



REPORT OF THE *AD HOC* GROUP ON VETERINARY LEGISLATION¹

Paris, OIE Headquarters, 23–25 January 2018

Report: Dr Howard Batho, VLSP/PVS Pathway expert and Chair of the *ad hoc* Group
Working versions of Chapter 3.4., Questionnaire and Brochure: Dr David Sherman, VLSP Coordinator
Minutes: Ms Camille Loi, VLSP Assistant

Dr Howard Batho, VLSP/PVS Pathway expert, and Dr David Sherman, Coordinator of the Veterinary Legislation Support Programme (VLSP) welcomed participants to the OIE *ad hoc* Group (*ad hoc* Group) on veterinary legislation.

The adopted agenda and the participants are listed in Annexes I and II. The Group was chaired by Dr Howard Batho. Apologies had been received from Ms Ambra Gobena, who was not able to participate but provided Dr Sherman with her comments on the VLSP Questionnaire to support the review planned in the agenda.

The following documents and links were made available in advance of the meeting:

- VLSP Questionnaire (parts 1 and 2, and advisory notes)
- [OIE Biological Threat Reduction Strategy](#)
- [OIE Guidelines on Disaster Management and Risk Reduction in Relation to Animal Health and Welfare and Veterinary Public Health](#)
- [The Biological Weapons Convention](#)
- [Resolution 1540 of the UN Security Council](#)
- [Vertic Legislative Guide to National Implementation of UN Security Council Resolution 1540](#)
- [ICRC and Vertic A Model Law: The Biological and Toxin Weapons Crimes Act](#)
- [Vertic Regulatory Guidelines for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540](#)
- [A Sample Act for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540](#)

1. Welcoming remarks

Dr Monique Eloit, OIE Director General, welcomed the members of the *ad hoc* Group. She reminded them to **differentiate the objectives from the means** when they review Chapter 3.4 on Veterinary Legislation of the OIE *Terrestrial Code* (hereinafter referred to as *Code*) to determine if the legislation basis for biological threat reduction (BTR) in the veterinary domain could be better clarified: the *Code* should include elements which fall in the scope of standards only, without too much detail, creating awareness of the obligations to address the issue of biological threats without being prescriptive on how to do so. Therefore, the *ad hoc* Group members would need to find the right balance between the adjustments needed in the *Code* and elements that could be developed in separate guidelines.

¹ Note: This *ad hoc* Group report reflects the views of its members and may not necessarily reflect the views of the OIE. This report should be read in conjunction with the September 2018 report of the Terrestrial Animal Health Standards Commission because this report provides its considerations and comments. It is available at <http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/code-commission-reports/meetings-reports/>

The OIE Director General took this opportunity to introduce Dr Karen Bucher, OIE Chargée de mission in charge of the creation of an “OIE Observatory”, a project intended to serve as a tool to monitor progress and constraints faced by OIE Member Countries (“OIE Members”) in the implementation of the OIE standards. The participation of Dr Bucher in the *ad hoc* Group meeting would enable her to get some reflection for the design of the Observatory, which should aim at: exploring the manner and extent to which OIE Members take into account OIE standards in their veterinary legislation and decision-making in particular for international trade; determining the relevance, effectiveness and practicability of OIE standards to Members in order to propose solutions to Members. The expected outcomes would be: more effective implementation of OIE standards and support to the OIE to develop a more strategic focus to its capacity building activities.

2. Introductory presentations

Dr Sherman presented a brief history of the *ad hoc* Group on Veterinary Legislation and the VLSP. Chronology is summarised below.

- PVS Evaluation missions having revealed deficiencies in the veterinary legislation of OIE Members from the start, the VLSP was initiated in 2008, with pilot missions undertaken from 2007.
- In 2009, at Members’ request, the OIE developed *Guidelines on Veterinary Legislation*, identifying the essential elements that should be covered by legislation to meet OIE standards.
- In 2010, the first OIE Global Conference on Veterinary Legislation was held in Djerba, Tunisia, and recommended that the OIE propose the adoption of these *Guidelines* as standards in the OIE *Code*.
- In response to this recommendation, OIE convened an *ad hoc* Group on Veterinary Legislation to develop the draft chapter on veterinary legislation. First meetings of the Group were held in July 2011, January and September 2012, and April 2013.
- The draft chapter on veterinary legislation was unanimously adopted by the World Assembly of Delegates at the 80th OIE General Session in May 2012 and updates adopted at the 81st General Session in May 2013. It is now Chapter 3.4. of the *Code*.

Dr Sherman presented also the Canada Biothreat Project “OIE Veterinary Legislation Support Programme in the Americas”, summarised below:

Following the Global Conference on Biological Threat Reduction organised at OIE Headquarters in June 2015, the Government of Canada, through its Global Partnership Program (GPP) in the Ministry of Foreign Affairs, Trade and Development, awarded a grant to the OIE to implement this project. The purpose of it is to strengthen health security and improve the preparedness of nations for biological threat reduction by enhancing the veterinary legislative basis in countries of the Americas: Canada requested that the OIE focus its efforts through this project on the Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA) Member Countries.

Key activities identified in the project are the following:

- A Training of OIE VLSP experts on biological threat legislation (December 2016)
- Pilot VLSP Identification missions on biological threat legislation: Belize (2016), Panama (2017), Guatemala (2018)
- A Workshop on Legislation and Biological Threat Reduction for OIRSA Member Countries (June 2017)
- An *ad hoc* Group on veterinary legislation focused on BTR (the *ad hoc* Group reported here - January 2018)

The legislative framework for biological threat reduction was then introduced by Dr Sonia Drobysz, Senior Legal Officer at the Verification Research, Training and Information Centre (Vertic). She notably presented:

- The background and main provisions of the 1972 Biological and Toxin Weapons Convention (BWC) and of the UN Security Council Resolution 1540 (UNSCR 1540, 2004) and national laws.
- The different type of provisions that need to be included in national legislation.
- The definitions of “biological weapons”, “biological agent” and “toxin”.
- The Vertic Tools, notably the BWC fact sheets, legislation database, model legislation and online drafting assistant.

During Dr Drobysz’s presentation, the *ad hoc* Group members noted the importance of raising awareness within Veterinary Services on the existence of national points of contact to the BWC’s Implementation Support Unit (ISU) –and on the relevance to liaise with them. Indeed, among the roles of the BWC’s ISU, located in Geneva, Switzerland are: to promote the universalisation 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. Among the provisions that need to be included in national legislation, one concerns the identification of such national points of contact.

It was also interesting to note that the UNSCR 1540, like for the OIE *Code*, focuses on the obligations and the objectives, but does not detail the means to reach them.

3. Review of the Chapter 3.4 of the OIE *Terrestrial Code*

The second part of Day 1 focused on the review of the quality and usefulness of current Chapter 3.4. on Veterinary Legislation of the OIE *Terrestrial Code* which was developed in 2011-2012 by the OIE *ad hoc* Group on Veterinary Legislation and approved at the 80th General Session . Objectives of this review were twofold:

- evaluate its continued suitability, in general, and as the basis for conducting VLSP Identification Missions (VLIM) and supporting development of new legislation under VLSP legislation Agreements; and,
- review the text to determine if the legislation basis for BTR in the veterinary domain could be better clarified.

ad hoc Group members reviewed the Chapter focusing on elements falling in the scope of standards, as required by the OIE Director General in her opening remarks: they identified several opportunities to include wording that created legal obligations to address the risk of biological threats and several instances to introduce wording that raised awareness concerning biological threats –while leaving the details of implementation to the countries themselves.

Dr Sherman reported an instance wherein an OIE Delegate had expressed to him that, considering their busy agenda, Delegates had no reason to treat BTR as a priority issue if it was not included in the *Code*. As other Delegates may share this opinion, Dr Sherman emphasized that including reference to BTR in Chapter 3.4. is therefore important.

The details of the review and proposals of the *ad hoc* Group members were incorporated into a working version of the revised Chapter 3.4. (Annex III - a). The rationales for the proposed revisions to Chapter 3.4. are provided in Annex III – b).

The inclusion of BTR in this Chapter raised the question of having a separate section dedicated to BTR in the Chapter or merging BTR provisions within the current Chapter. It was recalled however that the OIE Director General is not in favour of creating a specific chapter on BTR in the *Code* itself.

The same issue exists regarding the VLSP Questionnaire and the reports of the VLSP veterinary legislation Identification missions with a specific focus on BTR (“VLIM-BTR missions”). Regarding these reports, two formats were tested during the pilot VLIM-BTR missions mentioned above: in Belize, a separate report on BTR in addition to the standard report; in Panama, one single merged report. The first experience turned out to be more positive in terms of accessing the BTR specific information and preserving the integrity of the general mission report. *ad hoc* Group members were informed that the first option of a separate biothreat report (or “annex”) would be preferred for future VLIM-BTR missions.

The risk of providing legislation models to the country was mentioned: Dr Drobysz argued that, despite Vertic templates being available online, countries need the support of Vertic experts to tailor these templates to their individual conditions.

Further, it was suggested:

- to introduce biosafety/biosecurity into the figure of the veterinary domain to raise awareness of where it is important (e.g., laboratories, processing facilities, farms) (see Fig. 1) –this figure being often used during PVS Pathway/VLSP missions and in presentations made by OIE staff;
- to expand the introduction of the Chapter 3.4. or/and add a footnote stating that the provisions apply to the aquatic domain;
- to expand the introduction of the Chapter 3.4. to explain the context of legislation in this Chapter – however it was remarked that the audience of the *Code* is presumed to already know this information;
- to share with FAO the OIE guidance document for expert to conduct VLIM-BTR missions, proposing FAO to share its similar guidance document on antimicrobial resistance (AMR) in order to harmonise the approach to veterinary legislation by both organisations.

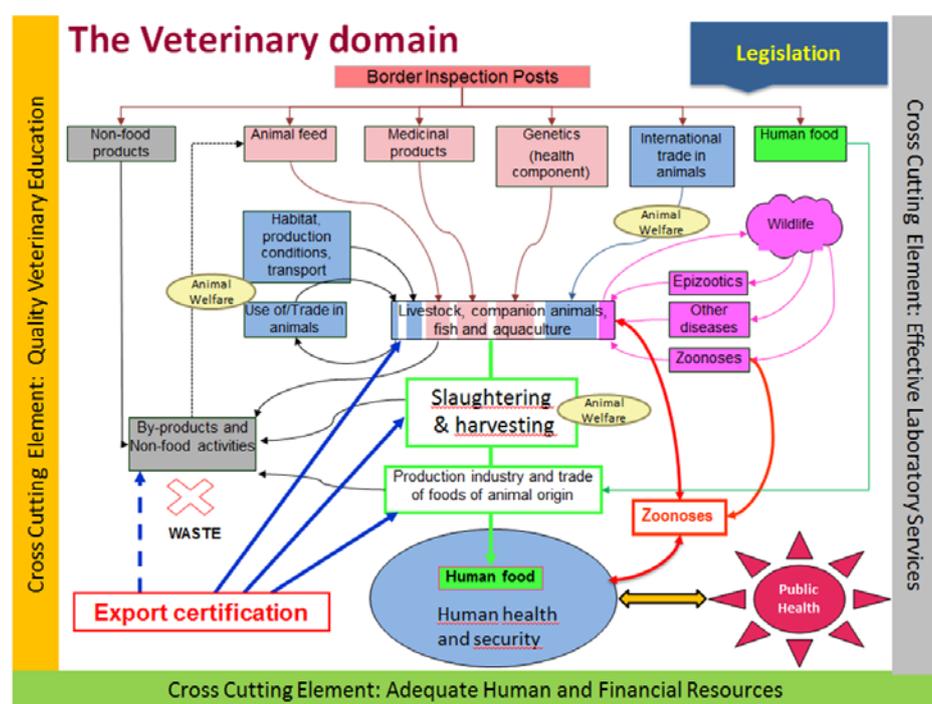


Fig. 1 - The Veterinary domain

Finally, for VLIM-BTR missions, it was agreed to develop:

- the guidance document for experts to conduct these missions;
- a specific template for the BTR report (or “BTR annex”) attached to the standard report.

Dr Sherman announced that the proposed revisions of the Chapter 3.4. (along with this report of the *ad hoc* Group) would be provided to the Terrestrial Animal Health Standards Commission (the “Code Commission”) for consideration at its meeting in September 2018. It was agreed that the version drafted during this *ad hoc* Group meeting would have to be completed by comments/explanations before being presented, and that the *ad hoc* Group members would provide additional support for this purpose.

The review of the Chapter 3.4 ended on the Day 2 morning.

4. Review of the VLSP Questionnaire

The rest of Day 2 and a part of Day 3 were dedicated to the integration of questions on BTR into the VLSP Questionnaire (Part I and II) that is utilised during VLIM to identify gaps in a country’s existing veterinary legislation. It was mentioned that questions relating to AMR may be included in the same way in due course.

It was also the opportunity to review the Questionnaire with the aim of improving it with regard to its general use during VLIM. The need for such improvements was based on the inputs of the VLSP experts, made notably during the VLSP Expert Feedback Session held on 8 December 2016 in Paris, France, back-to-back with the Veterinary Legislation Support Programme (VLSP) Expert Training Seminar on Legislation and Biological Threat Reduction.

Experts’ comments and suggestions were all interesting and helpful. Some being contradictory, however, they could not be all accommodated, thus Dr Sherman, as the VLSP Coordinator, with the support of the *ad hoc* Group members, had to arbitrate.

Regarding the inclusion of BTR-specific content in the Questionnaire, it was agreed that:

- There was more flexibility to include BTR content in the Questionnaire than in Chapter 3.4 because the Questionnaire is a fact-finding tool and not a standards document. After discussion among the *ad hoc* Group members, it was agreed to approach the issue in two ways – first to include biothreat-specific wording within the existing Questionnaire in appropriate sections (such as laboratories and disease control) to raise awareness about the need for veterinary legislation to address BTR. This content would be integrated into the Questionnaire for use in all VLIM. Second, was to add an additional section on BTR at the end of the Questionnaire Part II (new section 10) to include questions concerning BTR that would be utilised only during VLIM-BTR missions.

Regarding the generic legislation assessment, it was agreed that:

- The Questionnaire could be modified and not mirror the Chapter 3.4 exactly, even if it currently corresponds to the Chapter 3.4. Consequently, the revised version of the Questionnaire could be used before the Code Commission approves the *ad hoc* Group proposals on the Chapter 3.4.
- “The simpler the better”: the level of detail useful for the Questionnaire should be chosen regarding its relevance for assessment as well to make it more understandable for the Delegates. It would be then the role of VLSP experts, during the missions, to dig further according to Chapter 3.4.
- The Questionnaire should be attached to the letter acknowledging receipt of the country official request for a VLIM.

- Retaining the Questionnaire as part of the VLIM report enabled the readers used to this report format to find key information rapidly. It was also agreed that it was very useful to complete the mission report.
- Spending several days –as it is often the case –of the mission on finalising the Questionnaire leaves much less time for addressing other aspects necessary to complete the report. Even if the Questionnaire was provided earlier to the country, it would not change the fact that it will require some time to be reviewed and completed during the mission itself. The main solution is to simplify the questions, in order to decrease the frustration of the country and experts.
- The “Question 5” (Q5 of Part I), was deemed to be too complicated and should be deleted. As the original intent of Q5 was to identify the Competent Authority responsible for each of the various laws associated with different aspects of the veterinary domain, it was agreed that Q5 could be replaced by a simple legislation list that the country should provide in advance of the VLIM that included the responsible authority for each law. Dr Sherman would develop a template for such a list with the support of Ms Loi.
- Broad, open and ambiguous questions should be avoided.

During this second day of the *ad hoc* Group meeting, Dr François Caya, Head of the Regional Activities Department, and Dr John Stratton, Deputy Head, came to greet the *ad hoc* Group members and introduce Dr Stratton, who had not been met by some of the experts.

Dr Caya took this opportunity to highlight that in the “evolved PVS Pathway” (being developed following the PVS Pathway Think Tank Forum held in April 2017 at OIE Headquarters), legislation will be part of the “targeted support” (replacing the term of “treatment”).

Because of the length of the Questionnaire, the revised version is not included as part of this report but is available on request.

5. Review of a draft “BTR brochure” for OIE Delegates

On Day 3 the *ad hoc* Group members reviewed a draft brochure for OIE Delegates on the importance of a sound legal framework for effective control of biological threats in the veterinary domain.

A first working version of the brochure, drafted by Dr Sherman with the support of Ms Loi, had been sent to the members before the meeting for comments and suggestions, and further discussion during the *ad hoc* Group.

The details of the review and proposals made by the *ad hoc* Group members had been incorporated into the draft by Dr Sherman (Annex IV).

It was agreed to:

- keep the brochure concise and focus on the communication aspect of the brochure: objective being to orient the Delegates’ perspective;
- focus on deliberate misuse of a biological agent or toxin, even if the OIE Biological Threat Strategy focuses both on accidental and intentional misuse.
- insist on laboratory security and also on security in the field (on farms);
- contact Dr Jennifer Lasley, Project Coordinator at the OIE Programmes Department, in order to investigate if the BTR assessment, or part thereof, could be included in the *PVS Laboratory Tool*.

It was suggested to:

- include side bars (e.g. for examples) or images in the brochure. Examples that could be used: real case studies (e.g. 2001 anthrax attacks in New York), and/or potential event (e.g. FMD² in the USA). Dr Sherman agreed to draft a sample sidebar for the consideration of the *ad hoc* Group.

Finally, Dr Batho indicated that it was not clear in the brochure if OIE Delegates interested in requesting a VLIM-BTR mission could make a request to the OIE Director General even if a standard Identification Mission had already been conducted in their countries. Dr Sherman answered that the OIE had not defined a position on this subject for the moment and would therefore study any request on a case-by-case basis, depending on funds available. However, if a standard Identification mission had already been conducted and a VLIM-BTR mission was organised, it would focus more heavily on BTR.

Following the meeting the draft brochure will be sent to the members of the *ad hoc* Group for comments, before being finalised. The means of distribution to the OIE Delegates will be defined at a later stage.

As mentioned above, during Day 3 the Questionnaire review continued. It was decided to give priority to the brochure first, so BTR experts could leave, and then the *ad hoc* Group would focus on the generic issues of the Questionnaire.

6. Closing remarks

Dr Sherman reminded that the support of *ad hoc* Group members would be required to finalise the work on the Chapter 3.4. of the *Code*, the VLSP Questionnaire and the BTR brochure for OIE Delegates. Following the *ad hoc* Group, Dr Sherman will complete the working versions of these documents first, before sending them to the members.

The importance of keeping all the track changes (from the initial ones to the final ones) on the same working versions was stressed, in order to facilitate harmonisation and translation of French and Spanish versions.

Finally, the list below, representing collateral ideas that arose during the AHD deliberations, was captured for future consideration. Notably, it includes some points where alteration of Chapter 3.4. might suggest the need to consider changes elsewhere in the *Code* as well:

- Biosecurity definition: OIE vs others;
- Introduction of the *Code*;
- Definition of biologicals;
- Broaden definition of “laboratory” in the *Code*;
- Chapter 6.1. of the *Code*: include reference to risk of introduction;
- Consider biosecurity issues in the field including samples, transfers...;
- Consistent use of terms Veterinary Services vs Veterinary Authority in the *Code*;
- Definition of veterinary medicine / surgery;
- Proposal to include reference to BWC and UNSCR 1540 in the OIE Biological Threat Strategy.

Drs Batho and Sherman thanked the members for their fruitful participation in the *ad hoc* Group.

.../Annexes

² FMD: Foot-and-mouth disease.

**AD HOC GROUP ON VETERINARY LEGISLATION
OIE VETERINARY LEGISLATION SUPPORT PROGRAMME IN THE AMERICAS
23–25 January 2018**

Agenda

DAY 1: 23 January 2018

- 09:00 a.m. Welcoming remarks – Dr Monique Eloit, OIE Director General
- Adoption of the agenda – Chair, Dr Howard Batho
- Brief history of the *ad hoc* Group on Veterinary Legislation – Dr David Sherman
- Summary of the Canada Biothreat Project “OIE Veterinary Legislation Support Programme in the Americas” – Dr David Sherman
- The legislative framework for biological threat reduction: the 1972 Biological and Toxin Weapons Convention, the UN Security Council Resolution 1540 (2004) and national laws – Dr Sonia Drobysz
- Review of the quality and usefulness of current Chapter 3.4 on Veterinary Legislation of the OIE *Terrestrial Code* which was developed in 2011-2012 by the OIE *ad hoc* Group on Veterinary Legislation and approved and adopted by the OIE General Assembly in May 2012 in order to:
- evaluate its continued suitability, in general, and as the basis for conducting VLSP veterinary legislation identification missions and supporting development of new legislation under VLSP legislation Agreements; and,
 - review the text to determine if the legislation basis for biological threat reduction in the veterinary domain can be better clarified.
- 04:00 p.m. End of the *ad hoc* Group

DAY 2: 24 January 2018

- 09:00 a.m. Integration of questions on biological threat preparedness into the VLSP Questionnaire that is utilised during VLSP legislation Identification missions to identify gaps in a country’s existing veterinary legislation.
- 6.00 p.m. Restaurant dinner

DAY 3: 25 January 2018

- 09:00 a.m. Review and finalisation of a draft brochure for OIE Delegates on the importance of a sound legal framework for effective control of biological threats in the veterinary domain.
- Closing remarks
- 04:00 p.m. End of the *ad hoc* Group

Coffee breaks and lunch breaks will be included during the three days.

**AD HOC GROUP ON VETERINARY LEGISLATION
OIE VETERINARY LEGISLATION SUPPORT PROGRAMME IN THE AMERICAS
23–25 January 2018**

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Rationale for proposed revisions to
CHAPTER 3.4.
VETERINARY LEGISLATION

Background

In 2009, at the request of Member Countries, the OIE developed Guidelines on Veterinary Legislation, identifying the essential elements that should be covered by legislation to meet the OIE standards. In December 2010, the OIE held the first Global Conference on Veterinary Legislation in Djerba, Tunisia. A recommendation of that Conference was for the OIE Guidelines on Veterinary Legislation to be adopted as standards in the Terrestrial Code. In 2011, OIE convened an *ad hoc* group (*ad hoc* Group) on Veterinary Legislation to develop a draft Terrestrial Code chapter on veterinary legislation based on the Guidelines which was accomplished. Following required commission reviews and response to Member Country comments, the draft chapter on veterinary legislation was presented for consideration at the 80th OIE General Session in May 2012 and approved for adoption as Chapter 3.4 of the Terrestrial Code. Based on Member Country comments received at the General Session, the *ad hoc* group reconvened to address those comments and the revised version of Chapter 3.4 was adopted in 2013. That version is the current version.

Since its adoption, Chapter 3.4 has served as the basis for conducting OIE Veterinary Legislation Support Programme (VLSP) in which a OIE VSLP certified expert team, comprising a lawyer and a veterinarian, undertake a one-week mission in-country to review the country's veterinary legislation and identify gaps, redundancies and weaknesses relative to Chapter 3.4. In using the Chapter repeatedly and extensively, VLSP experts have identified some areas of ambiguity and inconsistency which they felt should be addressed if the opportunity to review the Chapter arose.

Under the project funded by the Canada Global Partnership Programme entitled 'the OIE Veterinary Legislation Support Programme in the Americas', which focused on veterinary legislation in the context of biological threat reduction, the opportunity arose to reconvene the *ad hoc* group on veterinary legislation. The *ad hoc* group met 23-25 January 2018 at OIE Headquarters.

The objectives of this *ad hoc* group meeting, as approved by the Director General, were:

- to reassess the quality and usefulness of current Chapter 3.4 on Veterinary Legislation of the OIE Terrestrial Code which was developed in 2011-2012 by the OIE *ad hoc* group on veterinary legislation and approved and adopted by the OIE General Assembly in May 2012 in order to:
 - evaluate its continued suitability, in general, and as the basis for conducting VLSP veterinary legislation identification missions and supporting development of new legislation under VLSP legislation Agreements; and,
 - review the text to determine if the legislation basis for biological threat reduction in the veterinary domain can be better clarified;

The deliberations of the *ad hoc* group resulted in a number of proposed changes in Chapter 3.4

Purpose

In order to assist the Code Commission with its review of the proposed revised Chapter 3.4, the following rationales are provided:

Rationales

Article 3.4.1 paragraph 2. Given the mandate of the *ad hoc* Group to address biological threats in the context of Chapter 3.4, the *ad hoc* Group believed that this opening paragraph of Chapter 3.4, which draws attention to international obligations in veterinary legislation should also draw attention to international obligations relative to biological threats (i.e., the Biological Weapons Convention and UN Security Council Resolution 1540).

Article 3.4.1 paragraph 3. Based on their experience on VLSP missions, VLSP experts on the *ad hoc* Group believed it was valuable to draw attention to the fact that not all legislation impacting the veterinary domain is within the Veterinary Authority and that relevant legislation may exist with other Competent Authorities as field experience suggests that the Veterinary Authority may not be familiar with other relevant legislation

Article 3.4.1 paragraph 4. Wording added to be consistent with paragraph 2 in regard to meeting obligations relative to international instruments.

Article 3.4.2 Definitions. The colon following each term that is defined has been deleted in order to make the style more consistent with the TAHC glossary definitions.

Article 3.4.2 Definition of veterinary domain modified to put the primary focus on animals rather than humans.

Article 3.4.3 sub-article 2, first paragraph. The *ad hoc* Group believed that it was sufficient to identify laws as being applicable to relevant administrative levels without reference to geography, which in fact was felt to introduce some confusion.

Article 3.4.3 sub-article 2, new second paragraph. The *ad hoc* Group noted that, based on expert experience on VLSP missions, many countries fail to produce regulations following enactment of primary legislation. Therefore, the *ad hoc* Group agreed that the importance of doing so should be emphasised as a general principle for legislation.

Article 3.4.3 sub-article 2, third paragraph. The *ad hoc* Group noted that numerous countries may belong to regional economic communities and therefore may subject to regional laws

Article 3.4.3 sub-article 4, first paragraph. The reference to impact analysis is included to draw attention to the fact that in addition to being scientifically, technically and legally sound, the law must be implementable and achieve its intended purpose, which is the purpose of impact analysis.

Article 3.4.3 sub-article 5, first change. Transparency is dealt with separately in point 3 preceding so is removed here.

Article 3.4.3 sub-article 5, second change. The *ad hoc* Group agreed that to ensure that the legislation is technically relevant, acceptable to society, etc., reference to periodic updating should be included as part of the general principle.

Article 3.4.4 sub-article 1. The *ad hoc* Group noted that the establishment of authorities or power is also important but was overlooked here.

Article 3.4.4 sub-articles 2 and 3. The *ad hoc* Group noted overlaps in the content of sub-articles 2 and 3 and proposes to combine them into one new sub-article 2. This changes the numbering of the sub-articles that follow.

Article 3.4.4 sub-articles 4 and 5. The *ad hoc* Group believed that there were other issues to address regarding definitions besides ambiguity and that the ambiguity issue related not only to definitions but to provisions in the text as well, hence original item 4 has been expanded and becomes new sub-article 3 with the addition of a new sub-article 4 also related to definitions, and provisions.

Article 3.4.4 sub-article 7. The *ad hoc* Group noted that sub-article 7 was ambiguous as presented. The semi colon has been removed and the word 'or' added to clarify that sub-article 7 was presenting two specific alternatives.

Article 3.4.5 first paragraph. The *ad hoc* Group agreed that legal mandate, capacitation and organisation of the CA should extend beyond, and not be limited to, emergencies, but all matters of concern related to animal health, animal welfare and public health.

Article 3.4.5 second paragraph. The *ad hoc* Group recognised the need to establish responsibility for addressing biological threats (and natural disasters) as an obligation of the relevant Competent Authority and proposes the inclusion of additional wording to that affect.

Article 3.4.5 third paragraph. In light of the inclusion in Article 3.4.5 of the power to delegate tasks related to official activities, the *ad hoc* Group believed that it was more consistent to refer to authorised personnel in addition to officials.

Article 3.4.5 sub-article 1.a. The *ad hoc* Group believed that the existing wording lacked clarity and did not convey a meaningful intent. Alternative wording has been proposed to improve clarity.

Article 3.4.5 sub-article 1.c. Wording adjusted for consistency with the proposed change in Article 3.4.5 third paragraph regarding officials and authorised personnel.

Article 3.4.5 sub-article 1.d.iii. The *ad hoc* Group believed it was important to clarify that these powers represented sanitary measures but not all necessary sanitary measures. Nevertheless, it was deemed important to add reference to add quarantine and movement controls to the list as they are fundamental sanitary measures.

Article 3.4.5 sub-article 2. The *ad hoc* Group believed that the itemized list included in sub-article 2 is essentially a repetition of the elements described in this opening paragraph of the sub-article and was therefore not necessary to include, particularly when the term 'the competencies required' is added to the paragraph for completeness.

Article 3.4.6. Members of the *ad hoc* Group noted serious concerns with Article 3.4.6 related to overall quality of drafting and the clarity of intent. It was pointed out that, in the original text, sub-article 2b appears to duplicate sub-articles 1 a-d. The original text also suggests that the criteria for regulating the professions (sub-article 1 a-d) should be included in law, while sub-article 2b suggests that the power to develop these criteria be delegated to a veterinary statutory body. This appeared as confusing and contradictory to the *ad hoc* Group. The *ad hoc* Group also noted a lack of clarity as to whether OIE expects Member Countries to establish veterinary statutory bodies, as the original text says that powers of regulation of the professions could *possibly* be delegated to a VSB. To address these concerns, it was proposed that the entire article be redrafted to make it clear in the first sub-article that countries should create a veterinary statutory body through legislation and empower the VSB to develop the criteria by which the professions are regulated. In the case that countries choose not to create VSB, then the second sub-article proposes that the criteria for regulating the professions be included in legislation.

Article 3.4.7 sub-article 1.c. The *ad hoc* Group believed that the wording in this sub-article was not sufficiently clearly to distinguish the nature and activities of laboratories in point c from the other laboratories described in points a and b. The wording has been changed to improve clarity.

Article 3.4.7 final paragraph of sub-article 1. The *ad hoc* Group believed that, in the context of biological threat reduction, this sentence offered a good opportunity to introduce the important concepts of biosafety and biosecurity for laboratories without altering the original intent.

Article 3.4.7 sub-article 2. The *ad hoc* Group believed that the original title here, Reagents, was too limited, as the dictionary definition of reagents is ‘a substance or mixture for use in chemical analysis or other reactions’. The expansion of the title to include diagnostic kits and biological agents better represents the reality of what needs to be regulated within a veterinary laboratory and also underscores the need to regulate biological agents in the context of biological threat reduction. Text in sub-article entries 2.a, 2.b and 2.c have been modified to address this change.

Article 3.4.7 new sub-article 3. In the context of the *ad hoc* Group’s focus on biological threats, and the importance of laboratory biosecurity, the *ad hoc* Group proposed to add this additional section on Laboratory containment of pathogenic agents to article 3.4.7. It is consistent with information already present in Chapter 5.8 of the TAHC and would not require any alteration of that Chapter.

Article 3.4.8 sub-article 2b. Advised by the Standards Department that the Code Commission is replacing ‘cleaning and disinfection’ with simply ‘disinfection’ where the term occurs throughout the Code.

Article 3.4.8 sub-article 3. The *ad hoc* Group believed that the term ‘as appropriate’ in this sentence was not informative. The interest of the Veterinary Authority in the context of animal reproduction should be specifically focused on health issues, i.e., ensuring that disease is not transmitted through genetic materials. The wording has been changed accordingly.

Article 3.4.8 sub-article 4.a. As in Article 3.4.8 sub-article 3 above, the *ad hoc* Group was concerned that Article 3.4.8 sub-article 4.a was too broad and implied that the Veterinary Authority was responsible for all aspects of animal feed e.g., nutritional quality, labelling. The wording has been revised to indicate that the VA is responsible for regulating animal feed only in the context of ensuring that it is not a vehicle for disease transmission.

Article 3.4.8 sub-article 5.b. The *ad hoc* Group recognised that rules should cover ‘transport’ as well as the other elements already present.

Article 3.4.9 opening paragraph. In the context of the *ad hoc* Group mandate to review the chapter in the context of biological threats, the *ad hoc* Group agreed that the legal basis for the Competent Authority to manage diseases (which are listed) should be extended to emerging diseases and novel threats (which by their nature cannot be listed because their existence or cause may be unknown). As a result of this addition, the sentence on listing diseases has been separated for clarity of meaning.

Article 3.4.9 sub-article 2.b.iii. In the context of the *ad hoc* Group mandate to review the chapter in the context of biological threats, the *ad hoc* Group believed that contingency plans should include consideration of risks associated with accidental and deliberate introduction of biological threats and the wording here has been changed to reflect this.

Article 3.4.9 sub-article 2c. This additional wording is proposed here to address the reality that in many countries the mechanism for financing animal disease control measures may not be provided through the veterinary legislation but through other existing national funding systems.

Article 3.4.9 sub-article 3. The *ad hoc* Group proposed to expand this existing provision to investigate and control emerging diseases to include novel threats, in particular the accidental or deliberate introduction of biological agents, using a risk-based approach. This creates awareness of such threats and gives the Veterinary Authority the leeway to act without being prescriptive.

Article 3.4.11. It was realised out that the TAHC glossary includes a definition for *veterinary medicinal products* and that definition is already worded to include veterinary medicines and biologicals. Therefore, to foster consistency throughout the code and to avoid lack of clarity it is proposed that wherever the term ‘veterinary medicines and biologicals’ appears in Chapter 3.4, it should be replaced by ‘veterinary medicinal products’.

Article 3.4.11 sub-article 1.b. The *ad hoc* Group recognized this as another appropriate place to raise awareness about the importance of regulating laboratory biosafety and biosecurity in the context of biological threat reduction, in this case relating to the use of biological agents for vaccine production.

Article 3.4.11 sub-article 2.b. The *ad hoc* Group proposes deletion, realizing that the establishment of drug withdrawal times had nothing to do with the regulation of raw materials and has moved this important item to a more logical location (sub-article 3.b.iii).

Article 3.4.11 sub-article 2.c (now new 2.b). The *ad hoc* Group believed that the term ‘requirements for substances’ was inappropriate as it sounded as if the sub-article was requiring the substances rather than regulating or restricting them, so the term was changed to ‘restrictions on substances’. Also, the *ad hoc* Group proposed additional wording in this sub-article for clarification as the *ad hoc* Group believed that the meaning of the sentence was not especially clear when referring only to ‘veterinary checks’, a broad and vague term.

Article 3.4.11 new sub-article 3.b.iii. The reference to withdrawal periods was moved here from sub-article 2.b, as the establishment of withdrawal times is a condition of marketing authorisation.

Article 3.4.11 sub-article 3.d.i. The use of the word ‘role’ lacked clarity. It is the function of the law to assign responsibilities to specific actors to establish accountability and the use of ‘responsibility’ here rather than ‘role’ addresses that more clearly.

Article 3.4.11 sub-article 4 deleted. The *ad hoc* Group believed that sub-article 4 was not necessary to include because sub-article 1.b of Article 3.4.11 (General Measures) establishes the legal basis for regulation of manufactured and imported veterinary medicinal products and the details for the conduct of clinical trials would fall under that umbrella. Further many countries would not have the capacity or resources to conduct clinical and would accept products on the basis of equivalency authorisations as covered in the preceding sub-article.

Article 3.4.11 sub-article 5 (formerly 6) c. Reworded to specifically identify veterinarians as distinct from other professionals (e.g., licensed pharmacists) who can engage in commerce of prescription drugs.

Article 3.4.11 sub-article 5 (formerly 6) d. The *ad hoc* Group believed that in the context of AMR, the issue of withdrawal times was important enough to create an obligation for manufacturers to establish withdrawal times as a condition of marketing authorisation in sub-article 3 above but also here to note the obligation for veterinarians and veterinary paraprofessionals to alert end users about withdrawal periods when prescribing or dispensing antimicrobials and for end users to observe withdrawal those withdrawal periods. This is consistent with Chapter 6.9 of the TAHC.

Annex III – b (contd)

Article 3.4.12 opening paragraph. In the context of biological threat reduction and the known history of incidents of intentional contamination of food, the *ad hoc* Group proposes additional wording here to raise awareness of the risk of accidental or deliberate contamination events when acting to safeguard the human food production chain.

Article 3.4.12 new sub-article 1.b. Given the importance of veterinary ante- and post-mortem inspection to food safety and the surveillance value of inspection data for the Veterinary Authority, the *ad hoc* Group expressed surprise that veterinary inspection was not explicitly mentioned as a general provision of food safety legislation in Chapter 3.4. Therefore, this new wording is being proposed to create an obligation for the conduct of veterinary ante- and post-mortem inspections.

Article 3.4.12 new sub-article 1.c. As primary production is not defined in the TAHC and there is some debate about when primary production ends, the *ad hoc* Group believed that for the sake of clarity, the obligation for recording all significant animal and public health events should be explicitly applied to primary production and slaughter, consistent with the new reference to ante- and post- mortem inspection in the preceding new sub-article 1.b.

Article 3.4.12 new sub-article 1.e. It is proposed that ‘or’ be changed to ‘and’ to improve clarity here.

Article 3.4.12 new sub-article 1.f. The reference to ‘audit’ has been moved here from sub-article 2 which follows, so it will apply more broadly to all facilities and not just limited to product as originally presented.

Article 3.4.12 sub-articles 2.a and 2.b. These sub-articles were consolidated and moved to the General provisions section above (Article 3.4.12 new sub-article 1.f).

Article 3.4.12 new sub-article 2.a. In the context of ensuring that the legislation addresses health standards during processing of products of animal origin intended for human consumption, the *ad hoc* Group felt believed it was appropriate to be more explicit in this sub-article, highlighting disease control and monitoring of maximum residue limits.

Article 3.4.12 new sub-article 2.b. It is proposed that ‘or’ be changed to ‘and’ to improve clarity.

Article 3.4.13 new second paragraph. In addition to Section 5 of the TAHC, the *ad hoc* Group identified Chapter 2.1 as also being an important reference in regard to risk analysis when developing legislation to provide a basis for actions to address import procedures.

“BTR brochure” for OIE Delegates

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 population³. 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, as well as on the economy.

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, in a multisectoral fashion, i.e., coordinating 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.

³ From, The OIE Biological Threat Reduction Strategy – Strengthening Global Biological Security, Paris, October 2015, http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/EN_FINAL_Biothreat_Reduction_Strategy_OCT2015.pdf

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-use⁴). 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.

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 Convention⁵, 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;

⁴ 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.

⁵ 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.'

- 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).

Implementation in national legislation⁶

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;

⁶ 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

Annex IV (contd)

- Jurisdiction;
- Laboratory biosafety and biosecurity;
- Transfer controls;
- Registration and audit of labs or bodies holding listed biological agents and toxins;
- 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 defined by the OIE 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;
- Licencing 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.

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 Unit⁷;
- 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.

⁷ 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.

The OIE Veterinary Legislation Support Programme

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 initiated 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/>

SIDEBAR: 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 sobering⁸. 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.

⁸ 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](https://doi.org/10.4172/2157-2526.S12-001)

