

**STANDARD OPERATING PROCEDURES:
2B. CASE DEFINITION
DEVELOPMENT PROCESS**

FAD PReP

**Foreign Animal Disease
Preparedness & Response Plan**



**United States
Department of
Agriculture**

United States Department of Agriculture • Animal and Plant Health Inspection Service • Veterinary Services

File name: Generic_FAD_PReP_Case_Definitions	SOP number: 0002
Lead section: Preparedness and Incident Coordination	Version number: 3.0
Effective date: January 2014	Review date: January 2017

The Foreign Animal Disease Preparedness and Response Plan (FAD PReP) Standard Operating Procedures (SOPs) provide operational guidance for responding to an animal health emergency in the United States.

These draft SOPs are under ongoing review. This document was last updated in **January 2014**. Please send questions or comments to:

National Preparedness and Incident Coordination
Veterinary Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
4700 River Road, Unit 41
Riverdale, Maryland 20737-1231
Telephone: (301) 851-3595 Fax: (301) 734-7817
E-mail: FAD.PReP.Comments@aphis.usda.gov

While best efforts have been used in developing and preparing the FAD PReP SOPs, the U.S. Government, U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service and other parties, such as employees and contractors contributing to this document, neither warrant nor assume any legal liability or responsibility for the accuracy, completeness, or usefulness of any information or procedure disclosed. The primary purpose of these FAD PReP SOPs is to provide operational guidance to those government officials responding to a foreign animal disease outbreak. It is only posted for public access as a reference.

The FAD PReP SOPs may refer to links to various other Federal and State agencies and private organizations. These links are maintained solely for the user's information and convenience. If you link to such site, please be aware that you are then subject to the policies of that site. In addition, please note that USDA does not control and cannot guarantee the relevance, timeliness, or accuracy of these outside materials. Further, the inclusion of links or pointers to particular items in hypertext is not intended to reflect their importance, nor is it intended to constitute approval or endorsement of any views expressed, or products or services offered, on these outside websites, or the organizations sponsoring the websites.

Trade names are used solely for the purpose of providing specific information. Mention of a trade name does not constitute a guarantee or warranty of the product by USDA or an endorsement over other products not mentioned.

USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, sex, religion, age, disability, political beliefs, sexual orientation, or marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and telecommunications device for the deaf [TDD]).

To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 1400 Independence Avenue SW, Washington, DC 20250-9410 or call (202) 720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.



FAD PreP
 Foreign Animal Disease
 Preparedness and Response Plan

Contents

- 2.1 Introduction 2-1
- 2.2 Goals... 2-1
 - 2.2.1 Preparedness Goal..... 2-1
 - 2.2.2 Response Goal 2-1
- 2.3 Purpose..... 2-1
- 2.4 Responsibilities 2-1
 - 2.4.1 CEAH..... 2-1
 - 2.4.2 SPRS National Preparedness and Incident Coordination (NPIC) 2-1
 - 2.4.3 VS Units and Stakeholders..... 2-1
 - 2.4.4 VS Deputy Administrator (VSDA) and VS Executive Team (VSET)..... 2-2
- 2.5 Development of Case Definitions (Animal Disease Case Definitions to Standardize Disease Reporting) 2-2
- Attachment 2.A Standard Template for Case Definitions..... 2-3
- Attachment 2.B Process Flowchart for Developing Case Definitions..... 2-4
- Attachment 2.C Abbreviations 2-6

2.1 Introduction

The Center for Epidemiology and Animal Health (CEAH) in Science, Technology, and Analysis Services (STAS), in cooperation and coordination with the Surveillance, Preparedness, and Response Services (SPRS), develops animal disease case definitions for animal health surveillance and reporting.

Case definitions enhance the usefulness of animal disease data by establishing uniform criteria for reporting purposes. Currently, CEAH is developing case definitions for World Organization for Animal Health (OIE)–listed diseases (<https://oie.int>) and other diseases of interest.

2.2 Goals

2.2.1 Preparedness Goal

The preparedness goal for case definition development is that CEAH, in conjunction with SPRS, will provide case definitions for foreign animal diseases to local, State, Tribal, Federal, and agricultural stakeholders prior to an incident.

2.2.2 Response Goal

The response goal for case definition development is to update case definitions at regular intervals, or update them as needed during incidents or outbreaks.

2.3 Purpose

The purpose of this SOP is to inform stakeholders regarding the development and approval of case definitions.

2.4 Responsibilities

2.4.1 CEAH

- Develops case definitions.
- Coordinates case definition development with VS, State Animal Health Officials (SAHOs), and appropriate stakeholders.
- Reviews and incorporates input from stakeholders into case definitions.
- Disseminates approved case definitions to stakeholders.
- Maintains the case definition library.

2.4.2 SPRS National Preparedness and Incident Coordination (NPIC)

Assists the CEAH in developing and reviewing case definitions.

2.4.3 VS Units and Stakeholders

Review draft case definitions and provide input to the CEAH.

2.4.4 VS Deputy Administrator (VSDA) and VS Executive Team (VSET)

Approve case definitions.

2.5 Development of Case Definitions (Animal Disease Case Definitions to Standardize Disease Reporting)

Case definitions have four purposes:

1. Surveillance planning and implementation
2. Disease outbreak response
3. National Animal Health Reporting System reporting standards
4. National reportable animal disease list development

CEAH has developed a standardized format ([Attachment 2.A](#)) that includes all the information needed to ensure that the case definitions meet these four purposes. The standardized format includes sections on general disease and pathogen information, laboratory criteria describing specific tests recommended by the OIE and the National Veterinary Services Laboratories, reporting criteria, control and surveillance procedures, and the classification of cases. The case definition section includes suspect, presumptive positive, and confirmed positive as the case classifications, which represent increasing levels of certainty of the disease or agent presence. Using a standardized document and review process will enable the case definitions under development to be useful for multiple purposes and will allow all stakeholders to comment and suggest revisions. The approved case definitions will be scientifically valid, widely accepted documents that aid in uniform surveillance and reporting of animal disease events.

Developing national, standardized case definitions requires collaboration among many partners. The goal is to allow all stakeholders (VS, SAHOs, and industry commodity groups) to comment on the case definitions as they are being developed or reviewed. To help ensure stakeholder input, CEAH created a case definition development and review process ([Attachment 2.B](#)).

To start, CEAH drafts a case definition, which is sent to subject matter experts (SMEs) and industry representatives for review and comment. CEAH reviews the comments for validity, incorporates those accepted, and updates the case definition. Next, CEAH contacts appropriate VS units to review and comment on the developed case definition. Once VS input is incorporated, SAHOs can review and comment on the case definition. The VSDA and VSET give final approval to the case definition. CEAH reviews approved case definitions periodically. CEAH, in coordination with NPIC and stakeholder input, can also modify approved case definitions during animal health emergencies, emerging animal disease situations, or changes in laboratory testing capabilities.

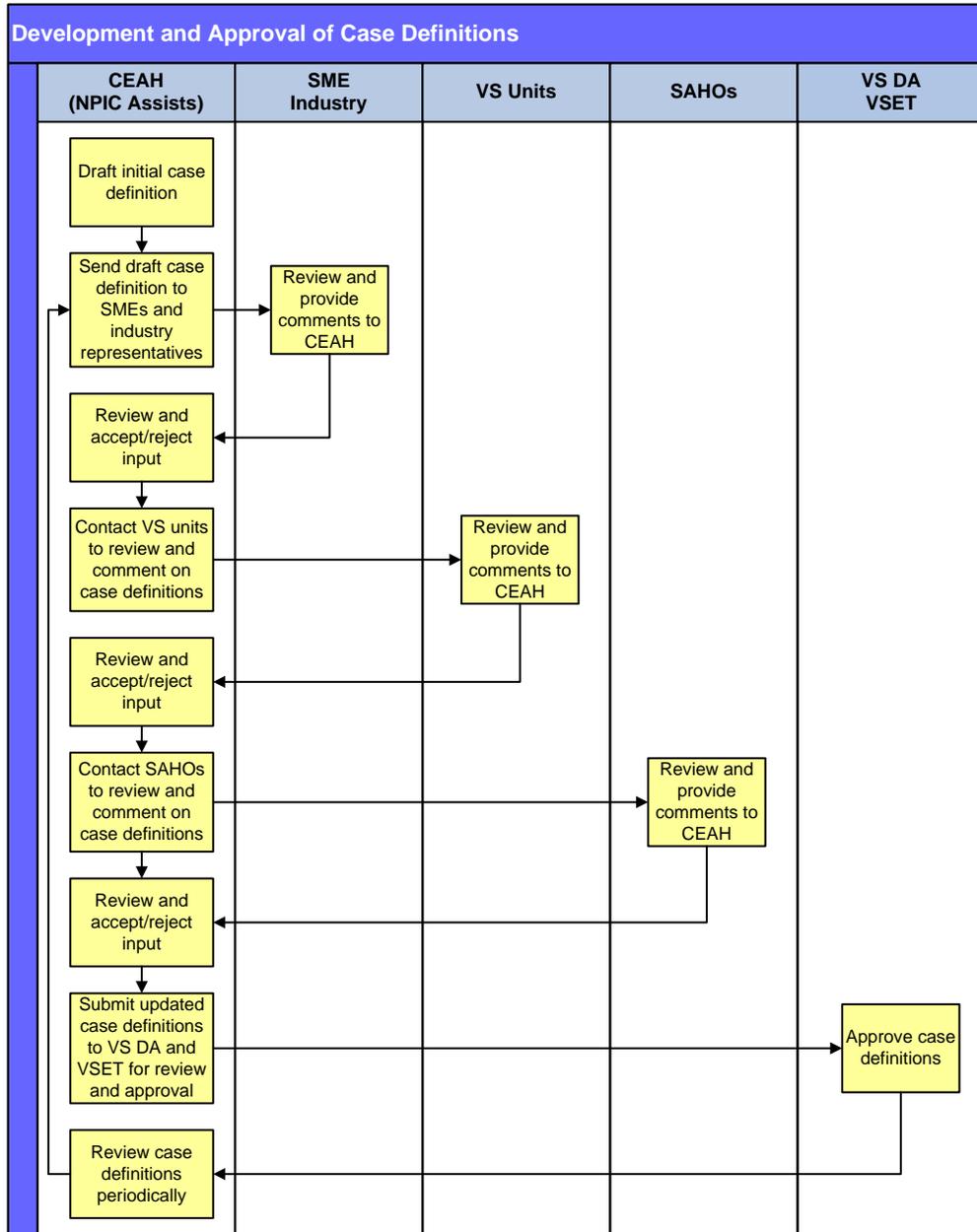
Attachment 2.A Standard Template for Case Definitions

1. General Disease and Pathogen Information
 - 1.1 Etiologic Agent
 - 1.2 Distribution
 - 1.3 Clinical Signs
 - 1.4 Incubation Period
 - 1.5 Differential Diagnosis
 - 1.6 Transmission and Reservoir
 - 1.7 Epidemiology
2. Laboratory Criteria
3. Case Definition
 - 3.1 Suspect Case
 - 3.2 Presumptive Positive Case
 - 3.3 Confirmed Positive Case
4. Reporting Criteria
5. Control and Surveillance Procedures

Attachment 2.B Process Flowchart for Developing Case Definitions

Table 2.B-1 depicts the development and approval process for case definitions.

Table 2.B-1. Process for Case Definition Development and Approval



Attachment 2.C Abbreviations

CEAH	Center for Epidemiology and Animal Health
FAD PReP	Foreign Animal Disease Preparedness and Response Plan
NPIC	National Preparedness and Incident Coordination
OIE	World Organization for Animal Health
SAHO	State Animal Health Official
SME	subject matter expert
SOP	standard operating procedure
SPRS	Surveillance, Preparedness, and Response Services
STAS	Science, Technology, and Analysis Services
USDA	U.S. Department of Agriculture
VS	Veterinary Services
VS DA	Veterinary Services Deputy Administrator
VSET	Veterinary Services Executive Team