



GUIDELINES FOR INVESTIGATION OF SUSPICIOUS BIOLOGICAL EVENTS

(GUIDELINES FOR NATIONAL VETERINARY SERVICES)



INTRODUCTION

The World Organisation for Animal Health (OIE) has developed these guidelines for the investigation of suspicious biological events with the goal of strengthening the capacity of Veterinary Services in Member Countries.

In response to the changing landscape of biological threats and the perceived likelihood of criminal or terrorist acts involving pathogens or toxins, guidance for prevention, preparedness and response so such attacks was issued by many countries, organisations and institutions. However, most of this guidance focuses on laboratory settings and protection of human health, leaving a gap regarding general guidance for Veterinary Service.

To address this gap, the OIE developed these Guidelines which should be understood as impulse on how to identify biological events that warrant further investigation and on good practices for (joint) investigations of such events.

SCOPE

The OIE supports an all-hazards approach to the management of natural, accidental or deliberate biological incidents (ranging from small-scale criminal acts to large-scale acts of bioterrorism). These Guidelines have been specifically developed to aid Veterinary Services to prepare for the investigation of suspicious biological events in relation to animal health, taking into account the additional challenges related to joint investigations.

These guidelines are not prescriptive; they provide a compilation of relevant issues that should be considered in planning for the response to suspicious disease events. In addition, these Guidelines call for intersectoral and interregional cooperation in relation to investigation and management of such events. Intersectoral relationships need to be developed and strengthened in advance of an event in order to agree on and implement effective and efficient response strategies (Box 1 and Box 2).

Containment and elimination of the threat to protect human and animal health, the environment, economic viability and trade in a One Health approach will require early detection,



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rapid response and effective communications. In case of a deliberately caused outbreak this includes the identification of the perpetrator(s), attribution and prosecution, to serve justice but also to prevent further criminal acts involving pathogens or biological toxins.

BOX 2. INTERNATIONAL INSTRUMENTS FOR BIOLOGICAL THREAT MITIGATION

BIOLOGICAL AND TOXINS WEAPONS CONVENTION (BWC):

prohibits the States Parties to the Convention to develop, produce or stockpile biological or toxin weapons.

UNITED NATIONS SECURITY COUNCIL RESOLUTION 1540 (UNSCR 1540):

addresses the non-proliferation of chemical, biological, radiological and nuclear weapons with focus on non-state actors.

INTERNATIONAL HEALTH REGULATIONS (IHR):

have the purpose to prevent, protect against, control and provide a public health response to the international spread of disease (Art.2, IHR)

PERFORMANCE OF VETERINARY SERVICES PATHWAY (PVS):

is a global programme for the sustainable improvement of a country's Veterinary Services' compliance with OIE standards on the quality of Veterinary Services

BOX 1. DEFINITIONS

Additional definitions are provided as hyperlinks in the electronic version of these guidelines.

BIOLOGICAL THREAT

(or biothreat) refers to the accidental or deliberate release of a pathogen or toxin into a susceptible population.

LABORATORY BIOSECURITY

describes the controls on biological materials within laboratories, in order to

prevent their loss, misuse, unauthorised access, or intentional unauthorised release.

LABORATORY BIOSAFETY

describes the principles and practices for the prevention of unintentional exposure to biological materials, or their accidental release.

ORGANISATIONAL GUIDELINES

1. LEGISLATION, LAW, REGULATIONS AND POLICY

The National Veterinary Services should have the legal authority to lead or support investigation and response in suspected or confirmed biological incidents related to animal health. Legislation for these biological threat events should be harmonised with existing or proposed national legislation including identification of a lead agency, communications lines and coordination of responsibilities. Where Veterinary Services lack appropriate legislation, regulations and policies to address biothreats countries should identify this as a priority area for development and work with national authorities to address these gaps.

2. ORGANISATIONAL STRUCTURE AND LEADERSHIP

The Chief Veterinary Office (CVO) or other Competent Authority should take the Veterinary Services lead in the biothreat domain and place it on the national agenda. Veterinary Services should appoint a position, held by an individual or a group, who is responsible for dealing with biothreats. This person or persons may be a nominated OIE Focal Point, or other similar position. Awareness and management of biothreats requires interaction with and involvement of Veterinary Services stakeholders, including the government (law enforcement and others), private sectors, laboratories, livestock and producer groups, animal owners, as well as the general public.

3. PERSONNEL CAPACITY AND CAPABILITIES

OIE's Performance of Veterinary Services (PVS) and World Health Organization's (WHO) Joint External Evaluation (JEE) are important tools, amongst others, that countries can use to identify gaps in personnel capacity and capability for response to outbreaks of disease, including biothreats. It is important to understand that additional personnel may be required at operational, field, and laboratory levels when responding to events that are suspected or proven to be intentional. These include, but are not limited to, capability to deal with inter-agency engagement and communication,

additional sample collection and testing, investigation, reporting and security.

4. FACILITIES

Veterinary Services should build into outbreak contingency response plans the provision for access to a range of facilities. These may be shared with law enforcement and other agencies, and include secure communications and IT networks, crisis management centres (that may be co-located with other operational agencies), additional laboratory diagnostics and sample storage spaces.

5. RESOURCES

Veterinary Services should be resourced to maintain day-to-day operations as well to having contingency funding to support the additional costs associated with responding to a biothreat event. These additional costs may include additional laboratory sampling and testing, sample storage, over time pay associated with the investigation, enhanced personal protective equipment, surge personnel, and other response requirements.

6. PARTNERSHIP: STAKEHOLDERS, PARTNERS, PUBLIC

Veterinary Services stakeholder and partnership relationships in biothreat events may include, for example:

- a. **National agencies and ministries** including health, law enforcement, interior, border and customs, environment, trade/commerce, foreign affairs, defence, finance, crisis management, civil protection and agriculture or rural affairs.
- b. **Industry** including producers, transport, processing, distributors and retail.
- c. **Intergovernmental organisations** including the OIE Network, INTERPOL, UN Bodies or Agencies, such as WHO, Food and Agriculture Organisation (FAO), United Nations Office for Disarmament Affairs (UNODA), United Nations Office of Counter-Terrorism (UNOCT) and United Nations Office for Disaster Risk Reduction (UNISDR).
- d. **Non-governmental organisations.**
- e. **Bordering countries and regional partners.**
- f. **General public** through appropriate communication strategies.

Stakeholder documents that regulate cooperation on different levels should be reviewed or developed to meet the requirements of the response to a biothreat event. These could include Partnership Memorandum of Understanding (MOU), Memorandum of Agreement (MOA), Standard Operating Procedures (SOP), and Mutual Support Agreements (MSA).



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OPERATIONAL GUIDELINES

1. PLANNING (PRE-EVENT)

Veterinary Service should pre-plan, train and exercise capabilities in preparation for a biothreat event. A capability assessment should be conducted to identify current gaps in capability and capacity related to biothreat events, using OIE Performance of Veterinary Services Pathway (PVS), Joint External Evaluation (JEE) and other appropriate assessment tools. Contingency planning should include meeting surge requirements including laboratory requirements that may not be nationally available. Pre-planning should include coordination with intersectoral partners and stakeholders (Box 3 and Fig. 1).

BOX 3. VETERINARY SERVICES PLANNING

- Identify and appoint a Veterinary Services lead/focal point for biothreat events
- Identify and coordinate with local, state and national agencies involved in biothreat events and identify roles and responsibilities
- Identify and coordinate with stakeholders and partners:
 - Develop protocols for joint response
 - Develop reporting requirements and protocols
 - Plan for biothreat response lead investigations and handover procedures
 - Plan for communications for different stakeholders
 - Develop and exercise biological threat mitigation response plans
 - Plan for surge capacity
 - Identify national and regional support laboratories and resources

2. INCIDENT ASSESSMENT

Veterinary Services in conjunction with law enforcement will assist in the joint assessment of biothreat events with evaluation of potential intentional activities (Fig. 2). Examples for triggers or indicators are given in Box 4.

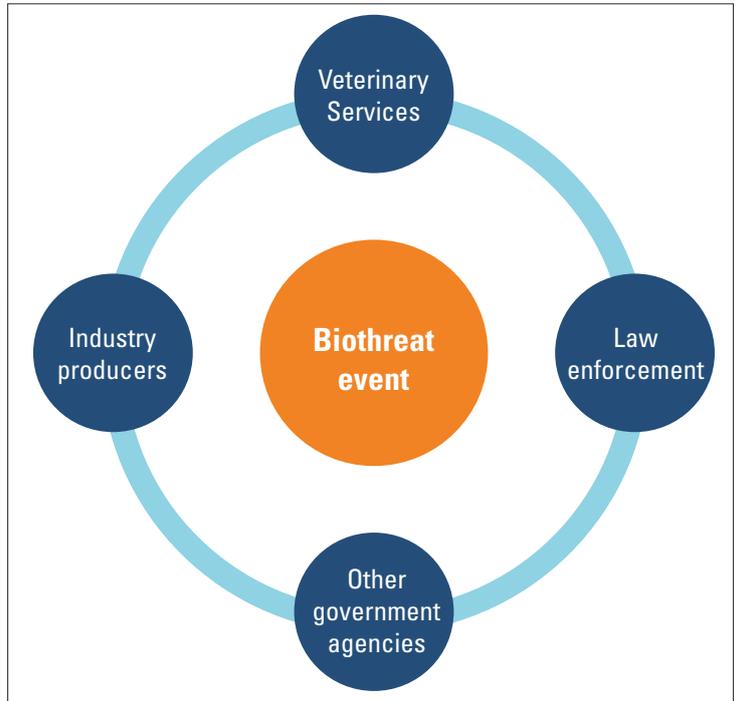


Fig. 2 Stakeholders in the mitigation of a biothreat event

Veterinary Services should provide notification to the OIE and appropriate authorities in accordance with *Terrestrial Animal Health Code* standards. Notification should include suspicion of an intentional event as appropriate.

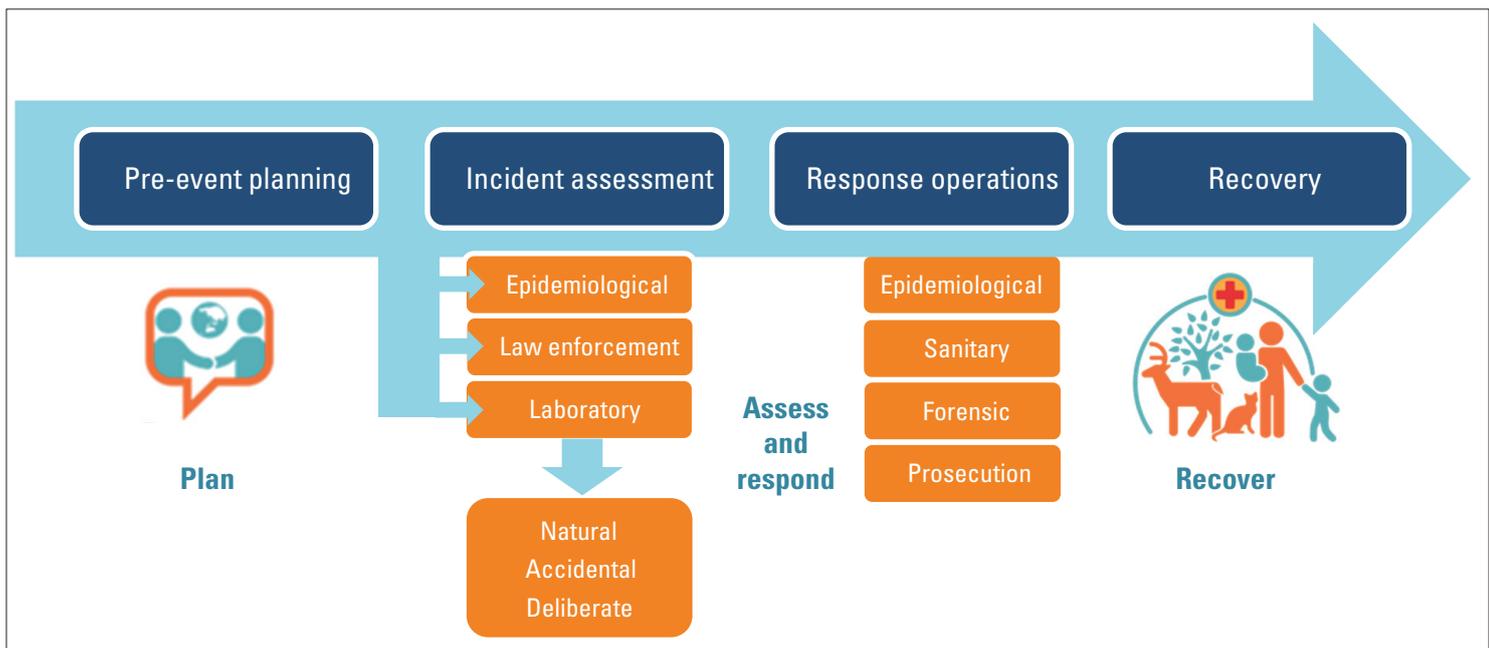


Fig. 1 Response flow

3. RESPONSE OPERATIONS

a. Disease surveillance, indicators & triggers

Routine in-country disease surveillance systems are essential for providing baseline data on disease prevalence, thus enabling identification of triggers or indicators of possible biothreats. Epidemiological

BOX 4. INDICATORS FOR ASSESSING SUSPICIOUS BIOTHREAT EVENTS

Epidemiological

- Cases of an eradicated disease
- Cases of an emerging/new/novel disease
- Cases of a disease which is exotic to the country or the geographic region
- Expansion of the geographical range of a disease
- Change of host range
- Suspicious location (e.g. around a laboratory)
- Novel or changed agent characteristics (e.g. changes in pathogenicity, transmissibility, stability)
- Sudden decreased susceptibility to antimicrobials/antivirals/vaccines/other countermeasures
- Changed or unusual epidemiology (e.g. lack of traceability between index properties)
- Multiple disease events (or serotypes/strains) presented at once (where unusual)
- Simultaneous disease events at two or more separate geographic locations
- Changed or unusual vector-borne disease patterns (e.g. vectors in new geographic locations, agents in previously unrecognised vectors)
- Multiple unusual disease events in wildlife animals, animals in the interface domestic-wildlife, or in companion animals

Laboratory

- Missing high-consequence pathogens or toxins
- Breach, or attempted breach, of laboratory security including cybersecurity
- Disappearance of PPE, biological materials, equipment, etc.
- Change in submission numbers/requests or increase in the proportion of positive test results

Law enforcement

- Credible threats
- Online chatter pertaining to biothreats or unusual outbreaks
- Accidental findings related to other investigations
- Identification of evidence (e.g. in laboratory)
- Suspicious behaviour
- Rumour tracking
- Whistle blower
- Cybersecurity breach
- Findings from darknet monitoring

and pathogen or toxin related factors that should be considered as possible triggers or indicators of an intentional event are listed in Box 4. These factors may occur in natural disease events but depending on the context might warrant further investigation. They should be considered as part of an overall assessment including, environmental and physical circumstances.

Law enforcement may, on occasion, be aware of suspicious activity before veterinary authorities. Good communication between relevant authorities should be established in advance of actual events and communication of biothreats should be made in a timely manner to ensure rapid investigation by veterinary authorities.

b. Continuity of operations

Veterinary Services should plan for continuity of operations with consideration to personnel, facilities, IT and communication capabilities, laboratory, mutual support, and focal points. Further information can be found in the OIE Guidelines on Disaster Management and Risk Reduction.

c. Information sharing

Secure communication channels should be established for biothreat information sharing among law enforcement, veterinary authorities, public health and other appropriate entities. During an actual biothreat investigation additional lines of communication may be required. Protocols need to be established for determining levels of information sharing and authority for release of information. Further information can be found in the OIE *Terrestrial Animal Health Code*, Chapter 3.3, Communication, and in the Communication Handbook for Veterinary Services.

d. Interviewing

Biothreat investigation differs from routine epidemiology and may require preparation and planning for joint interviews between animal health and the security sector. Conducting joint interviews can be advantageous to the investigative process. Information needs to be collected and preserved to support investigation and prosecution.

e. Logistics

Logistics will need to take into account surge capacity requirements in field, laboratory, epidemiological and countermeasure operations.

f. Joint investigations

Investigations of suspicious biothreat events may require concurrent criminal and epidemiological work for the purpose of identifying the source, controlling the event, determining attribution thus supporting apprehension and prosecution of perpetrators. Consider the possibility of a joint investigative team (collection



of information, data and samples) as part of your preparedness plan and train accordingly. Further Information can be found in the Joint Criminal and Epidemiological Investigations Handbook 2016 International Edition.

g. Safety and health

A biological agent involved in the suspicious event may be novel or possess changed characteristics. Enhanced personal protective equipment (PPE) and disinfection procedures need to be implemented for personnel safety and for mitigating the spread of the agent. Veterinary Services should prepare and train for enhanced PPE utilisation or other added measures in field investigation, sampling, transport and laboratory operations.

A biothreat event may have physical and psychological impact on responders (veterinarians, administrative, technical and laboratory personnel) and the general public. Safety and health (including physical and mental health) plans and standard operating procedures (SOPs) should be in place or be developed.

h. Sample collection, preservation and integrity

Veterinary Services should prepare and plan for specialised sampling in a biothreat event. For example, requirements for chain of custody (see paragraph on ‘sample integrity’ below) during the safe collection, packaging, transport and storage of samples will often be outside the normal scope of Veterinary Services and must be planned for and exercised.

There is not a single sample collection and preservation strategy that is suitable in all situations. It is important to identify experts or a relevant laboratory in advance to develop plans before sample collection, further information can be found in the OIE *Manual of Domestic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*, Chapter 1.1.2 on Collection, submission and storage of diagnostic specimens or in Chapter 5, Sampling and Preservation Methods in: Science Needs for Microbial Forensics: Developing Initial International Research Priorities (National Academies of Sciences, 2014).



– *Sample integrity*

The integrity of the sample starts at the point of sample collection and must be carried through to the final part of analysis and storage ensuring its traceability. Integrity can be compromised by inadequate sample volume, incorrect handling procedures, contamination, mislabelling, and inadequate packaging and storage.

– *Chain of custody*

Chain of custody encompasses the movement and location of physical evidence from the time it is obtained until the time it is presented in court and is a means of ensuring integrity of evidence. It includes the chronological documentation of the seizure, storage, any transfers, analysis and disposition of the evidence. Different means can be used for documentation, e.g. written or electronic logs. The purpose of chain of custody is to show that the evidence has been handled properly at all times and that no misconduct or tampering took place.

Evidentiary documentation has to provide information about the collection, transfer and disposal of the item, with supporting signatures. The documentation should be tamper proof and hold up in a court of law. Veterinary Services should engage with Law Enforcement as appropriate to ensure that when required this document is available.

A model of a Chain of Custody form can be found at the end of these guidelines.

4. LABORATORY OPERATIONS – ANALYSIS AND STORAGE

Veterinary Services should be aware of both national and international laboratory capabilities across veterinary, public health and forensic disciplines (such as OIE Reference Laboratories or human health laboratories). A plan should be developed and collaboration agreements in place with laboratories identified as having capability to test biological threat materials. This should include capability for surge capacity, maintaining chain of custody records, long term secured sample storage and waste management. Laboratories should meet international standards by adhering to established quality assurance, biosecurity and biocontainment, and transport of dangerous goods regulations. Further Information can be found in the OIE *Terrestrial Manual*, Chapter 1.1.: Management of veterinary diagnostic laboratories.

5. CRISIS MANAGEMENT CENTRE

The coordination and management of a bioterror event, whether suspicious or deliberate, will require the activation of a crisis management team. Primary command and control of the incident may move between Vet Services, Public health and law enforcement agencies, depending on the circumstances.

Veterinary Services should plan for staffing their internal and joint operation centres. Liaison officers from each office will be critical for information sharing and operational planning across sectors throughout the investigation.

6. CRISIS COMMUNICATIONS

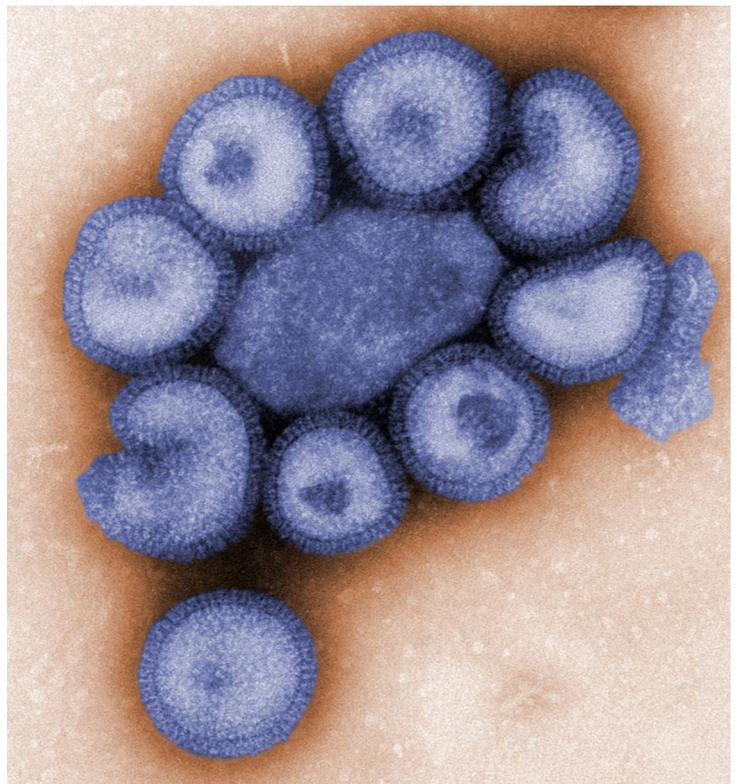
Veterinary Services, law enforcement and public health should work together to develop joint, timely communications using pre-scripted and event-specific messages through appropriate channels including traditional (TV, radio, paper) and social media.

7. TRAINING AND EDUCATION

Veterinary Services should develop and execute training for biological threat mitigation strategies. Training should include leadership training, interagency training, forensic application to field operations and laboratory specific training (chain of custody, material handling, select agent testing). Training should also be developed for veterinary students, private veterinary responders, and other appropriate responders. This training should include basic training, refresher training and just-in-time training. Table top and field exercises should be conducted to assess the competencies, capabilities and interoperability of responders at all levels, including intersectoral and regional exercises.

8. LESSONS LEARNED AND AFTER ACTION REPORT

Veterinary Services should plan for assessing response and developing Lessons Learned and After Action Reports to inform future operations.



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EVIDENCE CHAIN OF CUSTODY TRACKING FORM
(Generic template)

Chain of custody				
Item #	Date/time	Released by (signature & ID#)	Received by (signature & ID#)	Comments/location

Notes

Final disposal authority

Authorisation for disposal:

Witness to destruction of evidence

Item(s) #: on this document pertaining to incident (#)

Is (are) no longer required as evidence and is/ are authorised for disposal by (select means of disposal).

Name and ID# of Authorising officer/ laboratory Manager

Signature: Date:

Release to Legal Authority

Item(s) on this document was/ were released by the evidence custodian,
ID# in the presence of (witness)

to Name

Address

Country

Telephone number:

In accordance with relevant national legislation I receive these items into my possession.

Signature: Date:

This chain of custody form is to be retained as a permanent record by the pre-issuing police body in accordance with local and national requirements.

DRAFT chain of custody form for OIE Biothreat Ad hoc Group, November 2017, Dr Rebecca Hoile

