



Laboratories and the PVS Pathway

**From OIE Standards to
Improved Compliance and
Capacity Building**

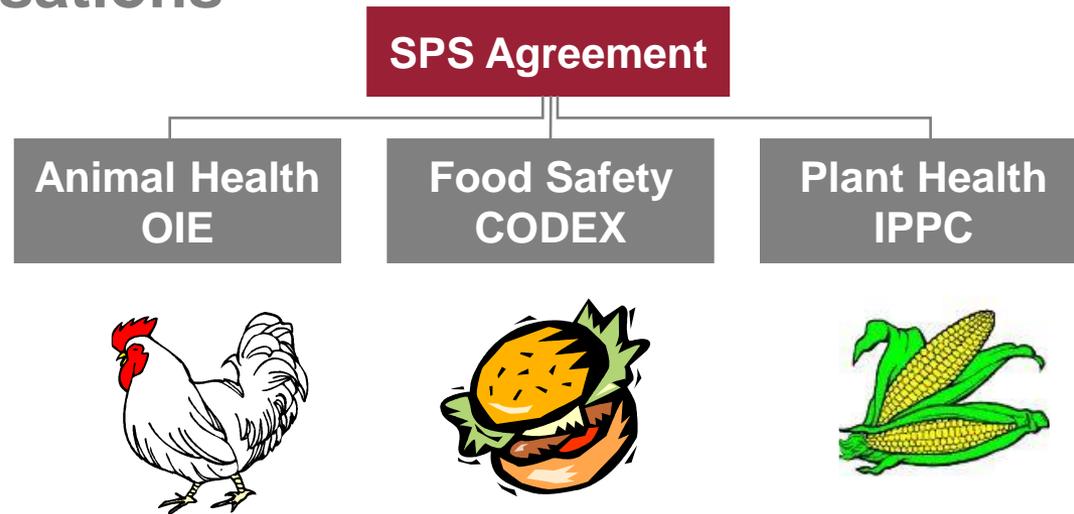


Jennifer Lasley, MPH
Scientific and Technical Department
OIE Headquarters



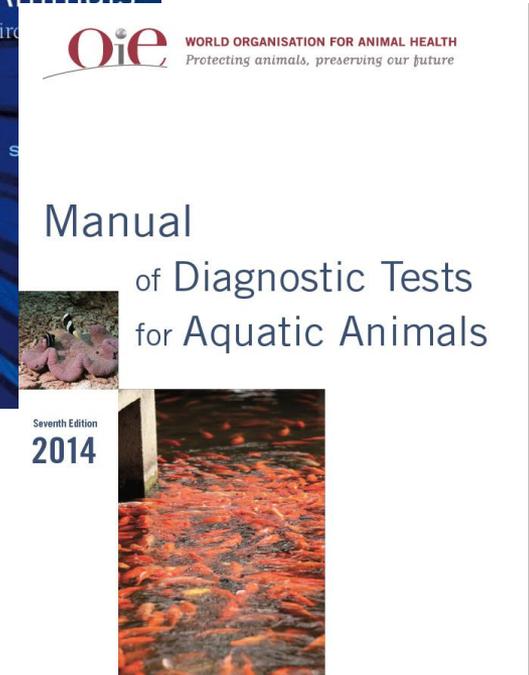
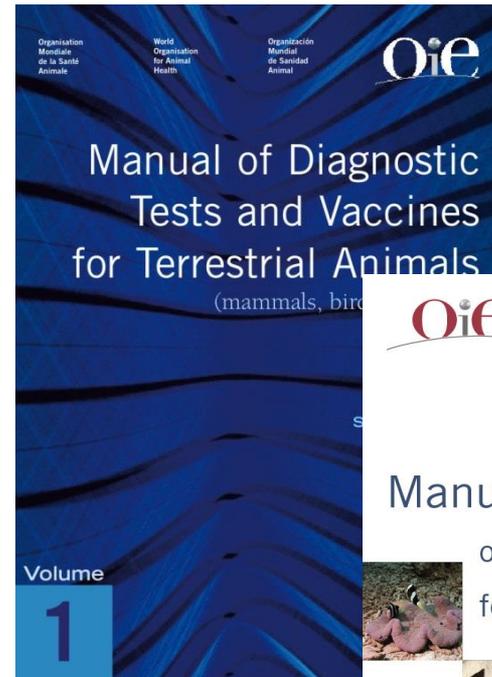
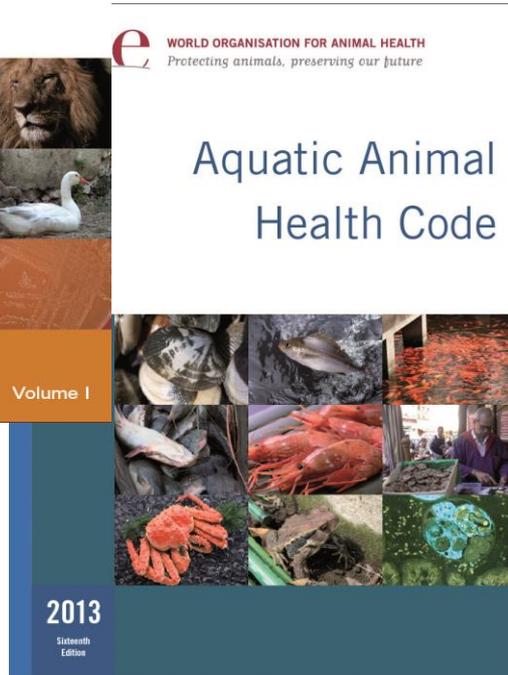
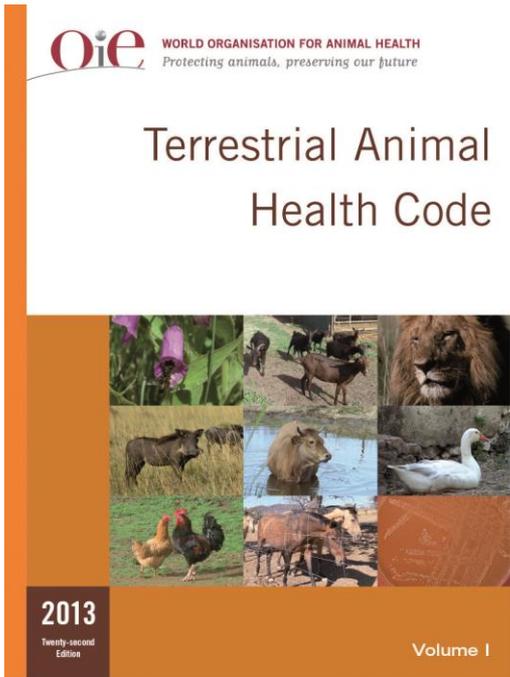
OIE International Standards

International standard setting organisations



- > OIE international standards, guidelines and recommendations for animal health (including zoonoses)
- > Including standards on quality of Veterinary Services and/or Aquatic Animal Health Services

OIE International Standards



OIE PVS Pathway

**is a continuous process aiming
to sustainably improve compliance
of Veterinary Services with international standards**

- > **The PVS Pathway is globally recognised as a:**

*“system of measurement and evaluation
that is an effective foundation
for improving animal and public health
at the national, regional, and international levels”*

**Chris Elias, President of the Global Development
Program, Bill & Melinda Gates Foundation, OIE World
Assembly, 2013**



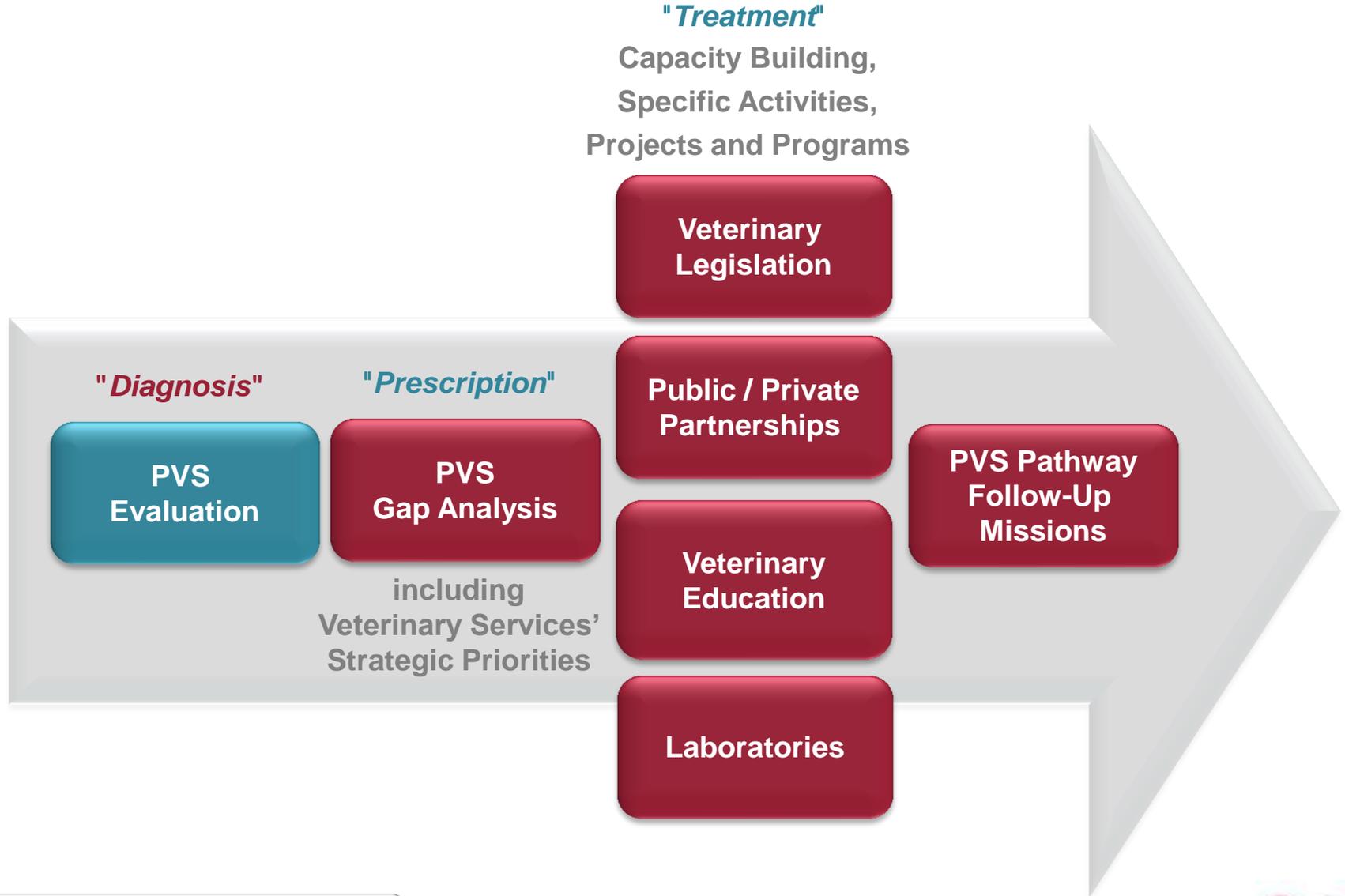


SO...
What about laboratories?

> **Laboratory**

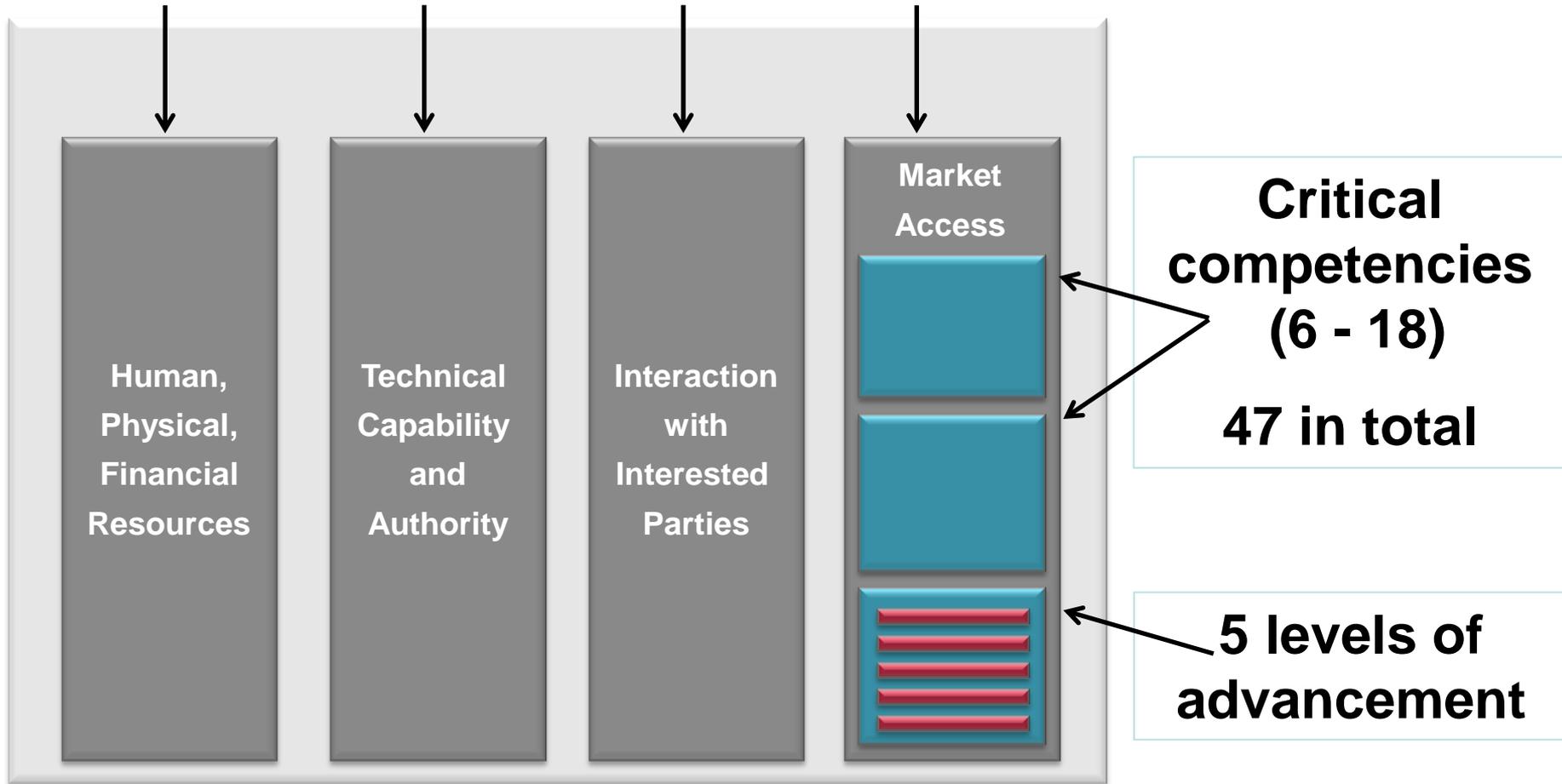
- > means a properly equipped institution staffed by technically competent personnel under the control of a specialist in veterinary diagnostic methods, who is responsible for the validity of the results.
- > The Veterinary Authority approves and monitors such laboratories with regard to the diagnostic tests required for international trade

The PVS Pathway



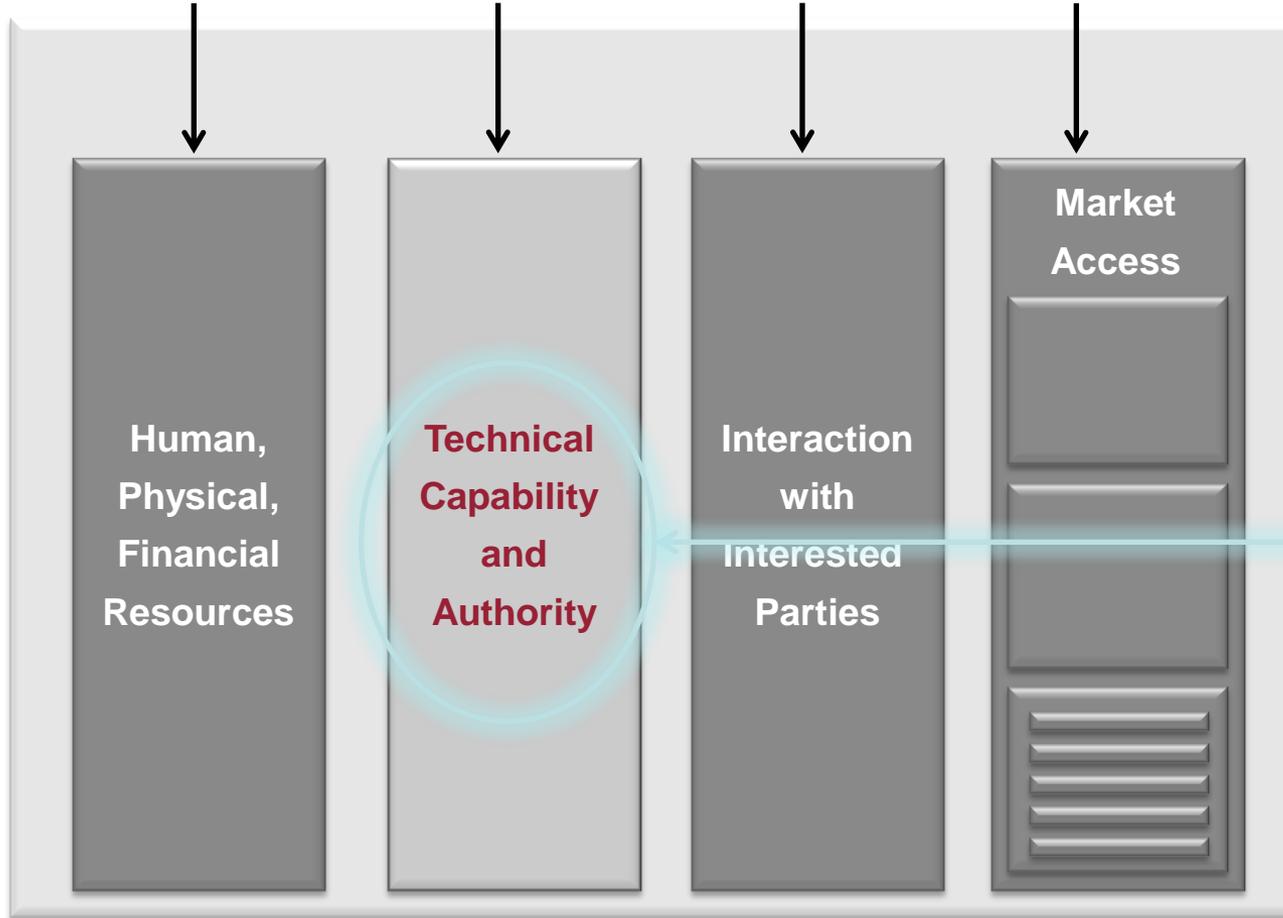
OIE PVS Evaluation

4 fundamental components



OIE PVS Evaluation

4 fundamental components



- > **II.1A: Access to veterinary laboratory diagnosis**
- > **II.1B: Suitability of national laboratory infrastructures**
- > **II-2: Laboratory quality assurance**

OIE PVS Evaluation – II-1A Access

II-1 Veterinary laboratory diagnosis	Levels of advancement
<p>A. Access to veterinary laboratory diagnosis</p>	<p>1. Disease diagnosis is almost always conducted by clinical means only, with no access to and use of a <i>laboratory</i> to obtain a correct diagnosis.</p>
<p>The authority and capability of the VS to have access to laboratory diagnosis in order to identify and record pathogenic agents, including those relevant for public health, that can adversely affect <i>animals</i> and animal products.</p>	<p>2. For major <i>zoonoses</i> and <i>diseases</i> of national economic importance, the VS have access to and use a <i>laboratory</i> to obtain a correct diagnosis.</p>
	<p>3. For other <i>zoonoses</i> and <i>diseases</i> present in the country, the VS have access to and use a <i>laboratory</i> to obtain a correct diagnosis.</p>
	<p>4. For <i>diseases</i> of zoonotic or economic importance not present in the country, but known to exist in the region and/ or that could enter the country, the VS have access to and use a <i>laboratory</i> to obtain a correct diagnosis.</p>
	<p>5. In the case of new and <i>emerging diseases</i> in the region or world, the VS have access to and use a network of national or international reference laboratories (e.g. an OIE Reference Laboratory) to obtain a correct diagnosis.</p>

OIE PVS Evaluation – II-1B Infrastructure

II-1 Veterinary laboratory diagnosis	Levels of advancement
B. Suitability of national laboratory infrastructures	1. The national laboratory infrastructure does not meet the need of the VS.
The sustainability, effectiveness and efficiency of the national (public and private) laboratory infrastructures to service the needs of the VS.	2. The national laboratory infrastructure meets partially the needs of the VS, but is not entirely sustainable, as organisational deficiencies with regard to the effective and efficient management of resources and infrastructure (including maintenance) are apparent.
	3. The national laboratory infrastructure generally meets the needs of the VS. Resources and organisation appear to be managed effectively and efficiently, but their regular funding is inadequate to support a sustainable and regularly maintained infrastructure.
	4. The national laboratory infrastructure generally meets the needs of the VS and is subject to timely maintenance programmes but needs new investments in certain aspects (e.g. accessibility to laboratories, number or type of analyses).
	5. The national laboratory infrastructure meets the needs of the VS, and is sustainable and regularly audited.

OIE PVS Evaluation – II-2 Quality Assurance

II-2 Laboratory quality assurance (QA)	Levels of advancement
<p>The quality of laboratories (that conduct diagnostic testing or analysis for chemical residues, antimicrobial residues, toxins, or tests for, biological efficacy, etc.) as measured by the use of formal QA systems including, but not limited to, participation in relevant proficiency testing programmes.</p>	1. No laboratories used by the public sector VS are using formal QA systems.
	2. Some laboratories used by the public sector VS are using formal QA systems.
	3. All laboratories used by the public sector VS are using formal QA systems.
	4. All the laboratories used by the public sector VS and most or all private laboratories are using formal QA systems.
	5. All the laboratories used by the public sector VS and most or all private laboratories are using formal QA programmes that meet OIE, ISO 17025, or equivalent QA standard guidelines.

The PVS Pathway



PVS Gap Analysis

1

- Determine and confirm the country's priorities

2

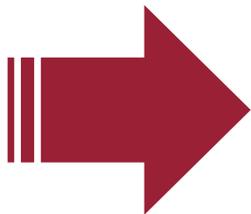
- Define the expected results for each priority

3

- Determine the activities required to reach the desired level of compliance to standards for Critical Competencies

4

- Determine corresponding human, physical & financial resources



Veterinary Services Annual budget for the next 5 years (including exceptional investments)

⇔ **Cost of compliance with international standards**

PVS Gap Analysis – 5 Pillars

PVS Gap Analysis (*PVS Costing Tool*)

Pillars and Critical Competency Cards

Trade

Veterinary
Public Health

Animal Health

Veterinary
Laboratories

Management
of Veterinary
Services
including
Regulatory
Services

Cost Estimation Cards

Trade 1 Trade 8

VPH 1 VPH 6

AH 1 AH 5

LAB 1 LAB 3

MVS 1 MVS 19

PVS Gap Analysis – Veterinary Laboratories

PVS Gap Analysis (*PVS Costing Tool*)

Pillars and Critical Competency Cards

Trade

Veterinary
Public Health

Animal Health

Veterinary
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Management
of Veterinary
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including
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Cost Estimation Cards

Trade 1

Trade 8

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AH 5

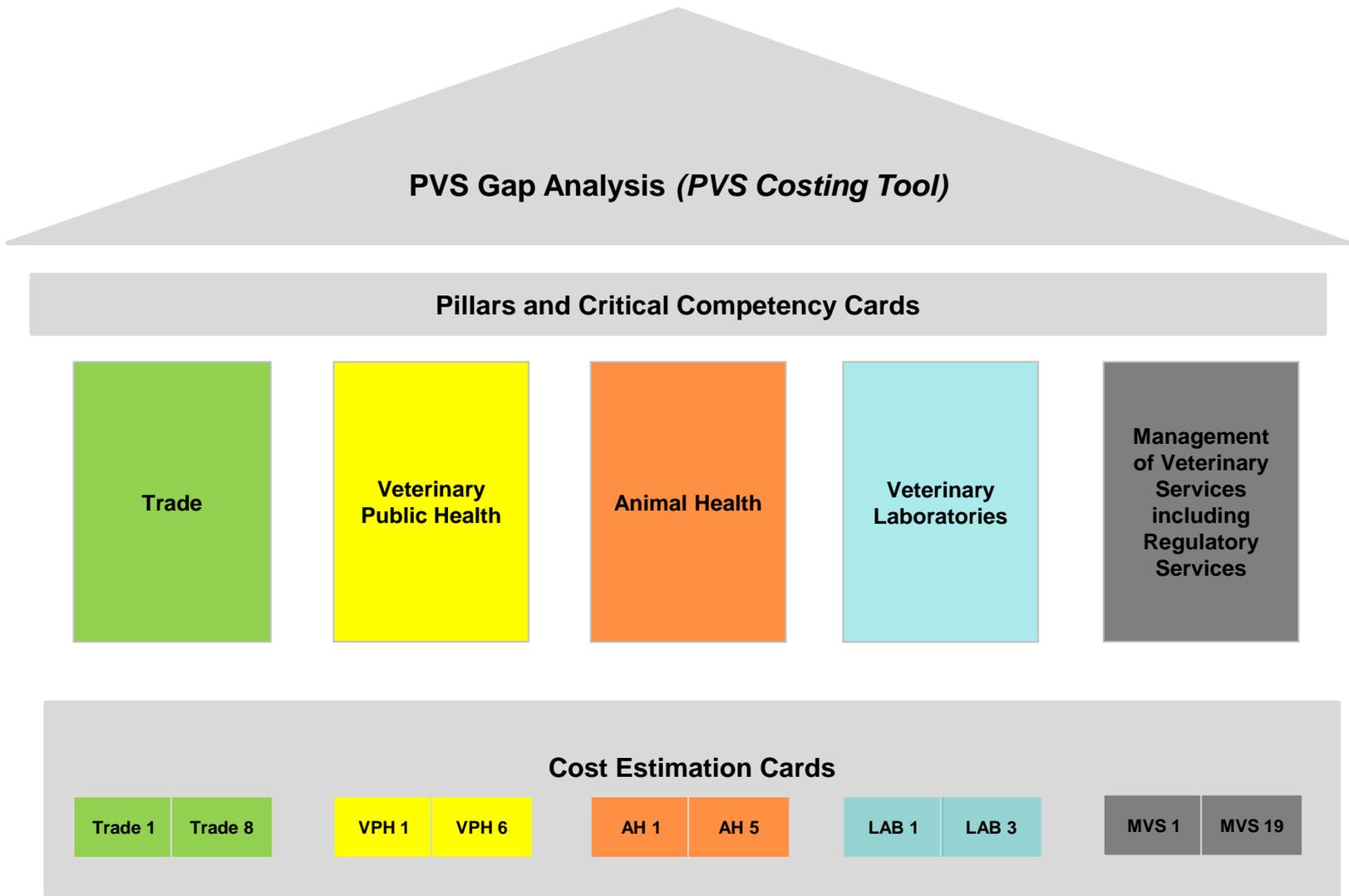
LAB 1

LAB 3

MVS 1

MVS 19

Minimum Objective for Veterinary Laboratories



LAB 1 – II-1. Veterinary laboratory diagnosis

A. Access to veterinary laboratory diagnosis

1. Specific objective (Critical Competency)		
<i>The authority and capability of the VS to have access to laboratory diagnosis in order to identify and record pathogenic agents, including those relevant for public health, that can adversely affect animals and animal products.</i>		
2. Result (Expected level of advancement)		
1. Disease diagnosis is almost always conducted by clinical means only, with no access to and use of a laboratory to obtain a correct diagnosis.		
2. For major zoonoses and diseases of national economic importance, the VS have access to and use a laboratory to obtain a correct diagnosis.		
3. For other zoonoses and diseases present in the country, the VS have access to and use a laboratory to obtain a correct diagnosis.		
4. For diseases of zoonotic or economic importance not present in the country, but known to exist in the region and/or that could enter the country, the VS have access to and use a laboratory to obtain a correct diagnosis.		
5. In the case of new and emerging diseases in the region or world, the VS have access to and use a network of national or international reference laboratories (e.g. an OIE Reference Laboratory) to obtain a correct diagnosis.		
3. Strategy (if relevant)		
Most of tests will be made in Libya for purpose of national independence and availability of laboratory infrastructure		
4. Activities to implement (chronological)		
Specific activities	<ul style="list-style-type: none"> - Ensure relevant agreements with relevant accredited laboratories for tests that may not be done or confirmed in Libya: for instance RVF, HPAI, doping for horse racing, some residue testing or pesticides, AHS, radionucleides - Ensure budget of the VS necessary to perform 100 000 serology (mainly Elisa type) and 10 000 PCR tests (supposed 10 % confirmation of serology) in order to be able to implement active surveillance programs and post vaccination serological control - Ensure budget of the VS necessary for residues testing (15 000 tests /year) - Ensure budget of the VS for regular diagnostic for other tests 	
Activities linked to cross-cutting competencies	III.2 Consultation	
	IV.1, 2, 3. Legislation	
	I.3. Continuing Education	
	III.1 Communication	
	I.11. Management of resources and operations	
	III.3. Official representation	
5. Objectively verifiable indicators (OIE PVS or specific)		
- lab activity reports or lab results proving access to all range of analysis in the country or abroad		

LAB 2 – II-1. Veterinary laboratory diagnosis

B. Suitability of national laboratory infrastructures

1. Specific objective (Critical Competency)	
<i>The sustainability, effectiveness and efficiency of the national (public and private) laboratory infrastructures to service the needs of the VS.</i>	
2. Result (Expected level of advancement)	
1. The national laboratory infrastructure does not meet the need of the VS.	
2. The national laboratory infrastructure meets partially the needs of the VS, but is not entirely sustainable, as organisational deficiencies with regard to the effective and efficient management of resources and infrastructure (including maintenance) are apparent.	
3. The national laboratory infrastructure generally meets the needs of the VS. Resources and organisation appear to be managed effectively and efficiently, but their regular funding is inadequate to support a sustainable and regularly maintained infrastructure.	
4. The national laboratory infrastructure generally meets the needs of the VS and is subject to timely maintenance programmes but needs new investments in certain aspects (e.g. accessibility to laboratories, number or type of analyses).	
5. The national laboratory infrastructure meets the needs of the VS, and is sustainable and regularly audited.	
3. Strategy (if relevant)	
The VS will maintain 2 national laboratories (Tripoli and Benghazi) and 7 regional laboratories for AH. The rational of the laboratory network in the country, including those currently working on food safety outside the VS, should be assessed during the next five years.	
4. Activities to implement (chronological)	
Specific activities	<ul style="list-style-type: none"> - 2 central labs should be functional for all laboratory functions : they will be used for the active surveillance official programs (50 to 100 000 tests / year) - 7 regional laboratory should be functional for basic parasitology, bacteriology and serology: they will not be used for official programs, but only for clinical diagnostic, and prepared for further official program of brucellosis surveillance (possibly testing 6 000 000 Rose bengal) - carry-out an overall study of the laboratory system in Libya, including all laboratories for AH, food safety, and private sector (estimated international expertise of 3 experts during 3 weeks) - provide 20 months specialised training for laboratory staff (for virology, residues, immuno-fluorescence, immuno-histo-chemistry)
Activities linked to cross-cutting competencies	III.2 Consultation
	IV.1, 2, 3. Legislation
	I.3. Continuing Education
	III.1 Communication
	I.11. Management of resources and operations
	III.3. Official representation
5. Objectively verifiable indicators (OIE PVS or specific)	
- resources and functioning of national laboratory infrastructure	

LAB 3 – II-2. Laboratory quality assurance

1. Specific objective (Critical Competency)

The quality of laboratories (that conduct diagnosis testing or analysis for chemical residues, antimicrobial residues, toxins, or tests for biological efficacy, etc.) as measured by the use of formal QA systems including, but not limited to, participation in relevant proficiency testing programmes.

2. Result (Expected level of advancement)

1. No laboratories used by the public sector VS are using formal QA systems.

2. Some laboratories used by the public sector VS are using formal QA systems.

3. All laboratories used by the public sector VS are using formal QA systems.

4. All the laboratories used by the public sector VS and most or all private laboratories are using formal QA systems.

5. All the laboratories used by the public sector VS and most or all private laboratories are using formal QA programmes that meet OIE, ISO 17025, or equivalent QA standard guidelines.

3. Strategy (if relevant)

The 2 central laboratories should use formal QA systems which should pave the way for ISO 17025

4. Activities to implement (chronological)

	Specific activities	Organise quality assurance in the two central laboratories (estimated need on 24 weeks of international expertise and 10 months of specialised training during the next five years)
Activities linked to cross-cutting competencies	<i>III.2 Consultation</i>	
	<i>IV.1, 2, 3. Legislation</i>	
	<i>I.3. Continuing Education</i>	
	<i>III.1 Communication</i>	
	<i>I.11. Management of resources and operations</i>	
	<i>III.3. Official representation</i>	

5. Objectively verifiable indicators (OIE PVS or specific)

- QA procedures in the 2 central laboratories

VETERINARY LABORATORIES - 1 /
CC: II-1.A Access to veterinary laboratory diagnosis

Resources and Budget lines	Required Number	Unit Cost	Nb of years for amortisation	Annual Budget	Exceptional Budget
Material investments					
Buildings (m ²)					
<i>Maintenance cost per (m²)</i>		35	1		
<i>Renovation cost per (m²)</i>		250	15		
<i>Building cost per (m²)</i>		700	25		
Transport (Purchasing cost)					
<i>Motorbikes</i>			3		
<i>Cars</i>		10 000	5		
<i>4x4 vehicles</i>		20 000	5		
Telecommunication equipment set		200	4		
Office equipment set		600	5		
Other specific equipment					
Sub-total Material investments					
Non material expenditure					
Training					
<i>Specialised training (man-months / 5 years)</i>		2 500			
<i>Continuing education (man-days / year)</i>		123			
<i>National expertise (days/5 years)</i>		250			
<i>International expertise (weeks/5 years)</i>		7 500			
<i>Special funds (/ 5 years) for ...</i>					
Sub-total non material expenditure					
Salaries / year					
Veterinarians		14 000			
Other university degree		14 000			
Veterinary para-professionals		8 000			
Support staff		7 200			
Sub-total Salaries					
Consumable resources / year					
Administration		20%			
Travel allowances					
<i>staff within the country (man-days) / year</i>		100			
<i>drivers within the country (man-days) / year</i>		100			
<i>staff abroad (man-weeks) / year</i>		1 900			
Transport fees					
<i>Km or miles Motorbikes / year</i>					
<i>Km or miles cars / year</i>		0,14			
<i>Km or miles 4x4 vehicle / year</i>		0,30			
Specific costs					
<i>Targeted specific communication</i>					
<i>Consultation (number of 1 day meetings)</i>					
<i>Kits / reagents / vaccines</i>	100 000	10,00		1 000 000	
<i>pcr and others</i>	10 000	35,00		350 000	
<i>residue testing</i>	15 000	45,00		675 000	
Sub-total Consumable resources				2 025 000	
Delegated activities / year					
Sub-total Delegated activities					



VETERINARY LABORATORIES - 2 /
CC: II-1.B Suitability of the national veterinary network

Resources and Budget lines	Required Number	Unit Cost	Nb of years for amortisation	Annual Budget	Exceptional Budget
Material investments					
Buildings (m ²)					
<i>Maintenance cost per (m²)</i>		35	1		
<i>Renovation cost per (m²)</i>		250	15		
<i>Building cost per (m²)</i>		700	25		
Transport (Purchasing cost)					
<i>Motorbikes</i>			3		
<i>Cars</i>		10 000	5		
<i>4x4 vehicles</i>		20 000	5		
Telecommunication equipment set		200	4		
Office equipment set		600	5		
Other specific equipment					
Sub-total Material investments					
Non material expenditure					
Training					
<i>Specialised training (man-months / 5 years)</i>	20,0	2 500			50 000
<i>Continuing education (man-days / year)</i>		123			
<i>National expertise (days/5 years)</i>		250			
<i>International expertise (weeks/5 years)</i>	9,0	7 500			67 500
<i>Special funds (/ 5 years) for ...</i>					
Sub-total non material expenditure					117 500
Salaries / year					
Veterinarians		14 000			
Other university degree		14 000			
Veterinary para-professionals		8 000			
Support staff		7 200			
Sub-total Salaries					
Consumable resources / year					
Administration		20%			
Travel allowances					
<i>staff within the country (man-days) / year</i>		100			
<i>drivers within the country (man-days) / year</i>		100			
<i>staff abroad (man-weeks) / year</i>		1 900			
Transport fees					
<i>Km or miles Motorbikes / year</i>					
<i>Km or miles cars / year</i>		0,14			
<i>Km or miles 4x4 vehicle / year</i>		0,30			
Specific costs					
<i>Targeted specific communication</i>					
<i>Consultation (number of 1 day meetings)</i>					
<i>Kits / reagents / vaccines</i>					
Sub-total Consumable resources					
Delegated activities / year					
Sub-total Delegated activities					



VETERINARY LABORATORIES - 3 / CC: II-2. Laboratory quality assurance

Resources and Budget lines	Required Number	Unit Cost	Nb of years for amortisation	Annual Budget	Exceptional Budget
Material investments					
Buildings (m ²)					
<i>Maintenance cost per (m²)</i>		35	1		
<i>Renovation cost per (m²)</i>		250	15		
<i>Building cost per (m²)</i>		700	25		
Transport (Purchasing cost)					
<i>Motorbikes</i>			3		
<i>Cars</i>		10 000	5		
<i>4x4 vehicles</i>		20 000	5		
Telecommunication equipment set		200	4		
Office equipment set		600	5		
Other specific equipment					
Sub-total Material investments					
Non material expenditure					
Training					
<i>Specialised training (man-months / 5 years)</i>	10,0	2 500			25 000
<i>Continuing education (man-days / year)</i>		123			
<i>National expertise (days/5 years)</i>		250			
<i>International expertise (weeks/5 years)</i>	24,0	7 500			180 000
<i>Special funds (/ 5 years) for ...</i>					
Sub-total non material expenditure					205 000
Salaries / year					
Veterinarians		14 000			
Other university degree		14 000			
Veterinary para-professionals		8 000			
Support staff		7 200			
Sub-total Salaries					
Consumable resources / year					
Administration		20%			
Travel allowances					
<i>staff within the country (man-days) / year</i>		100			
<i>drivers within the country (man-days) / year</i>		100			
<i>staff abroad (man-weeks) / year</i>		1 900			
Transport fees					
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<i>Km or miles 4x4 vehicle / year</i>		0,30			
Specific costs					
<i>Targeted specific communication</i>					
<i>Consultation (number of 1 day meetings)</i>					
<i>Kits / reagents / vaccines</i>					
Sub-total Consumable resources					
Delegated activities / year					
Sub-total Delegated activities					



What are the limits of the PVS Gap Analysis in terms of laboratories?

What it does

Analysis of the laboratory's resources based on needs arising from the **priorities defined** in the previous pillars/official programmes:

- **Trade** (e.g., specific programmes for zoning or compartmentalisation)
- **Animal health** (e.g., disease surveillance programmes, monitoring of vaccination efficacy, etc.)
- **Veterinary public health** (e.g., residue testing, food safety programmes, etc.)

Assessment of the **number & types of laboratory analysis required** for official programmes

Indicative operational budget for 5 years to enable VS to function appropriately

What it doesn't do

Does not calculate the cost of the whole veterinary laboratory network

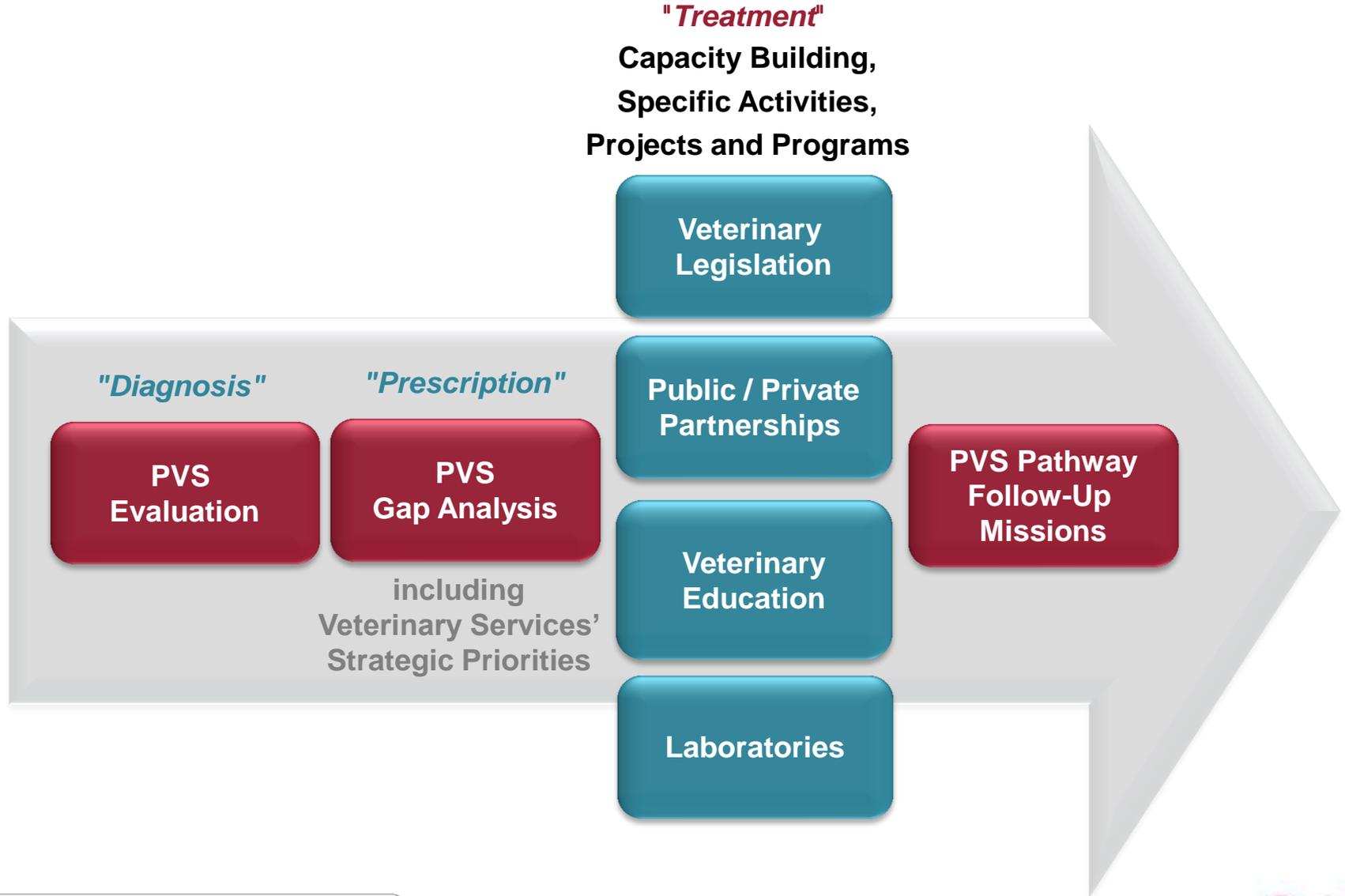
Is not a detailed and specialised study of each laboratory

Does not address strategic needs related to laboratories

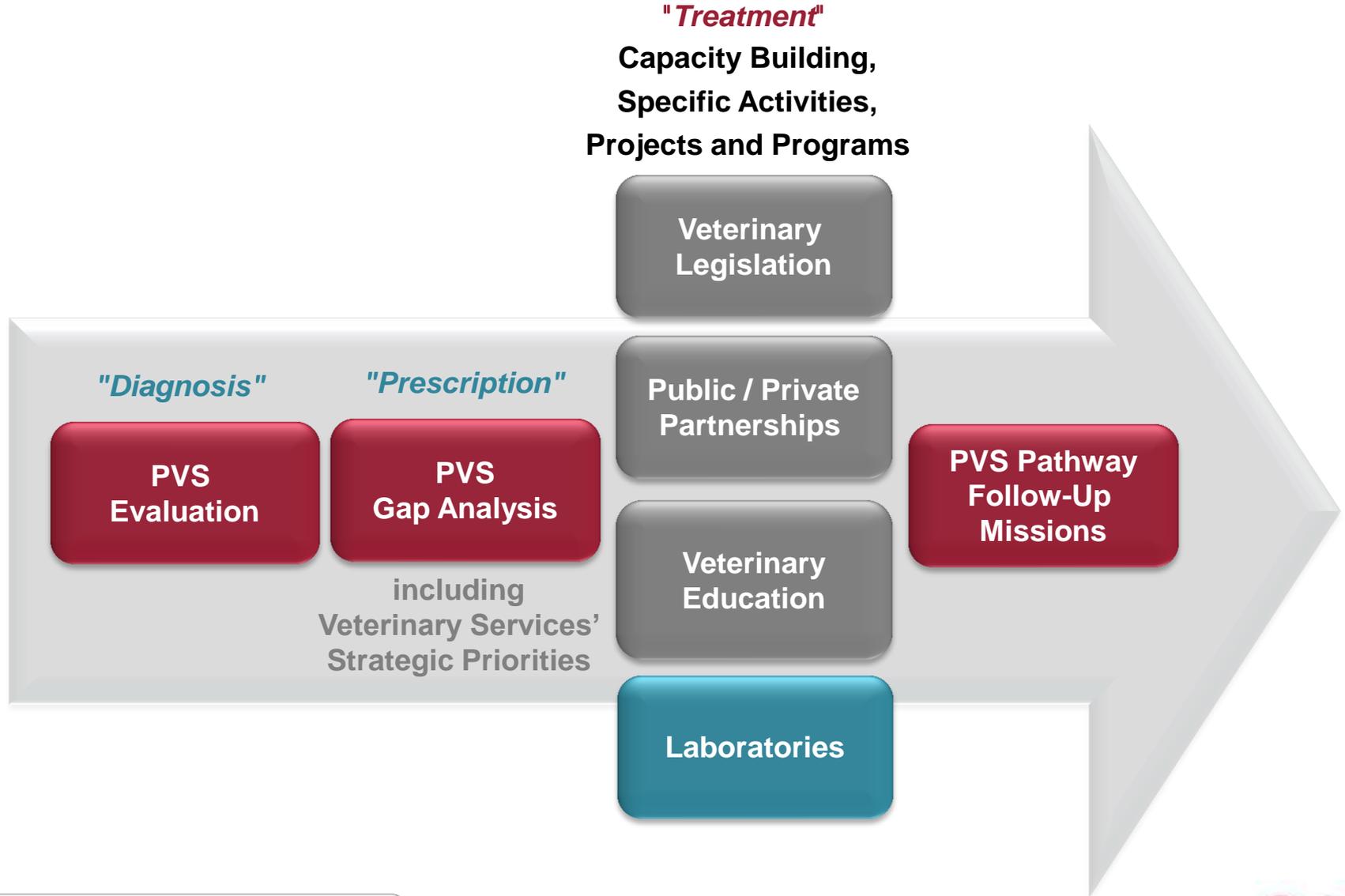
Is not a fine analysis of the relevance of / need for a national laboratory network

The national laboratory network **cannot be considered as a priority** in a PVS Gap Analysis

The PVS Pathway



The PVS Pathway



OIE National Focal Point Programme for Veterinary Laboratories

- To support of the OIE Delegate to fulfill his/her rights and responsibilities to OIE as set out in the Terms of Reference
- To present relevant OIE international standards and familiarise them with current or developing standards
- To provide tools to comply with OIE standards, implement activities and transfer knowledge at all levels of the laboratory network

PVS Pathway Laboratory Mission

- Helps Veterinary Services:
 - allocate appropriate resources to the National Veterinary Laboratory network
 - make strategic decisions to support accurate and timely diagnosis of animal diseases



PVS Laboratory Mission Manual

PVS Laboratory Tool



2013



> Helps Veterinary Services:



> **Stay tuned...**
> **more tomorrow**
> **morning!**

diseases

2013

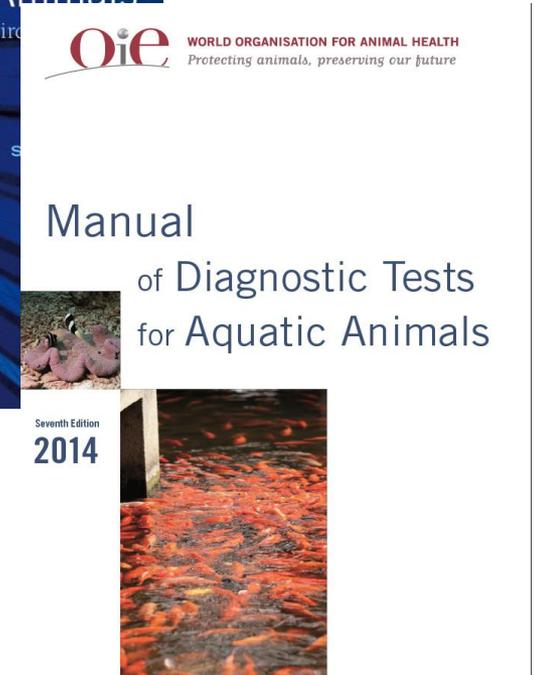
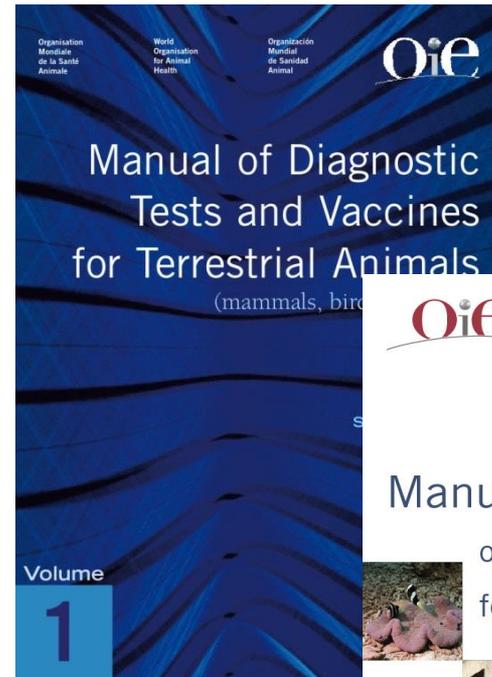
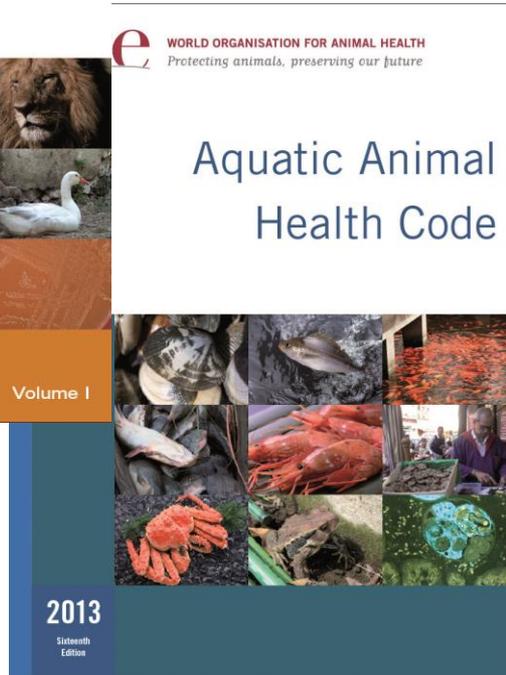
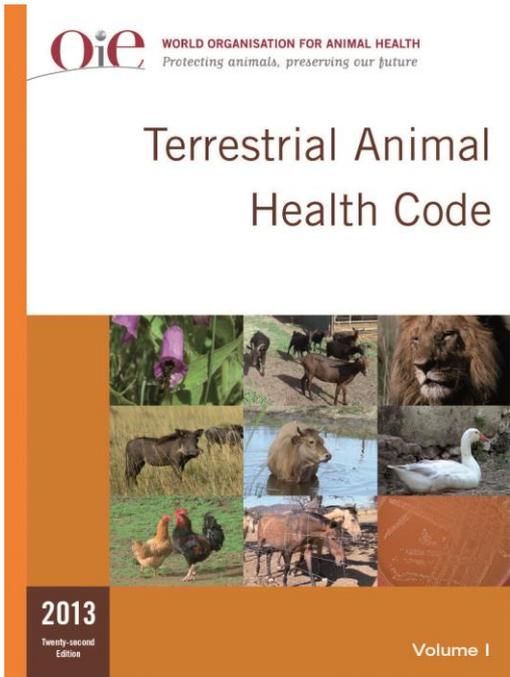




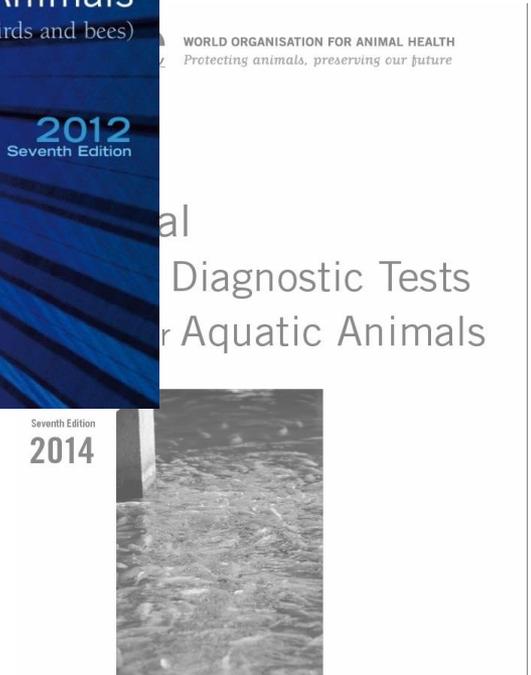
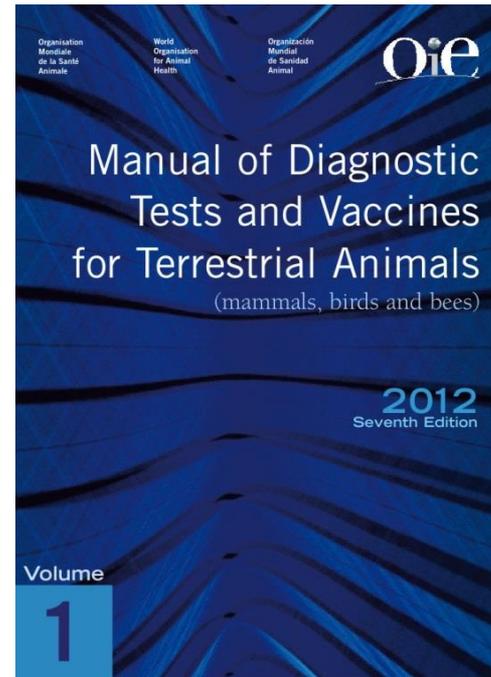
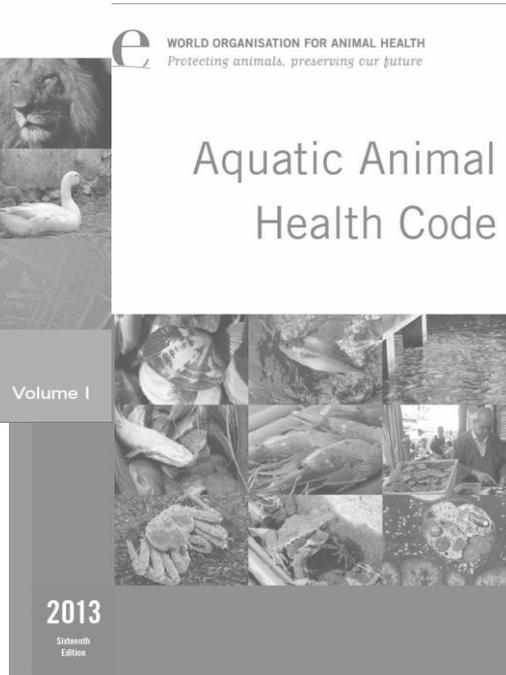
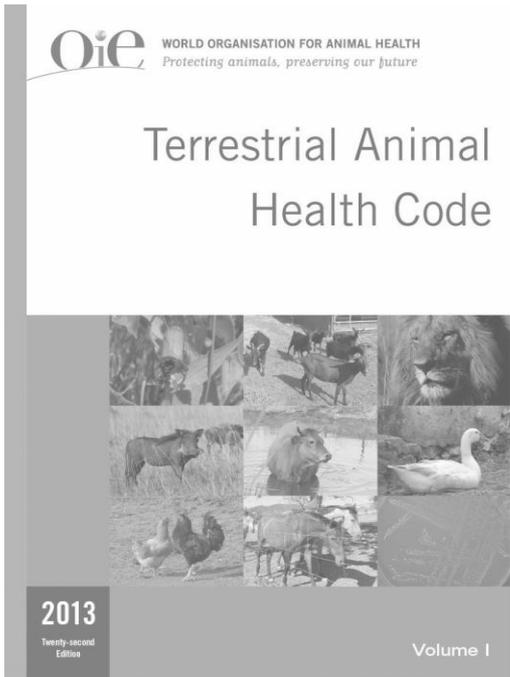
SO...

What about biosafety & biosecurity?

OIE International Standards



OIE International Standards



OIE Terrestrial Manual Introductory Chapters

- Chapter 1.1.0. [Management of veterinary laboratories](#) (NB: Version adopted in May 2015)
- Chapter 1.1.1. [Collection, submission and storage of diagnostic specimens](#) (NB: Version adopted in May 2013)
- Chapter 1.1.2. [Transport of specimens of animal origin](#) (NB: Version adopted in May 2013)
- Chapter 1.1.3. [Biosafety and biosecurity: standard for managing biological risk in the veterinary diagnostic laboratory and animal facilities](#) (NB: Version adopted in May 2015)
- Chapter 1.1.4. [Quality management in veterinary testing laboratories](#) (NB: Version adopted in May 2012)
- Chapter 1.1.5. [Principles and methods of validation of diagnostic assays for infectious diseases](#) (NB: Version adopted in May, 2013)
- Chapter 1.1.6. [Principles of veterinary vaccine production](#) (NB: Version adopted in May 2015)
- Chapter 1.1.7. [Tests for sterility and freedom from contamination of biological materials](#)
- Chapter 1.1.8. Minimum requirements for vaccine production facilities (under study)
- Chapter 1.1.9. Quality control of vaccines (under study)
- Chapter 1.1.10. [International standards for vaccine banks](#)

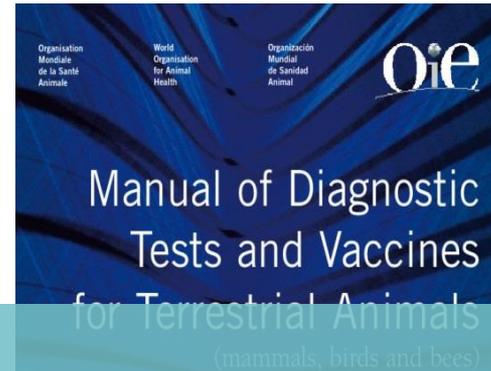
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OIE International Standards

Oie WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

Terrestrial Animal
Health Code



Manual of Diagnostic
Tests and Vaccines
for Terrestrial Animals
(mammals, birds and bees)

2012
Seventh Edition

**The OIE *Manual* is the tool
for Member Countries**

2013
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in regards to veterinary laboratories

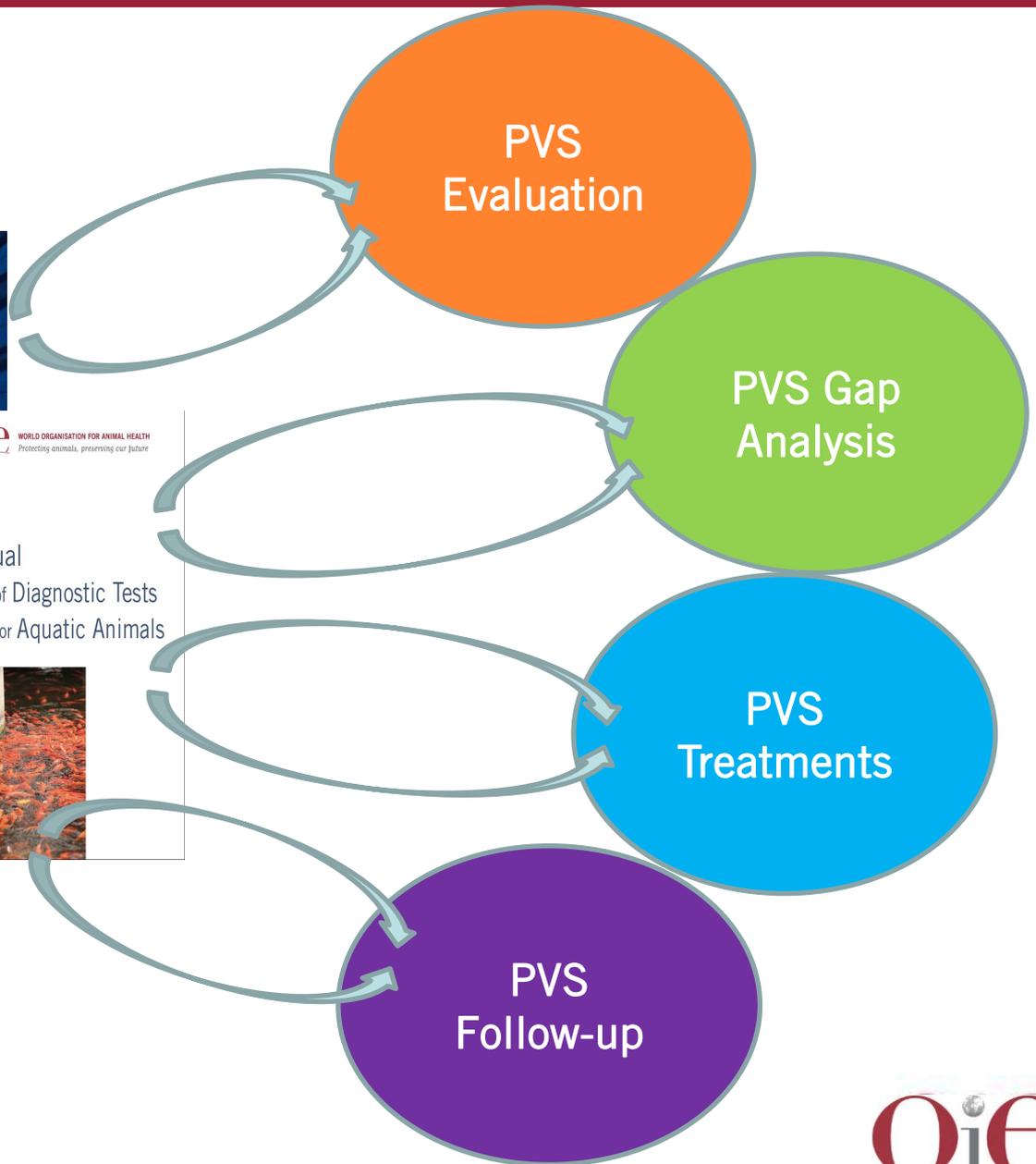
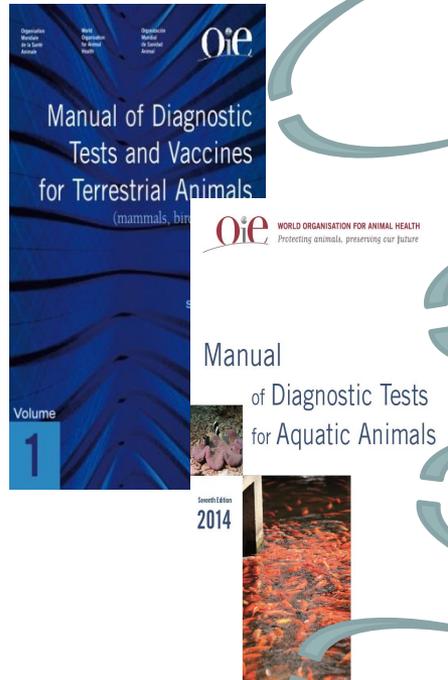
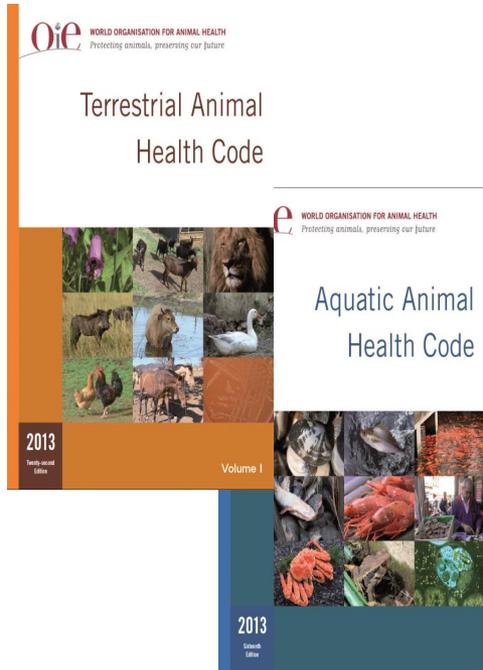


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OIE International Standards



Thank you

Jennifer Lasley, MPH

**OIE Project Coordinator
Scientific and Technical Department**

j.lasley@oie.int



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Protecting animals, preserving our future

