

# One Health Legislative Assessment Tool for AMR

## Background & Overview

ONE HEALTH QUADRIPARTITE COLLABORATION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization



World Organisation  
for Animal Health  
Founded as OIE



# Outline

- (1) The importance of legislation for AMR
- (2) Introduction to the OHLAT: development process, objectives, structure



# (1) The importance of legislation for AMR

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Food and Agriculture  
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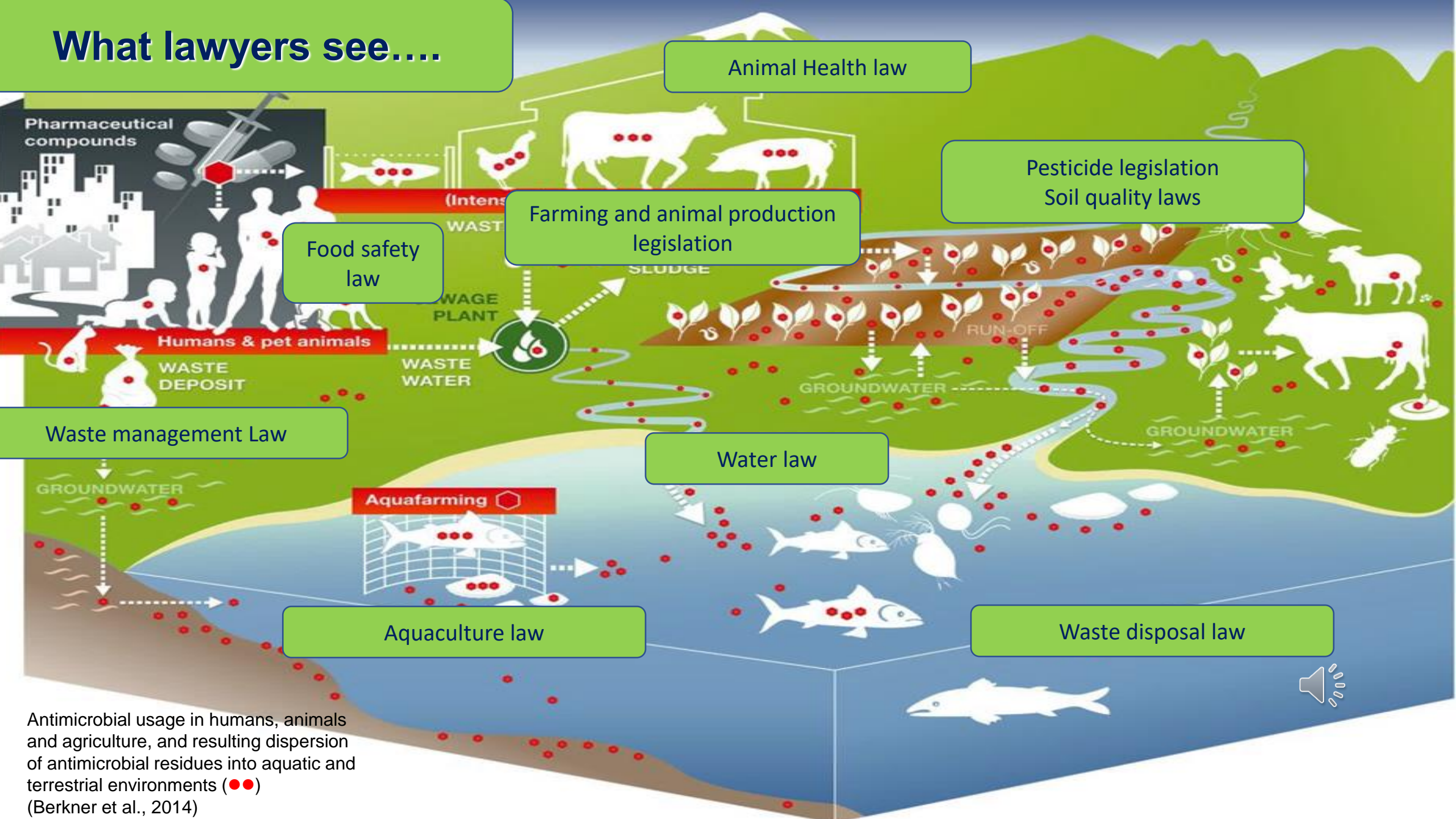
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# Why is legislation relevant for AMR?



# What lawyers see....



Animal Health law

Pesticide legislation  
Soil quality laws

Food safety law

Farming and animal production legislation

Waste management Law

Water law

Aquaculture law

Waste disposal law

Antimicrobial usage in humans, animals and agriculture, and resulting dispersion of antimicrobial residues into aquatic and terrestrial environments (●●)  
(Berkner et al., 2014)

Legislation turns policy objectives into clear obligations or legally enforceable mechanisms.



Legislation stipulates the roles of governments and stakeholders



# Legislation sets up mechanisms for coordination





Legislation establishes regulatory mechanisms for control



What can happen in the absence of legislation?



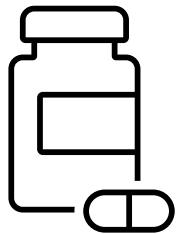
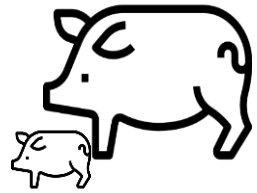
## Without legislation.....



Markets can be flooded with **substandard and falsified** antimicrobials

Inappropriate **prescription and use** of antimicrobials

Inappropriate use of **antimicrobials for growth promotion**



**Over the counter sale** of important antimicrobials

Government agencies, laboratories and practitioners may **refuse to share data**

**Release of antimicrobial waste** into nature



## Preliminary conclusions



- Legislation is instrumental to implement AMR policy objectives and make them enforceable and sustainable
- There are multiple legal areas relevant for AMR
- AMR considerations should be integrated across all the relevant sectors. This may require amendment of the legislation
- There is no need for specific AMR legislation to introduce most of the international relevant recommendations



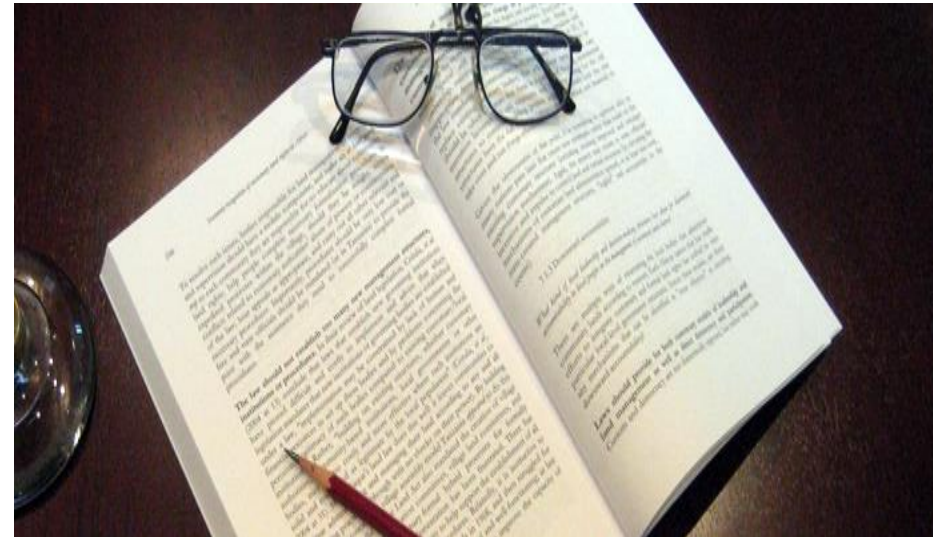
# **(2) Introduction to the One Health Legislative Assessment Tool for AMR: development process, objectives, structure**

ONE HEALTH QUADRIpartite COLLABORATION

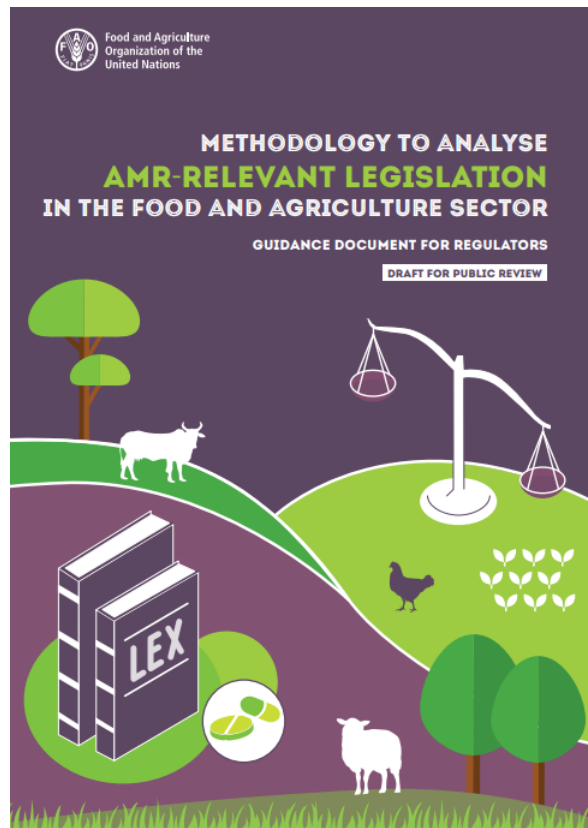


# 1) The AMR MPTF Legal Project

## Development and Piloting of a One Health Legislative Assessment Tool for AMR



# Background



## FAO Methodology to analyse AMR-relevant Legislation in the food and agriculture sectors (2015-2023)

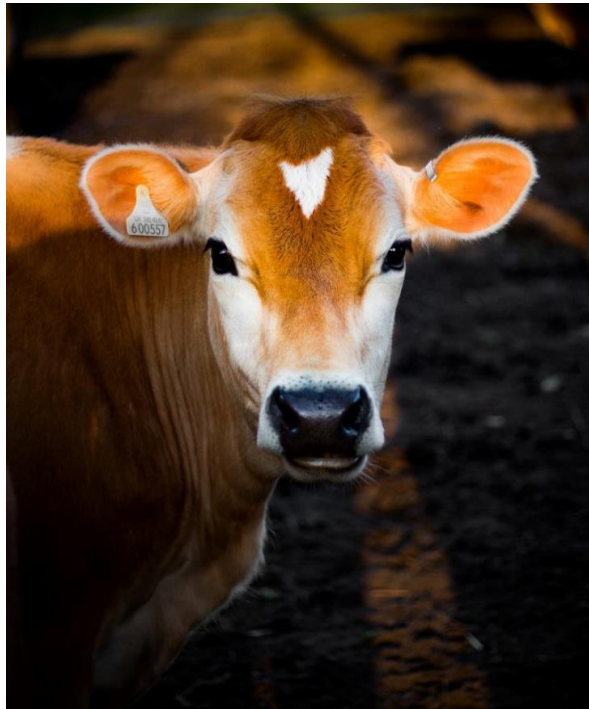
- Applied in 34 countries from 4 continents and 3 regional organization
- 5 regional workshops with over 45 countries participating



Demand for a One Health approach



## WOAH Veterinary Legislation Support Program (VLSP)



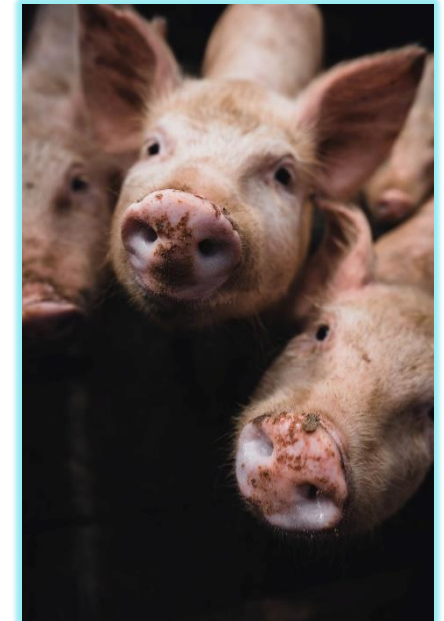
- VLSP = **targeted support of the WOAH PVS Pathway**, a continuous process to sustainably improve national Veterinary Services.
- For almost **3/4 of countries evaluated** through the PVS Pathway, Veterinary Services have **no – or limited – ability to regulate VMPs**.
- Identification of **weaknesses that have or may have an impact on AMR**.





## Since 2019: WOAAH (VLSP)-FAO collaboration on AMR

- ✓ review of the *FAO Methodology to analyse AMR-relevant legislation in the food and agriculture sector* (Guidance for national consultants)
- ✓ 1 joint pilot ‘VLSP AMR Identification mission’ (the Philippines)



### 2019: Pilot ‘VLSP AMR Questionnaire’

Comparison of the national legislation with the RECOMMENDATIONS of the WOAAH TERRESTRIAL CODE relevant for AMR:

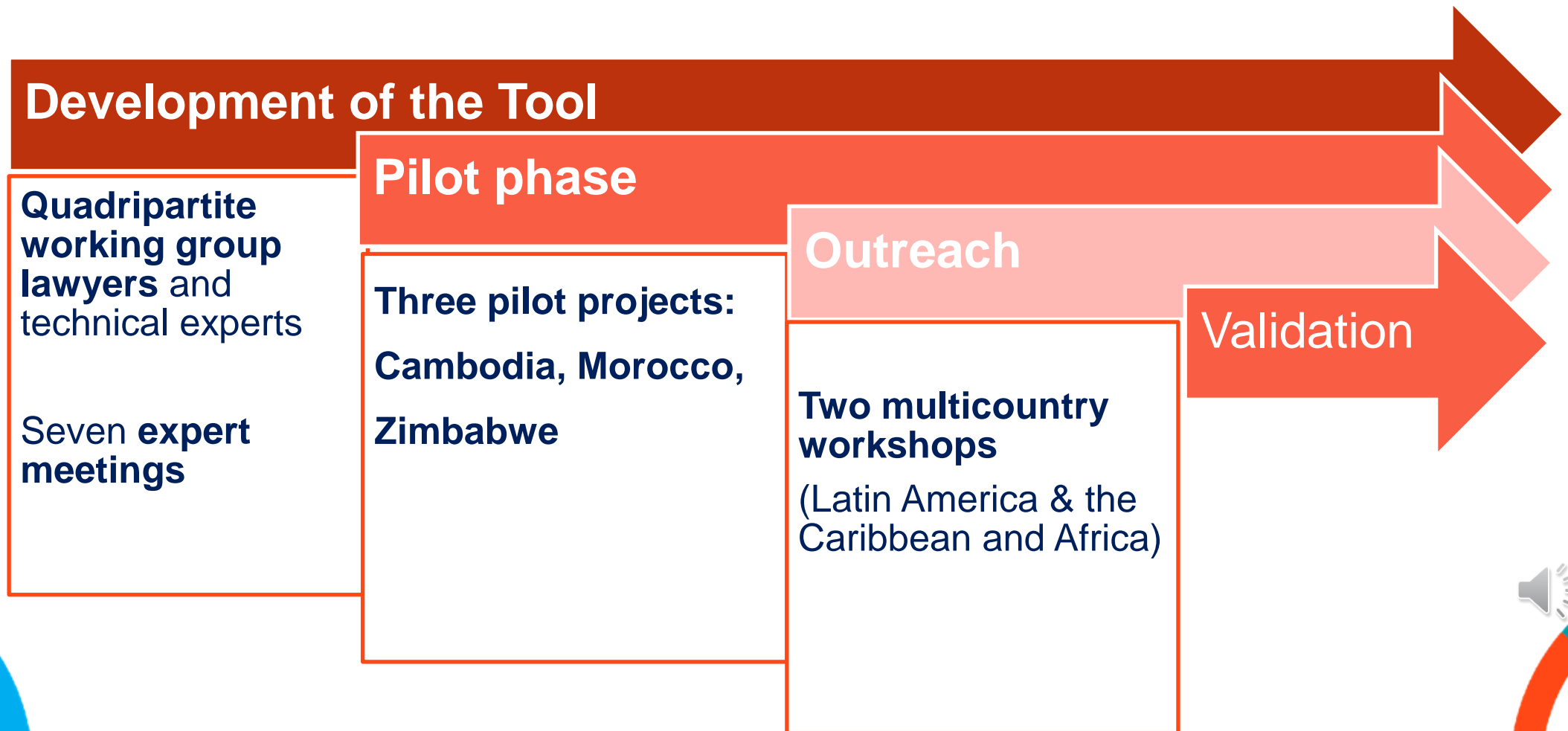
- for controlling AMR (Chapters 6.7., 6.8., 6.9., 6.10. and 6.11.)
- for the VS (Chapters 3.1. and 3.2.) in areas relevant to AMR
- for the veterinary legislation (Chapter 3.4.) in areas relevant to AMR



## 2) The One Health Legislative Assessment Tool for AMR



## Process 2020-2023



## Objectives

- Assess national legislation relevant for AMR, and identify gaps and opportunities for reform
- Facilitate an understanding of the sector-specific needs of each legal area relevant for AMR
- Contribute to AMR governance arrangements that are underpinned by a One Health approach
- It is **NOT a Guidance document**. It is based on existent international guidance by the different standard-setting organizations.

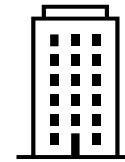


## What rules we take into consideration?



### Primary legislation (laws)

Legislative power: Parliament



### Secondary legislation

(i.e.: orders, decrees, by-laws)

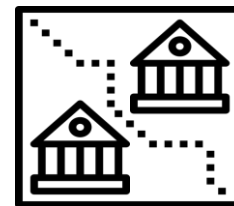
Executive power: Ministerial or administrative authority



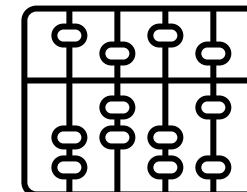
= “Legislation” in the broad sense



National / federal



Regional / decentralised



Self-regulation

## Chapters of the OHLAT



Governance



Human health



Food safety



Animal health and  
production



Pesticides



Plant health



Environment



## Internal Structure



All chapters follow a **common basic structure**:

- Background
- Where is it regulated?
- Key elements
- **Questions**



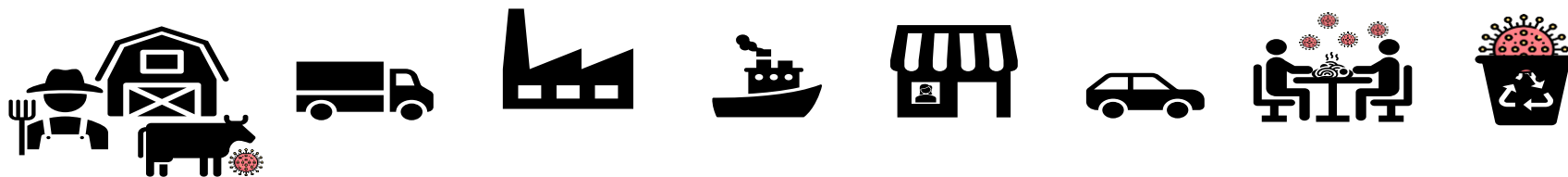
## CHAPTER 3.- FOOD SAFETY

*AMR implications at different stages of the food chain*



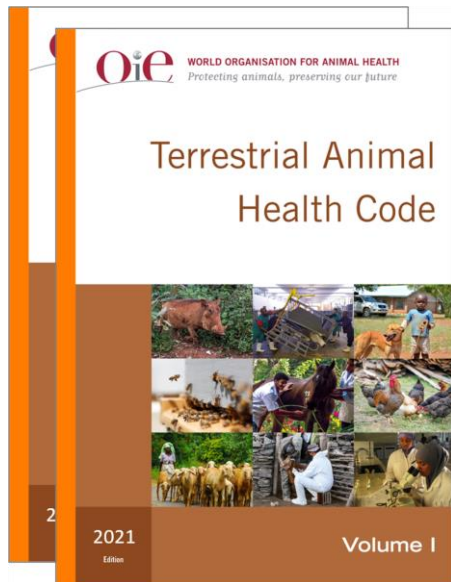
### EXAMPLE QUESTIONS

- Does legislation identify the authority responsible for a) issuing, establishing or setting an MRL for i) pesticides or ii) VMPs?
- Does legislation require the observance of withdrawal periods





## CHAPTER 4.- Animal health and production



Veterinary Medicinal Products (VMPs)



Animal feed

Animal health and production

### EXAMPLE QUESTIONS

Are VMPs regulated together with (in the same legal texts as) human medicines?

Does legislation prohibit the production, importation, distribution, sale and use of VMPs that are not authorised/registered?

# Application of the Tool

- Many options:
  - One chapter or selection of chapters at a time
  - Altogether as a Quadripartite effort
  - Animal Health and Production Chapter - WOAHP VLSP
  - Evolving methodologies – tailor to country's needs



# Thank you!



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