated by the outbreak investigation interview. The final outbreak investigation report should include information collected during the outbreak investigation interview and all subsequent investigations, audits and interviews.

## Form

A single form will be used to conduct the *industry-standard outbreak investigation* and report the results (Appendix C; separate document). The following is a description of the form.

- Organization
    - Section for each type of epidemiological information
    - Section for each *entry event*
        - Closed-ended questions for each *entry event* organized by *production processes*
- Closed-ended questions
    - Intended to guide the discussion of the *production processes* connected with each *entry event* to identify the *biosecurity hazards* that may result in any of the 3 *failures*
    - Will also serve as information that may be stored in an industry-wide outbreak investigation database

## Epidemiological information collected

The minimum set of epidemiological information for the *epidemiological investigation* collected prior to the outbreak investigation interview for the *industry-standard outbreak investigation* is listed below.

- Diagnostic reports with information used to confirm the etiology of the outbreak
- Name and address (and/or GPS coordinates) of the premises
    - Satellite image of the premises
    - When relevant, include other structures in satellite images (e.g., residence, feed mill, storage sheds, etc.)
- Names and contact information of farm manager and herd veterinarian
- Date and location where first clinical signs were recognized
- Database of swine premises within a 5-mile radius of the premises
    - Type and number of swine present (stages of production)
    - Pathogen status and genomic sequencing information if relevant
        - Sources of databases may include a production system database, veterinary clinic database and MSHMP (sow farms only for a defined geographic region)
    - Satellite image of 1, 3 and 5 mile radius around the premises
        - Identify roads and other swine related premises (e.g., markets, feed mills, truck washes, etc.)
- Database of swine premises within the production system or area disease control project with potential operational connections to the farm being investigated
    - Type of swine present (stages of production)

    - Pathogen status and genomic sequencing information if relevant
        - Sources of databases may include a production system database and veterinary clinic database
- Weather data for the nearest weather station during the investigation period
- Diagnostic results from testing boar studs, gilt development units, etc.
- Diagnostic results from environmental testing of any relevant sites or pathogen-carrying agent
- Dates or frequency of entry events that occurred during the investigation period
    - This information is reviewed during the *outbreak investigation interview* to establish that the final count of entry events that occurred during the *investigation period*
    - The frequency of entry events that occurred before the investigation period may be gathered as a baseline to compare the frequency of entry events that occurred during the investigation period.
    - It was suggested that information on entry events be collected for 30 days for all pathogens. The investigation period would determine the relevant entry events to investigate.
        - Standard data to collect

## Investigation period

In most cases, recognition of first clinical signs may be used as the endpoint of the investigation period. If diagnostic confirmation of the outbreak occurs before clinical signs are recognized, the date the diagnostic samples were collected may be used as the endpoint. For some outbreaks, such as those caused by PEDV in sow herds, the clinical signs are dramatic and are generally recognized quickly after the virus was first introduced. For others, such as PRRSV, clinical signs may not be recognized for weeks as the virus may spread slowly. The investigation period should depend on the pathogen. For the investigation of PRRS, we use a 28-day investigation window ending on the date clinical signs were first recognized. If clinical signs were not detected and the outbreak was detected with diagnostics, the 28 day investigation period from the date of diagnostic confirmation may be extended, depending on the circumstances. For PED outbreaks, we use a 10-day investigation period.

## Reporting

The investigation form also serves as the template for the report. Minimum reporting for the *industry-standard outbreak investigation* includes the following

- Responses to closed-ended questions in each section
- Frequency (and dates when relevant) of *entry events*
- For each *entry event*
    - Summary of *production processes* and significant *biosecurity hazards* for each entry event
        - Must include details (who, what, where, when and how)
    - Subjective rating of each event based on likelihood it was responsible for the outbreak
        - Significant *biosecurity hazards* for all 3 *failures* or;
        - Significant *biosecurity hazards* for 2 of 3 *failures* and uncertainty about likelihood of other *failure*

        - Consider including a measure of confidence in the rating
            - The confidence may be based on the epidemiological investigation. Some events may be rated high only because there was epidemiological evidence to link it to the outbreak
            - Develop a 2x2 table like those commonly used for subjective risk analyses
    - Biosecurity plan with control measures to address most significant biosecurity hazards
- Executive summary
    - Summary of *entry events* rated high
    - Significant epidemiological evidence and *biosecurity hazards* associated with each entry event rated high (i.e. justification for rating high)

The outbreak investigation report should include information collected during the outbreak investigation interview and all subsequent investigations, audits and interviews.

### Other issues

Requirements for completing investigations that can be included in the industry-wide outbreak investigation database

- Only entry events that occurred during the investigation period are evaluated. Information for closed-ended questions associated with *entry events* that did not occur is not entered.
    - Triage could be done to reduce the size of the form and time spent on the initial outbreak investigation
    - Start with survey of *entry events* that occurred during investigation period
    - Table in Appendix B may be used for survey

## Terminology

### Outbreak investigation

An integrated *hazard analysis* and *epidemiological investigation* of a clinical disease outbreak caused by the introduction of a pathogen. An outbreak investigation is done retrospectively immediately after the outbreak, with the objective of identifying significant biosecurity hazards, including those that may have led to the introduction of the pathogen. Identification and implementation of biosecurity control measures to address the most significant hazards is the expected outcome of an outbreak investigation. Equally important is what are NOT the objectives of the outbreak investigation. The objectives are not to identify the cause of the outbreak in every case or to assign blame for the outbreak to one or more individuals.

It is intended that the industry-standard outbreak investigation may be used to conduct prospective hazard analyses. A prospective hazard analysis may be done at any time and is done strictly as a hazard analysis. The objective of a prospective analysis is the same as that of an outbreak investigation, to identify significant biosecurity hazards.

## Pathogen-carrying agent**:**

Any agent that 1) can be infected or contaminated with a pathogen and 2) carry the pathogen from one herd to another.

Examples include pigs, people, livestock trailers, and semen. See Appendix A for a comprehensive list of pathogen-carrying agents that typically enter the perimeter buffer area of breeding herd (breed-to-wean) premises.

## Pathogen-carrying agent entry event (Entry event):

Occurs when one or more pathogen-carrying agent(s) enters the perimeter buffer area of the premises.

Examples include entry of semen, removal of culls, entry of employees, and entry of feed. See Appendix A for a comprehensive list of pathogen-carrying agents that typically enter the perimeter buffer area of premises (breed-to-wean).

## Biosecurity hazard:

A circumstance or action (or inaction) that is likely to result in a failure that may lead to the introduction of a pathogen into a susceptible herd

## Failures:

For a pathogen to be transmitted to a herd, 3 failures must occur. All 3 failures are necessary for transmission to occur. The 3 failures include

1. Failure to prevent *pathogen-carrying agent* from being contaminated or infected w/ infectious pathogen
    a. Typically occurs before the *entry event* but can occur in the perimeter buffer area of the swine premises
    b. This failure may occur at a swine farm and if the pathogen leaves the farm, it represents a biocontainment failure
2. Failure to mitigate the contamination or infection of the *pathogen-carrying agent*
    a. May occur before or after the *entry event*
3. Failure to prevent pig(s) in the herd from being infected with the pathogen from the *pathogen-carrying agent*
    a. Requires infection of one or more pigs in the herd via an appropriate route of entry to an infectious dose of pathogen from *pathogen-carrying agent*
    b. Occurs after the *entry event*
    c. For pathogen-carrying agents that cross the line of separation, failure may result from direct contact of pigs in the herd with pathogen carrying agent.
    d. For pathogen-carrying agents that do not cross the line of separation, failure may result from cross contamination of secondary pathogen-carrying agents (e.g. people, rodents, insects or air) that do cross the line of separation.

## Biosecurity hazard analysis

A biosecurity hazard analysis is used to determine the biosecurity hazards in the production process.

## Epidemiological investigation

Analysis of available epidemiological information to assess possible sources of the pathogen, and the potential role of specific entry events, pathogen carrying agents, and production processes in the transmission of the pathogen to the herd.

## Production process:

The processes related to the production of pigs. They include all of the circumstances, activities, and steps associated with each entry event.

## Investigation period

The investigation period includes the date of the introduction of the pathogen. Entry events that occurred during the investigation period are the subject of the investigation.

## Biosecurity control measure

Any change in a production process that can prevent, eliminate or reduce a significant hazard. Bio-security practices commonly found in publications offering advice on biosecurity don't address all of the potential hazards.

## Terminology from the Secure Pork Supply Plans that will be used for the industry-standard outbreak investigation instrument

### Perimeter Buffer Area (PBA):

The site has a PBA(s), which is established to serve as an outer control boundary around the buildings to limit movement of virus near animal housing. The PBA is established so that individuals can perform duties within the PBA during the course of their daily tasks and so that routine deliveries occur outside of the PBA as much as possible. The PBA is clearly defined in the biosecurity plan and is clearly marked around animal buildings on the premises.

### Line of Separation (LOS)

The site has one or more LOS, which is established as a control boundary to prevent movement of virus into areas where susceptible animals can be exposed. In many situations, the walls of the building housing the animals form the LOS. The LOS is clearly defined in the biosecurity plan and is clearly marked on the premises. Animals, people, or items only cross the LOS through clearly marked and controlled LOS Access Points(s), following appropriate biosecurity measures. Areas contaminated after loading/unloading animals are cleaned and disinfected according to the biosecurity plan.

## Appendix A. Comprehensive list of entry events and pathogen carrying agents that typically enter the perimeter buffer area of swine breeding herds (breed-to-wean).

**Semen delivered to premises**

- Semen
- Semen delivery driver
- Semen delivery vehicle
- Semen packaging and container(s)

**Replacements delivered to premises**

- Cab of gilt truck
- Gilt
- Gilt truck driver
- Gilt truck/trailer, animal compartment
- Gilt truck/trailer, non-animal compartment
- Sort boards and other devices to move gilts

**Cull sows hauled from premises**

- Cab of cull sow truck
- Cull sow
- Cull sow truck driver
- Cull sow truck/trailer, animal compartment
- Cull sow truck/trailer, non-animal compartment
- Sort boards and other devices to move cull sows

**Weaned pigs hauled from premises**

- Cab of weaned pig truck
- Weaned pig truck driver
- Weaned pig truck/trailer, animal compartment
- Weaned pig truck/trailer, non-animal compartment
- Weaned pigs
- Sort boards and other devices to move weaned pigs

**Dead pigs removed from premises**

- Dead pigs
- Rendering truck and dead pigs from other premisess
- Rendering truck driver

**Feed delivered to premises**

- Feed
- Feed truck
- Feed truck driver
- Tools and equipment used by feed truck driver

**Propane and fuel delivered to premises**

- Fuel truck
- Fuel truck driver

**Garbage removed from premises**

- Garbage truck

Garbage truck driver

**New tools and supplies delivered to premises**

New tools and supplies
New tools and supplies delivery vechicle
New tools and supplies delivery vehicle driver

**Transferred tools and supplies delivered to premises**

Transferred tools and supplies
Transferred tools and supplies delivery vechicle
Transferred tools and supplies delivery vehicle driver

**On-farm employee enters premises**

On-farm employee
On-farm employee personal items
On-farm employee vehicle

**Inside equipment repair service person works on premises**

Inside equipment repair tools and supplies
Inside equipment repair vehicle
Inside equipment repairmen

**Outside equipment repair service person works on premises**

Outside equipment repair tools and supplies
Outside equipment repair vehicle
Outside equipment repairmen

**Veterinarian, vendors/visitors and off-farm production personnel enters premises**

Veterinarian personal items
Veterinarian
Veterinarian vehicle
Veterinary tools and supplies

**Pork and other food product enters premises**

Cooked or processed pork meat
Food containers and utensils
Other food
Uncooked pork meat

**Manure removal equipment enters premises**

Manure
Manure removal equipment away from barns
Manure removal equipment in pit or next to barns
Manure removal personnel
Manure removal vehicles

**Entry of other animals and birds (inside and outside of barns)**

Feral swine
Rodents
Non-swine domestic animals (cats, dogs, horses, cattle, etc.)
Non-swine wild animals (raccoons, opossum, coyotes, etc.)
Non-migratory birds
Migratory birds

**Entry of insects**

Insects

**Air and water enters premises**

Air

Water

## Apppendix B. List of Entry events and production processes connected with each event.

| Entry event | Production process | Significant biosecurity hazards for failure 1 | Significant biosecurity hazards for failure 2 | Significant biosecurity hazards for failure 3 |
|---|---|---|---|---|
| Entry of semen | | | | |
| | Production and packaging of semen | | | |
| | Transport of semen | | | |
| | Entry of semen through LOS access point | | | |
| | Use of semen | | | |
| Entry of breeding replacements | | | | |
| | Production, development, acclimation, and isolation of replacements | | | |
| | Transport of replacements | | | |
| | Unloading of replacements through LOS access point | | | |
| | Housing of replacements | | | |
| Removal of weaned pigs | | | | |
| | Loading of weaned pigs through LOS access point | | | |
| | Transport of weaned pigs | | | |
| | Unloading of pigs at destinations | | | |
| Removal of culls | | | | |

| | |
|---|---|
| | Loading of culls through LOS access point |
| | Transport of culls |
| | Unloading of culls at destinations |
| Dead pigs removed from premises | |
| | Removal of deads from barns |
| | Movement of pigs to rendering pick up or on-site disposal |
| | Transport of dead pigs to rendering |
| | Management of on-site disposal |
| Feed delivered to premises | |
| | Procurement of raw ingredients |
| | Manufacturing of feed |
| | Transport of feed to farm |
| | Unloading of feed |
| Propane and fuel delivered to premises | |
| | Transport of propane and fuel to farm |
| | Unloading of propane and fuel |
| New tools and supplies delivered to premises | |

| | |
|---|---|
| | Procurement of new tools and supplies |
| | Warehousing of new tools and supplies |
| | Transport of new tools and supplies to farm |
| | Unloading of new tools and supplies at farm |
| | Storage and use of tools and supplies on farm |
| Transferred tools and supplies delivered to premises | |
| | Procurement of transferred tools and supplies |
| | Warehousing of transferred tools and supplies |
| | Transport of transferred tools and supplies to farm |
| | Unloading of transferred tools and supplies at farm |
| | Storage and use of tools and supplies on farm |
| On-farm employee enters premises | |
| | Employee and vehicle activity while away from farm |
| | Transport of employee to farm |
| | Parking of employee vehicle on farm |

| | | |
|---|---|---|
| | Entry of employee through LOS access point | |
| | Employee activity on farm | |
| Inside (barns) equipment repair service person works on premises | | |
| | Service person and vehicle activity while away from farm | |
| | Transport to farm | |
| | Parking of service vehicle on farm | |
| | Entry of service person, tools and supplies through LOS access point | |
| | Service person activity on farm | |
| Outside (barns) equipment repair service person works on premises | | |
| | Service person and vehicle activity while away from farm | |
| | Transport to farm | |
| | Parking of service vehicle on farm | |
| | Entry of service person, tools and supplies through LOS access point | |
| | Service person activity on farm | |

| | |
|---|---|
| Veterinarian, vendors/visitors and off-farm production personnel enters premises | |
| | Personnel and vehicle activity while away from farm |
| | Transport to farm |
| | Parking of vehicle on farm |
| | Entry of personnel through LOS access point |
| | Personnel activity on farm |
| Pork and other food product enters premises | |
| | Procurement and preparation prior to entry |
| | Transport to farm |
| | Entry of food through LOS access point |
| | Storage and consumption on farm |
| Manure removal equipment enters premises | |
| | Manure removal personnel, vehicle and equipment activity while away from farm |
| | Transport to farm |
| | Parking of vehicles and equipment on farm |

| | |
|---|---|
| | Manure removal activity on farm |
| Entry of other animals and birds (inside and outside of barns) | |
| | Source and movement of insects |
| | Control of insects |
| Entry of insects | |
| | Source and movement of other animals and birds |
| | Control of other animals and birds |
| Air and water enters premises | |
| | Source and movement of water |
| | Movement of air |
| | Treatment of air and water |