Prepared in cooperation with the Canadian Wildlife Health Cooperative

[Disease/Condition] Case Definition [Template] for Wildlife

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Acknowledgments

[Insert text here indicating acknowledgements. Example: The U.S. Geological Survey National Wildlife Health Center and Canadian Wildlife Health Cooperative Case Definition Joint Working Group would like to thank the staff and pathologists in both organizations, as well as our students and colleagues, for the generous contribution of their collective knowledge, expertise, and time in creating this case definition template.]

[Supplemental Information]

[**Instructions for use**: Follow the instructions outlined in this template. Instructions are provided in square brackets [ ]. All text in square brackets [ ] and the examples should be deleted once the definition is drafted. If a section does not apply to a specific case definition, indicate “not applicable.” Insert in-text citations where appropriate.]

Abbreviations

[Insert abbreviations used in the report here. Separate an abbreviation from its definition using a tab. Examples:

CFIA Canadian Food Inspection Agency

CWHC Canadian Wildlife Health Cooperative

NWHC National Wildlife Health Center

ppm part per million

USDA U.S. Department of Agriculture

USGS U.S. Geological Survey]

Introduction

Diagnostic laboratories receive carcasses and samples for diagnostic evaluation and pathogen/toxin detection. The intent of a case definition is to provide scientifically based criteria for determining (1) if an individual carcass has a specific disease and the confidence of that diagnosis; and (2) if a pathogen or toxin is evident in a carcass or sample (for example, swab, tissue sample, skin scraping, blood/serum sample, environmental sample, or other). Using these criteria, cases diagnosed with a specific disease (diagnosing disease) will be classified as “confirmed,” “presumptive,” or “suspected;” and evidence of a pathogen or toxin (detecting pathogen/toxin) will be classified as “exposed” or “present/detected.” Classification is based on a combination of factors: individual, place, time, history, clinical signs, diagnostic observations, and (or) diagnostic test results. Case definitions can bring clarity and consistency to the evaluation process. Their use within and between organizations allows more uniform reporting of diseases and etiologic agents.

Case definitions are proposed for use in wildlife diagnostic laboratories and are not intended to replace regulatory standards provided by Government reporting agencies. Ideally, case definitions would be updated periodically as new information becomes available and new test methods are developed. Refer to the glossary for terminology definitions.

*Disease/condition*.—[Insert disease common name (specifying taxa if it applies to a specific group). Example: Avian salmonellosis.]

*Pathogen/toxin etiologic agent(s)*.—[Insert text here.]

Scope of the Case Definition

This case definition applies to [insert text here indicating to what species, when and (or) where this protocol applies; for example, animal class, sex, age group, location, season, antemortem or post-mortem sample collection, specifics regarding the disease agent, environmental samples, and so on. Example: This case definition applies to amphibians in the orders Anura (frogs and toads) and Caudata (salamanders) in all life stages.]

Case Definition Criteria

The case definition criteria are a concise summary of the current science regarding the clinical signs, history, gross and microscopic observations, and laboratory test results associated with a specific disease or pathogen. Various combinations of the criteria result in different case classifications representing the degree of certainty of the diagnosis.

Individual, Place, and Time Criteria for Diagnosis and Testing

*Individual*.—[Insert text here indicating common age groups, species, or other characteristics that increase disease or pathogen/toxin suspicion.]

*Place*.—[Insert text here indicating locations and other geographic features that increase disease or pathogen/toxin suspicion.]

*Time*.—[Insert text here indicating season, months, or other temporal factors that increase disease or pathogen/toxin suspicion.]

Field Criteria for Diagnosis

*History and clinical signs*.—Diagnostically compatible illness may present with [insert text here detailing field observations or clinical signs in live animals/populations that are diagnostically compatible with disease. This may include photographic/video evidence, if appropriate.]

*Other*.—[Insert text here detailing additional pertinent comments about presentation; for example, potential for carrier status.]

Laboratory Criteria for Diagnosis

[Insert text below detailing the gross, microscopic, molecular, analytical, or other laboratory test criteria used to determine the presence of a pathogen or toxin and evidence of a specific disease. Laboratory criteria are categorized as: “laboratory confirmed,” “laboratory supported,” “exposed,” or “present/detected.” Where possible, references to the current accepted science for a disease are provided in the case definition. For some select new or emerging diseases, the laboratory criteria for diagnosis may be based on the collective expertise of pathologists at the U.S. Geological Survey National Wildlife Health Center and the Canadian Wildlife Health Cooperative or other institutions. All categories will not necessarily be used for every case definition.]

*Gross examination*.—Diagnostically compatible findings may include [insert text here detailing gross necropsy observations in a carcass or sample that are diagnostically compatible with disease.]

*Histopathology*.—Histopathological findings may include [insert text here detailing general histopathology observations in a carcass or sample that are diagnostically compatible with disease.]

*Diagnostic test(s)*.—[Insert text here detailing laboratory tests typically used to determine this diagnosis or detect the pathogen/toxin; for example, bacterial culture.]

Laboratory Criteria Categorization

*Laboratory confirmed*.—[Insert text here detailing the combination of laboratory criteria that is considered most definitive for a particular disease. Example: Positive bacterial isolation for *Salmonella* sp. and compatible gross and (or) histopathological lesions.]

*Laboratory supportive*.—[Insert text here detailing the combination of laboratory criteria that is considered less definitive for a particular disease. Example: Gross and (or) histopathological lesions compatible with salmonellosis without a positive *Salmonella* sp. culture (either culture not done or culture results negative).]

*Exposed*.—[Insert text here detailing the laboratory criteria for detection of a toxin in the absence of known lethal thresholds, or within the range between recognized “background” concentrations and lethal thresholds. Also applies to serological evidence of infection in the absence of other evidence of disease. Example: No gross or histopathological lesions compatible with lead poisoning with lead concentrations above background concentrations but below poisoning threshold concentrations for that species.]

*Present/detected*.—[Insert text here. This classification is often used when tracking a known or suspected asymptomatic carrier state or documenting a pathogen/toxin of interest. Laboratory detection of a potentially pathogenic agent or evidence of a pathogen/toxin without knowledge of disease status. Example: No gross or histopathological lesions compatible with salmonellosis but has a positive *Salmonella* sp. culture result from the intestinal tract.]

Supplemental Diagnostic Information

*Additional diagnostic comments*.—[Insert text here detailing any additional diagnostic notes pertinent to recording/reporting, for example, requests for strain/serovar/variant reporting, or inconclusive/ambiguous results.]

*Notifiable/reportable disease*.—[Insert text here detailing if this is considered a reportable disease at the State, Provincial and (or) Federal level in (insert Canada, Canada and the United States, or the United States). Please check and report to the appropriate agricultural and (or) public health authorities as needed.]

Epidemiologic Linkage Criteria for Diagnosis

[Insert text here providing a description of the epidemiologic linkages that are pertinent for this disease, including comments on geographic scales or time periods that link to other cases that meet the criteria described in the previous “Case Definition Criteria” sections. Any additional information that might guide determination of epidemiologic linkages; for example, serovar or genetic information might be used to establish linkages during migration season for birds when geographic clustering might be less reliable.]

An epidemiologic linkage can be established by close geographic and temporal proximity (in other words, part of the same mortality event) as one or more confirmed cases of [insert disease name here] or at a site with a recent history of confirmed [insert disease name here] with similar presentation as described in the previous “Case Definition Criteria” sections.

Case Classification

The sum of the criteria listed in the “Case Definition Criteria” sections (individual, place, time, field, laboratory, and epidemiologic linkage criteria) associated with a particular disease or pathogen/toxin in an individual animal or specimen add up to a case classification (fig. 1).



**Figure 1.** Case definition criteria add up to the case classifications.

Depending on the confidence in the results, cases of a specific disease will be classified as “confirmed,” “presumptive,” or “suspected;” and evidence of a pathogen or toxin will be classified as “exposed” or “present/detected” (table 1; refer to glossary for definitions). A specific case classification may have more than one pathway to it. Not all classifications may be used for every disease. Although an epidemiological linkage may be present in all classifications, the “suspected” case classification requires compatible epidemiological linkage criteria are met. Individual disease and pathogen specific details are presented in table 2.

*Note*.—The field and laboratory criteria in table 2 reflect the typical presentation of this disease. The exact presentation in an individual animal or specimen may vary from what is presented in table 2 but still conforms with the information presented in the “Field Criteria for Diagnosis” and “Laboratory Criteria for Diagnosis” sections.

**Table 1.** Case classification chart template.

[This basic classification table should be removed from the individual case definitions. A more detailed version (refer to table 2) should be filled in for each case definition and renumbered to table 1; ensure citations to tables are updated as well]

| Individual, place, and time criteria | Field criteria (if available) | Laboratory criteria | Epidemiological linkage criteria | Classification |
| --- | --- | --- | --- | --- |
| **Diagnosing disease** |
| Compatible | Compatible | Meets laboratory confirmed criteria | May be compatible but not required | Confirmed |
| Compatible | Compatible | Meets laboratory supportive criteria | May be compatible but not required | Presumptive |
| Compatible | Compatible | Some information but not enough to meet laboratory supportive criteria | Must be compatible; is required | Suspected |
| **Detecting pathogen/toxin** |
| Compatible | Not applicable | Meets exposed criteria | May be compatible but not required | Exposed |
| Compatible | Not applicable | Meets present/detected criteria | May be compatible but not required | Present/detected |

**Table 2** Case classification chart for [insert text for disease and pathogen/toxin name as applicable].

[Fill this table in with the correct information for the case definition. Note: If case classifications are not used, remove the rows from the table and insert text here that the classifications are not applicable to this case definition.]

| Individual, place, and time criteria | Field criteria (if available) | Laboratory criteria | Epidemiological linkage criteria | Classification |
| --- | --- | --- | --- | --- |
| **Diagnosing disease [Insert text: disease name]** |
| [Insert key information] | [Insert key information] | Meets laboratory confirmed criteria:*Gross examination*.—[Insert text using **and, or, and (or)**]*Histopathology*.—[Insert text using **and, or, and (or**)]*Diagnostic test(s)*.—[Insert text here] | Optional: [Insert key information] | Confirmed |
| [Insert key information] | [Insert key information] | Meets laboratory supportive criteria:*Gross examination*.—[Insert text using **and, or, and (or)**]*Histopathology*.—[Insert text using **and, or, and (or)**]*Diagnostic test(s)*.—[Insert text here] | Optional: [Insert key information] | Presumptive |
| [Insert key information] | [Insert key information] | Some information but not enough to meet laboratory supportive criteria:*Gross examination*.—[Insert text using **and, or, and (or)**]*Histopathology*.—[Insert text using **and, or, and (or)**]*Diagnostic test(s)*.—[Insert text here] | Required: [Insert key information] | Suspected |
| **Detecting pathogen/toxin [Insert text: pathogen/toxin name]** |
| [Insert key information] | Not applicable | Meets exposed criteria:*Gross examination*.—[Insert text using **and, or, and (or)**]*Histopathology*.—[Insert text using **and, or, and (or)**]*Diagnostic test(s)*.—[Insert text here] | Optional: [Insert key information] | Exposed |
| [Insert key information] | Not applicable | Meets present/detected criteria:*Gross examination*.—[Insert text using **and, or, and (or)**]*Histopathology*.—[Insert text using **and, or, and (or)]***Diagnostic test(s)*.—[Insert text here] | Optional: [Insert key information] | Present/detected |

Quality-Assurance Review Schedule

The [insert text here of drafting organization name(s); for example, Canadian Wildlife Health Cooperative and the U.S. Geological Survey National Wildlife Health Center] staff plan to review this case definition periodically to incorporate new scientific information and test methods as needed.

*Planned date for next review*.—[Insert date month day, year here.]

*Review schedule*.—[Version 1 should be reviewed 1 year after publication; and subsequent versions should be reviewed and updated as needed 3–5 years after publication of each version or sooner if science about the disease/condition changes substantially.]

Impact

Applying case definitions in diagnostic, surveillance, and research efforts can help standardize data, making it easier to understand and analyze within and between diagnosticians and laboratories. Laboratories are encouraged to store the case classification assigned to each specimen or sample in their data system so that it can be readily and reliably retrievable.

References Cited

[Insert references used for construction of the case definition, including case definitions for this disease used by other entities, scientific literature, agency websites, or book chapters. For guidance formatting references and in-text citations in the report, refer to Suggestions to Authors of the Reports of the U.S. Geological Survey (7th ed.; STA7, p. 234–241, available at https://doi.org/10.3133/7000088) and, for online sources, Science Publising Network Publishing Standards Memorandum 2014.03 (available at https://www.usgs.gov/media/files/usgs-publishing-standards-memorandum-no-201403)—or use your agency/organization’s reference format. A few example references are provided in this section.]

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Glossary

**[additional diagnostic term]** [Definition of term; use a tab stop to separate term from definition.]

**additional diagnostic comments** Any additional diagnostic notes pertinent to recording/reporting (for example, requests for strain/serovar/variant reporting, inconclusive/ambiguous results, or “not applicable”).

**case classification** The sum of the factors in the “Case Definition Criteria” sections of the case definition including individual (for example, species, age group), place, time, history, clinical signs, diagnostic observations, and (or) diagnostic test results, associated with a particular disease or pathogen/toxin in an individual animal or specimen. Depending on the confidence in the results, cases of a specific disease will be classified as “confirmed,” “presumptive,” or “suspected;” and a pathogen or toxin will be classified as “exposed” or “present/detected.”

**case definition** A consistently applied, scientifically based and clearly defined set of field, gross, histopathology, laboratory, or epidemiologic criteria used to classify an individual animal or sample to a specific disease or pathogen/toxin for surveillance or outbreak reporting purposes (based on the combination of the criteria and confidence in the results).

**confirmed case** The combination of individual (for example, species, age group), place, time, history, clinical signs, and laboratory criteria for diagnosis with the highest level of certainty for accepted diagnostic testing as stated in the case definition. Example: Cardinal with clinical signs, gross and microscopic lesions compatible with salmonellosis, and positive bacterial culture for *Salmonella enterica enterica* in the liver.

**diagnostic test(s)** Laboratory tests typically used to determine this diagnosis or detect the pathogen/toxin; for example, bacterial culture.

**diagnostically compatible** An animal that meets the individual (for example, species, age group), place, time, field, and laboratory criteria for a particular disease as stated in the case definition.

**disease** Any disorder of structure or function that may produce specific clinical signs; disease can be infectious or noninfectious.

**disease agent** Any pathogen, toxin, or other known cause of disease.

epidemiologically linked A case that has temporal, geographic, or other relevant linkages to one or more confirmed cases as described under “Epidemiologic Linkage Criteria for Diagnosis” in the case definition.

**exposed** Detection of a toxin in tissues or body fluids at a concentration above acceptable background levels but below the documented lethal threshold level for the species. This may apply to a toxin detected in the absence of documented lethal threshold levels. This category can also include serological evidence of infection in the absence of other information such as organism detection or disease diagnosis.

**gross examination** Gross necropsy observations in a carcass or sample that are diagnostically compatible with disease.

histopathology General microscopic observations in a carcass or sample that are diagnostically compatible with disease.

**history and clinical signs** Field observations and changes to behavior, appearance, or abilities in live animals/populations that are diagnostically compatible with disease. Photograph or video evidence may be used when appropriate.

**individual** The common age groups, species, or other characteristics that increase disease or pathogen/toxin suspicion.

**laboratory confirmed** The strongest degree of assurance in identification of a disease agent of interest and evidence of the associated disease based on one or more accepted laboratory methods. A test or combination of methods that has been scientifically accepted as definitive for a particular disease agent and the associated disease. Example: Positive bacterial isolation for salmonella plus compatible gross and histologic lesions for salmonellosis.

**laboratory criteria for diagnosis** The gross, microscopic, molecular, culture, analytical or other laboratory test criteria used to determine the presence of a specific disease agent and evidence of the disease itself. These are categorized based on the validity and performance of the test(s). Categories are “laboratory confirmed,” “laboratory supportive,” “exposed,” and “present/detected.” Where possible, references for the current accepted science for a given disease and pathogen are provided in the case definition. For some select new or emerging diseases the laboratory criteria may be based on the collective expertise of pathologists at the U.S. Geological Survey National Wildlife Health Center and the Canadian Wildlife Disease Cooperative or other institutions.

**laboratory supportive** Laboratory results that are less than definitive for a specific disease agent and the associated disease. A test or combination or methods whose results support the diagnosis or a particular disease but are not considered definitive; for example, a screening test. Test result interpretation may be based on the tissue tested (for example, culture of amphibian skin surface versus internal tissue) or postmortem condition of the sample. Example: Gross and histologic lesions compatible with salmonellosis (without laboratory testing).

notifiable/reportable disease A disease or pathogen that by law must be disclosed to State, Provincial, and (or) Federal agricultural or public health authorities.

**other (field criteria)** Additional pertinent comments about presentation (for example, potential for carrier status).

**place** Locations and other geographic features that increase disease or pathogen/toxin suspicion.

**present/detected** Laboratory detection of a potentially pathogenic agent in the absence of findings diagnostically compatible with the associated disease. Often used when tracking a known or suspected asymptomatic carrier state (for example, *Salmonella* or duck virus enteritis) or when documenting detection of an agent that is of increased diagnostic or epidemiologic interest, even in the absence of evidence of illness (for example, new or emerging disease or syndrome).

**presumptive case** The combination of individual (for example, species, age group), place, time, history, clinical signs and laboratory criteria for diagnosis that has a moderate degree of certainty as stated in the case definition. This uncertainty may be due to the test performed, postmortem decomposition of the carcass affecting observation or interpretation of gross and or histopathologic lesions, inadequate sample for testing due to scavenging or carcass size, inconclusive test results, or lack of a definitive diagnostic test. Enough information is available to conclude the disease is most likely present but not enough information available to conclude the disease is definitively present. Example: Raccoon with compatible histologic lesions for parvovirus without additional laboratory test results.

**scope** Indicates what species, when and (or) where this protocol applies; for example, specifics regarding the disease agent, animal class, sex, age group, location, season, antemortem or postmortem sample collection, environmental samples, and so on.

**suspected case** This is primarily based on a combination of individual, place, time, minimal or nonspecific field and laboratory information and a geographic and temporal (epidemiologic) connection to a confirmed case. Not enough information is available to meet the threshold in the case definition for a confirmed or presumptive case, but the diagnosis can reasonably be inferred by the close association with confirmed cases of a particular disease in other animals collected from the same general location and time. Example: A specimen with a geographic or temporal link to a confirmed case of a disease that is not tested but was examined and may have nonspecific gross or histopathologic findings that are compatible with that disease.

**time** The season(s), months, or other temporal factors that increase disease or pathogen/toxin suspicion.

**wildlife** Free ranging vertebrate species (mammals, birds, reptiles, amphibians, and fish).