

Biological Threats and Veterinary Legislation – A Primer for OIE Delegates

What are biological threats?

The **OIE Biological Threat Reduction Strategy** defines biological threat (or 'biothreat') as the **accidental or deliberate release of a pathogen or toxin into a susceptible population**¹. In the case of deliberate misuse, biological threats historically have been associated with state-sponsored biological weapons programmes and, more recently, with criminal and terrorist acts. As the nature of conflict continues to change, non-state actors will continue to explore new attack options, taking advantage of advances in the life sciences and biotechnology that may make it easier to acquire dangerous pathogens, or even produce novel disease agents. Therefore, it is becoming increasingly likely that biological agents and toxins will be used to further the agendas of criminal and terrorist groups. From the perspective of these actors, biological agents may be attractive as weapons because some harmful pathogens are relatively easy to obtain and, due to their infectious nature, can result in broad and rapid dissemination, having a severe impact on human, animal and plant populations.

Why should Veterinary Services be concerned?

A key function of Veterinary Services is the detection, control and prevention of infectious diseases in animal populations as well as zoonotic diseases that can spread from animals to humans. Traditionally, the assumption has been that when an infectious disease is noted in animals, it has occurred under natural circumstances. However, in today's world, the very real possibility exists that infectious disease occurrence may be the result of deliberate introductions of infectious or toxic agents into animal populations. If the agents are zoonotic in nature, humans as well as animals may be affected.

Deliberately caused outbreaks of highly infectious diseases in livestock populations can have enormous economic consequences – affecting jobs, livelihoods, trade and the availability of food. In the case of a zoonotic disease outbreak, the event is likely to further contribute to social unrest and political instability due to heightened concerns about the loss of human life, and, in the event of terrorism, possible further attacks. These are the outcomes desired by criminals and terrorists and the Veterinary Services must be prepared to do their part to prevent the occurrence and limit the impact of such events.

Therefore, Veterinary Services need to be very much aware of not only the risks of natural and accidental disease events but also the deliberate introduction of animal and zoonotic pathogens. They must be ready to respond quickly and effectively and, when necessary, to coordinate their disease control activities with human health agencies, human and veterinary diagnostic laboratories, and law enforcement and national security agencies, among others. The importance of interagency cooperation is underscored by the facts that 60% of existing human infectious diseases are zoonotic, 75% of the pathogens causing emerging infectious diseases of humans (e.g., Ebola, HIV, and influenza) have an animal origin and as many as 80% of potential bioterrorism agents are zoonotic pathogens.

Veterinary legislation and biological threats

Section 3 of the OIE *Terrestrial Animal Health Code*, entitled 'Quality of Veterinary Services', describes the operating principles and resources that should be in place for national Veterinary Services to function efficiently and effectively, including for the control of disease outbreaks, whether they occur naturally, accidentally or deliberately. Comprehensive, high quality veterinary legislation to support good governance and provide the regulatory framework for all essential activities of the Veterinary Services is a key resource. Such legislation must clearly define the powers and authorities granted to the Veterinary Services in order to effectively ensure public safety and promote the public good.

There are a number of issues related to biological threats which should be addressed in national legislation. In general, the goal of such legislation is to ensure the proper regulation of biological agents and toxins that are kept for legitimate purposes but have the potential to be used for harm (i.e., dual-use²). Such legislation should also regulate the organisations, businesses, agencies and persons that handle them, including veterinary laboratories and their personnel. Equally important is having the power and resources to effectively enforce the laws and regulations aimed at controlling biological threats and punishing those who perpetrate or try to perpetrate them.

Each country will have its own approach to addressing these issues. They will do so in the context of their own legal frameworks, the relevant international laws, including conventions to which they are party, and the legal texts that they have adopted to fulfil their international obligations. Veterinary Services should be aware of and review existing legislation to ensure that they provide the necessary powers and authorities for Veterinary Services to effectively control biological threats within the veterinary domain. In that context, it is useful to review the international legal framework that exists for the control of biological threats.

¹ The OIE Biological Threat Reduction Strategy – Strengthening Global Biological Security, Paris, Oct.2015, http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/EN_FINAL_Biothreat_Reduction_Strategy_OCT2015.pdf

² The term 'dual-use' originally described a technology that could be used for military but also for civilian purposes, e.g. microwaves, internet or satellites. Over time, the use of the term has expanded to describe something that can be used not only for good, but also for malevolent purposes, including in the life sciences.

The potential costs of a deliberate introduction of an animal pathogen into livestock

In 2001, in the United States, the anthrax bacteria, a common animal pathogen and zoonotic agent, was used as an instrument of terror – sent through the mail in personal letters to public figures in government and the media. The episode resulted in 5 deaths, motivated thousands to pursue precautionary treatment, caused widespread fear, disrupted economic activities, resulted in clean-up costs in excess of one billion US dollars, and triggered what became one of the largest and most complex criminal investigations in the history of the US Federal Bureau of Investigation (FBI). The event left no doubt that animal pathogens can be used as biological threats.

While there are currently no documented cases of animal pathogens being used by non-state actors to deliberately create disease outbreaks directly in livestock, the possibility of such events is very real and must be taken seriously.

Take for instance the first occurrence of mad cow disease in the United States. The agent that causes mad cow disease would not be a good candidate as a bioterrorist agent for a number of reasons. Nevertheless, the episode underscores the potential damage of selecting livestock as a target for bioterrorism. When mad cow disease was first reported in the United States in 2003, there were 96.1 million head of cattle in the country. The disease incident, which occurred in the state of Washington, involved a single cow, which had earlier been imported from Canada. Yet as a result of the diagnosis in this one animal, beef exports from the entire US were virtually halted. U.S. ranchers and processors lost almost \$11 billion in revenue between 2004 and 2007 after major importers, notably Japan and the Republic of Korea, barred U.S. beef imports. As mad cow disease can potentially infect people, the outbreak also undermined confidence in the safety of beef. National consumption slumped considerably, causing further hardships and financial losses for beef producers and processors.

Unlike the agent that causes mad cow disease, the virus that causes foot and mouth disease is considered by experts to be a very likely candidate for use in bioterrorism. It is highly contagious, can be easily transmitted via inanimate objects and can be spread by wind. The United States is free of foot and mouth disease and therefore, the risk of deliberate introduction into the country's livestock would have a devastating effect. The impact of deliberate FMD outbreaks in US cattle has been modelled and the outcomes are sobering³. An isolated outbreak perpetrated at a single location, even if quickly recognized and effectively controlled, was still estimated to cost the US \$37 billion in economic disruption of the cattle industry. Outbreaks orchestrated by terrorists to occur simultaneously at different locations around the country were estimated to result in economic losses of up to \$228 billion.

In 2001, the United Kingdom, also free of FMD, experienced an outbreak of the disease in cattle which highlighted the enormous economic and social consequences that such a highly contagious livestock disease can produce. It resulted in 10,124 affected farms, more than 4 million slaughtered animals, and an economic impact of approximately 14 billion USD. In addition to the direct costs to the agriculture sector, the UK tourist industry experienced high indirect costs due to movement restrictions and the visual impact of the cattle cull and the burning animals throughout the UK countryside. Though the outbreak was deemed to have been a natural, unintended event, it could well have been a deliberate event and thus underscores the potentially destructive impact of deliberate biological threats in the livestock sector.

Clearly national Veterinary Services need to be ready to respond to deliberately caused disease events just as they are for naturally and accidentally occurring disease events and need to be properly resourced to do their jobs, as the failure to control such outbreaks can be catastrophic.

³ Oladosu G, Rose A, Lee B (2013) *Economic Impacts of Potential Foot and Mouth Disease Agroterrorism in the USA: A General Equilibrium Analysis*. J Bioterr Biodef S12: 001. doi:10.4172/2157-2526.S12-001

International legal framework for biological threat reduction

At the international level, there are two key instruments that commit countries to biological threat reduction and which provide the legal basis for control of biological threats. These are the Biological Weapons Convention⁴, which entered into force in 1975, and the United Nations Security Council Resolution 1540, adopted in 2004.

The Biological Weapons Convention (BWC) was the first multilateral disarmament treaty banning an entire category of weapons, covering biological agents, toxins, their means of delivery, and all future scientific and technological developments relevant to the Convention. In brief, States Parties to the BWC commit to the following:

- To never, under any circumstances, acquire, retain or use biological weapons;
- To destroy or divert to peaceful purposes biological weapons and associated resources prior to joining;
- To not transfer, or in any way assist, encourage or induce anyone else to acquire or retain biological weapons;
- To take any national measures necessary to implement the provisions of the BWC domestically;
- To consult bilaterally and multilaterally to solve any problems with the implementation of the BWC;
- To request the UN Security Council to investigate alleged breaches of the BWC and to comply with its subsequent decisions;
- To assist States which have been exposed to a danger as a result of a violation of the BWC;
- To do all of the above in a way that encourages the peaceful uses of biological science and technology.

United Nations Security Council Resolution 1540 (UNSCR 1540) obliges all Member States to adopt and enforce legislation to prohibit non-state actors to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical or biological weapons, related materials and their means of delivery. It also obliges Member States to take and enforce effective measures to prevent the proliferation of such weapons and their means of delivery, including by establishing controls over related materials (measures to account for, physically protect, and develop border and transfer controls).



⁴ Though commonly referred to as the Biological Weapons Convention, the complete name is 'The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction.'

Each country must adopt, in accordance with its own Constitution and law-making process, appropriate and effective legislation and regulatory measures to carry out and enforce the obligations under the BWC and UNSCR 1540. While such legislation should identify offences and penalties for any misuse of biological agents and toxins by non-state actors, it should also include provisions enabling a State to effectively regulate legitimate activities involving biological agents and toxins.

Depending on the prevailing situation in the country, a State may draft a single new law to address biological threats, or the State may utilize an array of existing and new laws in various relevant sectors, such as anti-terrorism laws, penal codes, criminal procedure codes, public health laws, animal and plant health laws, trade laws and customs laws, among others.

Regardless of the approach, at a minimum, national laws should address a number of key points which are further elaborated in the paragraphs that follow:

***Definitions / Offences and penalties / Jurisdiction /
Biosafety and biosecurity / Transfer and import/export controls /
Enforcement and emergency preparedness***

Definitions – National legislation should clearly define relevant terms such as biological weapon, biological threat, biological agent, toxin, non-state actor, and laboratory biosafety and biosecurity, among others.

Offences and penalties – Offences related to the illegal development, production, acquisition, possession, transport, transfer, import/export, storage and use of biological agents and toxins should be clearly set out and the associated penalties stated. Any forms of participation in these offences, for example, attempts, conspiracies, threats and financing should also be criminalized.

Jurisdiction – Legislation should extend the reach of legal prohibitions to natural and legal persons and apply territorially as well as extraterritorially, if allowed by the Constitution (e.g. jurisdiction on the basis of nationality of perpetrator, nationality of victim, impact on State interests).

Biosafety and biosecurity measures – In the general veterinary /animal health context, biosecurity is considered to be the set of management and physical measures designed to reduce the risk of entry, establishment and spread of animal diseases, infections or infestations to, from and within an animal population. The notion of biosecurity as it applies to the farm is well known to veterinarians. In relation to biological threats however, special emphasis must also be placed on *laboratory* biosafety and biosecurity. Laboratory biosafety refers to the containment structures, technologies and practices applied for the prevention of unintentional exposure of people to biological materials, or their accidental release (i.e., 'keeping germs away from people'). Laboratory biosecurity describes the protection, control and accountability for high-risk biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or deliberate release (i.e., 'keeping people away from germs').

Specific laboratory biosafety and biosecurity measures that should be present in national law include:

- Lists of controlled biological agents and toxins;
- Registration, licencing and audit systems;
- Systems for notification of accidents, loss or theft;
- Comprehensive record-keeping;
- Physical security for laboratories;
- Laboratory biosafety and biosecurity training for personnel;
- Secure transportation.

Transfer and import/export controls – Internal and international movement of biological agents and toxins must be regulated. Suitable measures should include:

- Lists of controlled biological agents and toxins, and dual-use biological equipment and technology;
- Transfer and import/export permit system;
- End-user certificate;
- Effective border controls.

⁵ The discussion which follows in this section draws considerably from the excellent legislation tools developed by the Verification Research, Training and Information Centre (VERTIC) to assist countries with drafting legislation in compliance with UNSCR 1540 and the BWC, most notably: *VERTIC's Legislative Guide to National Implementation of UN Security Council Resolution 1540* (2004); *VERTIC's Sample Act for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540*; and, *VERTIC's Regulatory Guidelines for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540*. All are available at http://www.vertic.org/pages/homepage/publications/special-publications.php?searchresult=1&sstring=sample+law#wb_69

Enforcement and emergency preparedness – The impact of legislation may be of limited value if the mechanisms and resources for effective enforcement and response are not accounted for. In this regard, the legislation should establish suitable measures, including:

- Identification of a national point of contact with the BWC Implementation Support Unit ⁶;
- Creation of an authority (an interagency body) responsible for overall policy co-ordination and enforcement of the legislation and any regulations at the national level;
- Creation of a system to respond to and investigate biological emergencies;
- Inspections of laboratories and other facilities where controlled biological agents or toxins may be found;
- Training and special powers for law enforcement officials including customs and other border officials, sea port and airport authorities;
- Disease surveillance; response capability in the event of a natural, accidental or deliberately caused outbreak;
- Co-operation agreements among law enforcement, Veterinary Services and health officials as well as Ministries of Health, Environment and Agriculture, among others;
- International co-operation on judicial and criminal matters;
- Specialised investigative techniques such as joint interviews and record-keeping with public health personnel and law enforcement.

The OIE envisions a world that is safe and secure from the accidental or deliberate release of animal pathogens, including zoonoses, and recognizes relevant legislation as a core component of national capabilities to prevent, detect, prepare and respond to biological threats. OIE also recognises the value of adopting a One Health approach to achieve this vision. The OIE can provide assistance to its Member Countries in reviewing and strengthening legislation in the veterinary domain relative to biological threats through its Veterinary Legislation Support Programme.

The OIE Veterinary Legislation Support Programme (VLSP)

The Veterinary Legislation Support Programme (VLSP) is one component of the OIE Performance of Veterinary Services (PVS) Pathway. The PVS Pathway is a set of tools and programmes designed by the OIE to assist its Member Countries in the strengthening of their Veterinary Services. The OIE established the VLSP in 2008 to help Member Countries recognise and address their needs for modern, comprehensive veterinary legislation in compliance with international standards to support strong and effective Veterinary Services.

In 2016, OIE VLSP Experts received additional training for the assessment of national veterinary legislation in the context of biological threat reduction, so that during a Veterinary Legislation Identification Mission (initial phase of the VLSP), they are better able to assess compliance of national laws with the requirements of the BWC and UNSCR 1540 as they relate to the veterinary domain.

Following a Veterinary Legislation Identification Mission with a special focus on biological threat reduction, if a country wishes to strengthen its veterinary legislation relative to biological threats, based on recommendations in the mission report, the country OIE Delegate can request further assistance from the OIE in the form of a follow-on Veterinary Legislation Agreement (second phase of the VLSP) wherein the OIE identifies a designated VLSP expert to support the country in drafting new legislation.

OIE Delegates interested in requesting a Veterinary Legislation Identification Mission with a special focus on biological threat reduction may do so by making a written request to the OIE Director General, Dr Monique Eloit (m.eloit@oie.int) with a copy to the Coordinator of the Veterinary Legislation Support Programme, Dr David Sherman (d.sherman@oie.int).

Delegates interested in learning more about OIE's involvement in biological threat reduction can find additional information on the OIE website at the following link:

<http://www.oie.int/en/our-scientific-expertise/biological-threat-reduction/>

⁶ The BWC Implementation Support Unit (ISU), located in Geneva, was established by States Parties to the Convention during the Sixth Review Conference to provide administrative support in relation to the BWC, to receive and distribute Confidence Building Measures (CBMs) among States Parties, to promote the universalization of the BWC, to serve as a focal point for the exchange of information on national implementation measures, and to act as a clearinghouse for assistance requests and offers.