# Technical Reference Document Listing Antimicrobial Agents for Aquatic Species

Workshop on enhancing aquatic animal health and biosecurity

**Dr Dante Mateo** 

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Scientific Coordinator

Antimicrobial Resistance and Veterinary Products Department, WOAH



World Organisation for Animal Health

Organisation mondiale de la santé animale Organización Mundial de Sanidad Animal







## WOAH List – Background



FAO/OIE/WHO Expert Workshops on Non-Human Antimicrobial Usage and Antimicrobial Resistance (Geneva, 2003 and Oslo 2004) recommendation:



WHO List of critically important antimicrobial agents in human medicine

**OIE List of** critically important antimicrobial agents in veterinary medicine

Risk management (balance between animal health and welfare, and public health)

- OIE ad hoc Group on antimicrobial resistance, supported by a Collaborating Centre in Veterinary **Medicine Products**
- List adopted at the 75th General Session in May 2007 (Resolution No. XXVIII)



### WOAH List - Scope





#### WOAH List of Antimicrobial Agents of Veterinary Importance (January 2025)

The WOAH 1 International Committee unanimously adopted the List of Antimicrobial Agents of Veterinary Importance at its 75th General Session in May 2007 (Resolution No. XXVIII).

Antimicrobial agents are essential drugs for human and animal health and welfare. Antimicrobial resistance is a global public and animal health concern that is influenced by both human and non human antimicrobial usage. The human, animal and plant sectors have a shared responsibility to prevent or minimise antimicrobial resistance selection pressures on both human and non-human pathogens and reduce the spillover of antimicrobial resistance into the environment

The FAO 2/OIE /WHO 3 Expert Workshops on Non-Human Antimicrobial Usage and Antimicrobia Resistance held in Geneva, Switzerland, in December 2003 (Scientific Assessment) and in Oslo Norway, in March 2004 (Management Options) recommended that WOAH should develop a list of critically important antimicrobial agents in veterinary medicine and that WHO should also develop such a list of critically important antimicrobial agents in human medicine.

#### Conclusion No. 5 of the Oslo Workshop is as follows:

5. The concept of "critically important" classes of antimicrobials for humans should be pursued by WHO. The Workshop concluded that antimicrobials that are critically important in veterinary medicine should be identified, to omplement the identification of such antimicrobials used in human medicine Criteria for identification of these antimicrobials of critical importance in animals should be established and listed by OIF. The overlap of critical lists for appropriate balance to be struck between animal health needs and public

Following this recommendation, WOAH's ad hoc Group on antimicrobial resistance began working or this topic in November 2004. The terms of reference, aim of the list and methodology were endorse by the Biological Standards Commission in its January 2005 meeting and adopted by the International Committee in May 2005.

#### 2. Preparation of the draft list

The Director General of WOAH sent a questionnaire prepared by the ad hoc Group accompanied by a letter explaining the importance of the task to all WOAH Delegates and international organisations, having signed a Co-operation Agreement with WOAH in August 2005.

- World Organisation for Animal Health (founded as OIE). FAO: Food and Agriculture Organization of the United N

- Addresses antimicrobial agents authorised for use in foodproducing animals and non-food producing animals
- Does not include antimicrobial classes/sub classes only used in human medicine
- Does not include antimicrobial agents only used as growthpromoters
- Focuses currently on antibacterials used in veterinary medicine
- Includes only antimicrobial agents that are authorised for use as sole agents or as part of well-established combinations



## WOAH List - Categorisation criteria



**Criterion 1**: Response rate of a questionnaire regarding Veterinary Important Antimicrobial Agents (>50% identified the importance)

**Criterion 2:** Treatment essential against specific infections and lack of sufficient therapeutic alternatives

VCIA (Veterinary Critically Important Antimicrobial)

Both Criteria (1 & 2) are met

VHIA (Veterinary Highly Important Antimicrobial)

One Criterion (1 or 2) is met

VIA (Veterinary Important Antimicrobial)

No Criteria (1 nor 2) are met

#### CATEGORISATION OF VETERINARY IMPORTANT ANTIMICROBIAL AGENTS AUTHORISED FOR USE IN ANIMALS

Antimicrobial Agents (Class, Subclass and Substance by International Nonproprietary Name [INN])	Species	Specific comments	VCIA	VHIA	VIA
AMINOCOUMARIN		Aminocoumarins are used in:			
Novobiocin (vet only)	AVI, CAP, OVI	Poultry: staphylococcal infections;     Small ruminants: mastitis (topical use)     This class is currently only used in animals.			x
AMINOCYCLITOL					
Spectinomycin	AVLBOV, CAN, CAP, EQU, FEL, LEP, OVL, SUI	The wide range of applications and the nature of the diseases treated make aminocyclitols extremely important for veterinary medicine when there are few economical alternatives available.  Aminocyclitols are used in:  Bodine animals: respiratory infections  Cate and dog: respiratory, gastrointestinal, urinary and, skin infections  Poutry: gastrointestinal and systems: infections	x		
AMINOGLYCOSIDES					
Dihydrostreptomycin Streptomycin	AVI, BOV, CAN, CAP, EQU, FEL, LEP, OVI, SUI API, AVI, BOV, CAN, CAP, EQU, FEL, LEP, OVI, SUI	The wide range of applications and the nature of the diseases treated make aminoglycosides extremely important for veterinary medicine when there are few economical alternatives available.			
AMINOGLYCOSIDES + 2 DEOXYSTREPTAMINE		Aminoglycosides are used in: - Crustaceans and fish: infections	x		
Amikacin (synonyms: amikacillin, amicacin)	BOV, CAN, EQU, FEL	<ul> <li>Crustaceans and fish: infections caused by Aeromonas spp., Edwardsiella spp. and Vibrio spp.</li> </ul>			
Apramycin (vet only)	AVI, BOV, LEP, OVI, SUI				
Astromycin (synonym: fortimycin)	LEP, OVI	<ul> <li>Poultry: gastrointestinal and skin infections; histomoniasis.</li> </ul>			
Framycetin	CAN, CAP, FEL, OVI				

WOAH List of Antimicrobial Agents of Veterinary Importance



### **Recommendations for the WOAH List**

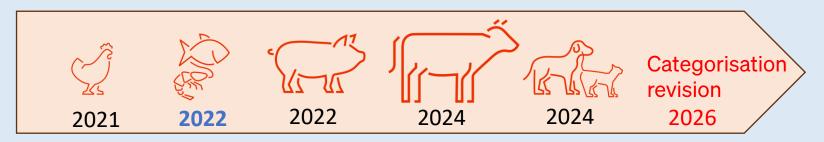






- Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials (Rome, 2007): Revise on a regular basis and further refine the categorisation of antimicrobial agents with respect to their importance in the treatment of specific animal diseases.
  - > Updates (not in categorization): May 2012, 2018, 2019, 2021 and 2024
- Global Conference on Antimicrobial Resistance (Marrakesh, 2018): 'To continue to develop the list... considering... b) the sub-division of the List in the different animal species...'
  - Working Group on AMR with support of "Sub-Groups" and ad hoc
     Group of experts list sub-division by species

Working Group on Antimicrobial Resistance - WOAH





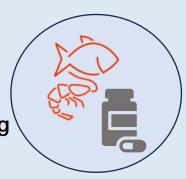
## Ad hoc Group for the "Aquatic List"



Ad hoc Group	Reviewers
<b>Dr Donald Prater</b> (chair) FDA – USA	<b>Dr Victoria Alday-Sanz</b> Naqua – KINGDOM OF SAUDI ARABIA
<b>Dr Gérard Moulin</b> ANSES – FRANCE	<b>Dr Aihua Li</b> Chinese Academy of Sciences – CHINA
Prof Moritz van Vuuren Ministerial Advisory Committee on AMR – SOUTH AFRICA	<b>Dr Hamish Rodger</b> VAI Consulting – IRELAND
<b>Dr Ruben Avendaño-Herrera</b> U. Andres Bello & INCAR – CHILE	<b>Dr Nobuyuku Takahashi</b> Ministry of Agriculture, Forestry and Fisheries – JAPAN
<b>Dr Siow Foong Chang</b> National Parks Board – SINGAPORE	<b>Dr Gillian Taylor</b> U. of Pretoria – SOUTH AFRICA
<b>Dr Kevin Christisson</b> Dep. Forestry, Fisheries & Scientific Services – SOUTH AFRICA	HealthforAnimals Rick Clayton (Technical Secretariat)
<b>Dr Nelly Isyagi</b> AU-IBAR – KENYA	<b>World Veterinary Association</b> Dr Dušan Palić (Technical Representative)
<b>Dr Eduardo Leaño</b> NACA – Thailand	
<b>Dr Carl Uhland</b> Public Health Agency of Canada – CANADA	
Dr David Verner-Jeffreys CEFAS – UK	

#### Aquatic list, focused on:

- ✓ Antibiotics only
- ✓ Those used in finfish and crustacean aquaculture only
- ✓ Antibiotics used in food-producing species only (no ornamental)
- ✓ Well established combinations
- ✓ Off-label use not considered





AHG meeting, August 2022



#### (III) Technical Reference Document Listing Antimicrobial Agents of



#### **Veterinary Importance for Aquatic Species**



#### Technical Reference Document Listing Antimicrobial Agents of Veterinary Importance for Aquatic Species

Species (hereafter referred as Aquatic Technical Reference Document) is to provide additional specific and updated information to the List of Antimicrobial Agents of Veterinary Importance. By identifying antimicrobial agents used in aquatic species, it aims to contribute to the development and update of national treatment guidelines, advice on prevention

and crustaceans. Although the use of antibiotics in the mollusc, amphibian and ornamental fish indu recognized, these applications are not within the scope of this document.

Only those antimicrobial agents in authorized products labelled for the treatment of bacterial infection

crustaceans are considered. It is acknowledged that extra-label/off-label use often occurs in aquaculture, e

those countries where there are few antimicrobial alternatives. In some countries, where regulations are minim

o implement, there are antimicrobial products being marketed. Individually, or in combination with other r re commonly used in aquaculture establis

Antimicrobial Agents (Class, Sub-class and Substance by

nternational Nonproprietary Name [INN]

MINOGLYCOSIDES

AMINOGLYCOSIDES + 2

NSAMYCINS-RIFAMYCINS

nd best practice management, risk management, and risk prioritisation to mi (AMR). This document is not intended to serve as a treatment guide



23 fish diseases 5 crustacean diseases

LIST OF MAJOR BACTERIAL PATHOGENS AND DISEASES AFFECTING AQUATIC SPECIES

Pathogens!	Examples of diseases	Examples of susceptible host species
Fish		
Aeromonas spp. (A. caviae, A. hydrophila, A. veronii)	Motile Aeromonas septicaemia	Cyprinids (carps), Salmonids (salmon, trout), Situriformes (catfish)
Aeromonas salmonicida	Furunculosis	Cichlids (tilapia), marine fish (various species), Salmonids (salmon, trout)
Chlamydiaspp.	Epitheliocystis	Cichilds (tilapia), Siluriformes (catfi:
Edwardsiella ictalud	Enteric septicaemia of catfish	Siluriformes (catfish)
	Edwardsiellosis	Anguilliformes (eel), Cichlids (tilapi fish (various species), Plecoglossid

26 antimicrobials for fish diseases 4 antimicrobials for crustacean dis

> AVI. BOV. CAN. CAP EOU. FEL. LEP. OVI. SL

AVI BOY CAN CAP EQU, FEL, LEP, OVI, SUI

API AVI BOV CAP

BOV, CAN, EQU, FEL

AVI. BOV. CAM. CAN.

CAP, EQU, FEL, LEP,

API, AVI, BOV, CAN, CAP, CRU, EQU, FEL LEP, OVI, PIS, SUI AVI BOV CAN CAP FEL, OVI, LEP, SUI

CAN FOLLEFI CAN, FEL

AVI BOY CAN CAP OVI. PIS. SUI

AVI BOV CAN CAL

OVI. SUI AVI, BOV, CAN, EQU

FEL, SUI

VI, BOV, LEP, OVI, SU LEP. OVI

ANTIMICROBIAL CLASSES USED IN VETER

#### Sections:

- Background rationale
- Main table of antimicrobials used in aquaculture (fish and crustaceans)
- Appendix 1: List of major bacterial pathogens and diseases affecting aquatic species
- Appendix 2: Table of antimicrobial classes used to treat major bacterial infections in aquaculture

#### ANTIMICROBIAL AGENTS OF VETERINARY IMPORTANCE AUTHORISED FOR USE IN FISH AND CRUSTACEAN IN AQU.

Dihydrostreptomyci

ramycetin Sentamicin

Kanamycin

Neomycin

Amikacin (synonym: amikacilli Apramycin (vet only

Tohramycin (synonym: tohramicin)

Torfenical (vet only

Thiamphenicol

VCIA VHIA VIA

Use of antimicrobials in fish species are rep
fish and crustacean aquaculture of this
Veterinary Importance, Use of antimicrob
should be kept in mind that the antimicrobi
or appropriate to treat all susceptible fish
species utilized in aquaculture, that varie
salinities, the use of veterinary medicinal pr

of on-label use in any country), or in unaut

It is acknowledged that the situation is ver and susceptibility to antimicrobial agen might not be the same in all countries to tre

uidelines (namely in the Aquatic Animal hould be considered in conjunction with t

Group on Antimicrobial Resistance (AMR):

product labels and official lists of authorize of important bacterial pathogens of fish a

типольни эрр	Franciscinosis	species), Siluriformes (catfish)
Lactococcus garvieae, L. petauri	PiscineLactococcosis	Cichlids (tilapia), marine fish (variou species), Salmonids (trout)
Nocardiaspp.	Nocardiosis	Cichlids (tilapia), marine fish (variou species)
Photobacterium damselaesubsp. piscicida (formerly Pasteurella piscida), P. damselae subsp. damselae	Pseudotuberculosis, pasteurellosis, photobacteriosis	Cichlids (tilapia), marine fish (various species), Salmonids (salmon, trout)
Piscirickettsia salmonis	Piscirickettsiosis	Salmonids (salmon, trout)
Pseudomonasspp.	Pseudomoniasis,Pseudomonas septicaemia	Siluriformes (catfish)
Pseudomonas anguilliseptica	Red spot disease, Pseudomoniasis	Anguilliformes (eel)
Renibacterium salmoninarum	Bacterial kidney disease	Salmonids (salmon, trout)
Streptococcusspp. (S. Iniae, S. agalactiae)	Streptococcosis	Cichlids (tilapia), marine fish (varior species), Salmonids (salmon, trout Siluriformes (catfish)
Tenacibaculum dicentrarchi	Tenacibaculosis	Salmonids (salmon, trout)
Tenacibaculum maritimum(formerly Flexibacter maritimus)	Marine flexibacteriosis, tenacibaculosis	Marine fish (various species), Salm (salmon, trout)
Vibrio anguillarum (formerly Listonella anguillarum)	Classical vibriosis	Cichlids (tilapia), Plecoglossids(ayı fish (various species), Salmonids (s trout), Siluriformes (catfish)
Vibriospp. (V. harveyi, V. ordali)	Atypical vibriosis	Marine fish (various species), Salm (salmon)
Aliivibrio salmonicida(formerly Vibrio salmonicida)	Cold water vibriosis	Plecoglossids (ayu), Salmonids (sal trout)
Yersinia ruckeri	Enteric redmouth disease,	Salmonids (salmon, trout)

In parenthesis are examples of common pathogenic species

	PYRIMIDINES	×	×		×	×		×					×					×		×	×		
AC)	ACYCLINES X X X X X			×	X	×	×	X		×	X	X		×	×		×	X	х	×			
	CR	UST/	CEA	NS				SI	omonas pp.– moniasi		virio Gaff	coccu fans- kemia d tail		Hep	anam	acter ei- sing			ettsia p.– ttsios		SD	nio p. – iosis	
	AMINOGLYCOSIDE	S+2	DEO)	CYSTE	REPT.	AMIN	E		X	Т											->		7
	AMPHENICOLS									$\perp$					X						)		
	QUINOLONES 2 <sup>10</sup> GENERATION (FLUOROQUINOLONES)						х										K		х				
	TETRACYCLINES								Х			X			Х			- 1	K		- >		

Edwardsieliosis	fish (various species), Plecoglossid Salmonids (trout), Siluriformes (cat
Bacterial gill disease	Salmonids (salmon, trout)
Columnaris disease	Cichlids (tilapia), Cyprinids (carp), S (salmon, trout), Siluriformes (catfisl
Bacterial cold water disease, rainbow trout fry syndrome	Plecoglossids (ayu), Salmonids (sal trout)
Francisellosis	Cichlids (tilapia), marine fish (various species), Siluriformes (catfish)
PiscineLactococcosis	Cichlids (tilapia), marine fish (various species), Salmonids (trout)
Nocardiosis	Cichlids (tilapia), marine fish (various species)
Pseudotuberculosis, pasteurellosis, photobacteriosis	Cichlids (tilapia), marine fish (various species), Salmonids (salmon, trout)
Piscirickettsiosis	Salmonids (salmon, trout)
Pseudomoniasis,Pseudomonas septicaemia	Siluriformes (catfish)
Red spot disease, Pseudomoniasis	Anguilliformes (eel)
Bacterial kidney disease	Salmonids (salmon, trout)
Streptococcosis	Cichlids (tilapia), marine fish (various species), Salmonids (salmon, trout), Siluriformes (catfish)
Tenacibaculosis	Salmonids (salmon, trout)
Marine flexibacteriosis, tenacibaculosis	Marine fish (various species), Salm: (salmon, trout)
Classical vibriosis	Cichlids (tilapia), Plecoglossids(ayu fish (various species), Salmonids (s trout), Siluriformes (catfish)
Atypical vibriosis	Marine fish (various species), Salm: (salmon)
Cold water vibriosis	Plecoglossids (ayu), Salmonids (sal
	Bacterial gill disease  Culturnaris disease  Bacterial cold water disease, rashbort trout fry syndrome  Francisellosis  Prancisellosis  Prancisellosis  Prancisellosis  Prancisellosis  Prancisellosis  Prancisellosis, photobacteriosis  Practicidad action consistence of the consistence of the colding pasteriorisis, photobacteriosis  Practicidad practicidad action consistence of the coldinario coldinario consistence of the coldinario co



## **WOAH TRD-AS - Main table**



Class/Sub-class	Molecules	PIS	CRU	Specific comments for aquatic species by class	VCIA	VHIA	VIA
AMINOGLYCOSIDES + 2 DEOXYSTREPTAMINE	Neomycin	Х	Х	The aminoglycoside + 2 deoxystreptamine neomycin is used to treat infections caused by Aeromonas, Edwardsiella and Vibrio in fish and crustaceans.	Х		
AMPHENICOLS	Florfenicol	Х	Х	Amphenicols are broad spectrum antibiotics used for treatment of a wide range of bacterial diseases of freshwater and marine fish	X		
	Thiamphenicol	Х		wide range of bacterial diseases of freshwater and marine fish			
LINCOSAMIDES	Lincomysin	Х		Lincosamides are mainly used for infections caused by Streptococcus spp. and Lactococcus spp.		Х	
MACROLIDES	Erythromycin	Х		Macrolides are broad spectrum antibiotics for treatment and control of bacterial diseases in aquatic animals, both for marine and freshwater	Х		
	Kitasamycin	Х		species. They are used for infections with Streptococcus spp.,  Lactococcus spp., intracellular bacteria such as Renibacterium			
	Tilmicosin	Х		salmoninarum and Francisella sp., and against Chlamydia sp.			
AMINOPENICILLINS	Amoxicillin	Х		Semi-synthetic penicillins (amoxicillin and ampicillin) are widely used in aquaculture for treatment of bacterial diseases in most species of	Х		
	Ampicillin	Х		farmed fish, particularly for infections with Aeromonas spp., Photobacterium sp., and Streptococcus spp.			
PHOSPHONIC ACID DERIVATIVES	Fosfomycin	Х		Fosfomycin, a Phosphonic acid derivatives, are used to treat infections with Photobacterium damselae and Edwardsiellosis in marine fish, and infections with Streptococcus iniae in Tilapia		Х	
PLEUROMUTILINS	Tiamulin	Х		Pleuromutilins such as tiamulin are used to treat infections with Tenacibaculum dicentrarchi in salmon		Х	



## **WOAH TRD-AS – Main table**



Class/Sub-class	Molecules	PIS	CRU	Specific comments for aquatic species by class	VCIA	VHIA	VIA
QUINOLONES 1G	Flumequine	Х		First generation quinolones such as flumequine and oxolinic acid, and second-generation fluoroquinolones, such as enrofloxacin, and		Х	
	Oxalinic acid	Х		ciprofloxacin, are used to treat a wide variety of bacterial infections in marine and freshwater species, and crustaceans. Fluoroquinolones are			
FLUOROQUINOLONES	Ciprofloxacin	Х		subject to specific recommendations in the OIE List of Antimicrobial  Agents of Veterinary Importance			
	Enrofloxacin	Х	Х	_ /,gents or vetermary importance			
SULFONAMIDES	Sulfadiazine	Х		Sulfonamides are used typically in combination with  diaminopyrimidines in infections caused by a wide range of bacterial	Х		
	Sulfadimethoxine	Х		diseases in freshwater and marine fish			
	Sulfamerazine	Х		_			
	Sulfamonomethoxine	Х		_			
	Sulfisozole sodium	Х					
SULFONAMIDES + DIAMINOPYRIMIDINE	Ormetoprim + sulfonamide	Х		_			
TETRACYCLINES	Chlortetracycline	Х		Tetracyclines are broad spectrum antibiotics used for treatment of a wide range of bacterial diseases of freshwater and marine fish, and	Х		
	Doxycycline	Х		crustaceans			
	Oxytetracycline	Х	Х				
	Tetracycline	Х					



## WOAH TRD-AS - Main pathogens/diseases



Pathogens <sup>9</sup>	Examples of diseases	Examples of susceptible host species					
Fish							
Aeromonas spp. (A. caviae, A. hydrophila, A. veronii)	Motile Aeromonas septicaemia	Cyprinids (carps), Salmonids (salmon, trout), Siluriformes (catfish)					
Aeromonas salmonicida	Furunculosis	Cichlids (tilapia), marine fish (various species), Salmonids (salmon, trout)					
Chlamydia sp.	Epitheliocystis	Cichlids (tilapia), Siluriformes (catfish)					
Edwardsiella ictaluri	Enteric septicaemia of catfish	Siluriformes (catfish)					
Edwardsiella piscicida (formerly E. tarda)	Edwardsiellosis	Anguilliformes (eel), Cichlids (tilapia), marine fish (various species), Plecoglossids (ayu), Salmonids (trout), Siluriformes (catfish)					
Flavobacterium branchiophilum	Bacterial gill disease	Salmonids (salmon, trout)					
Flavobacterium columnare (formerly Flexibacter columnaris)	Columnaris disease	Cichlids (tilapia), Cyprinids (carp), Salmonids (salmon, trout), Siluriformes (catfish)					
Flavobacterium psychrophilum	Bacterial cold water disease, rainbow trout fry syndrome	Plecoglossids (ayu), Salmonids (salmon, trout)					
Francisella spp.	Francisellosis	Cichlids (tilapia), marine fish (various species), Siluriformes (catfish)					
Lactococcus garvieae, L. petauri	Piscine Lactococcosis	Cichlids (tilapia), marine fish (various species), Salmonids (trout)					
Nocardia spp.	Nocardiosis	Cichlids (tilapia), marine fish (various species)					
Photobacterium damselae subsp. piscicida (formerly Pasteurella piscida), P. damselae subsp. damselae	Pseudotuberculosis, pasteurellosis, photobacteriosis	Cichlids (tilapia), marine fish (various species), Salmonids (salmon, trout),					
Piscirickettsia salmonis	Piscirickettsiosis	Salmonids (salmon, trout)					
Pseudomonas spp.	Pseudomoniasis, <i>Pseudomonas</i> septicaemia	Siluriformes (catfish)					

Pathogens <sup>9</sup>	Examples of diseases	Examples of susceptible host species
Pseudomonas anguilliseptica	Red spot disease, Pseudomoniasis	Anguilliformes (eel)
Renibacterium salmoninarum	Bacterial kidney disease	Salmonids (salmon, trout)
Streptococcus spp. (S. iniae, S. agalactiae)	Streptococcosis	Cichlids (tilapia), marine fish (various species), Salmonids (salmon, trout), Siluriformes (catfish)
Tenacibaculum dicentrarchi	Tenacibaculosis	Salmonids (salmon, trout)
Tenacibaculum maritimum (formerly Flexibacter maritimus)	Marine flexibacteriosis, tenacibaculosis	Marine fish (various species), Salmonids (salmon, trout)
Vibrio anguillarum (formerly Listonella anguillarum)	Classical vibriosis	Cichlids (tilapia), Plecoglossids (ayu), marine fish (various species), Salmonids (salmon, trout), Siluriformes (catfish)
Vibrio spp. (V. harveyi, V. ordalii)	Atypical vibriosis	Marine fish (various species), Salmonids (salmon)
Aliivibrio salmonicida (formerly Vibrio salmonicida)	Cold water vibriosis	Plecoglossids (ayu), Salmonids (salmon, trout)
Yersinia ruckeri	Enteric redmouth disease, yersiniosis	Salmonids (salmon, trout)
Crustaceans		
Aeromonas spp.	Aeromoniasis	Penaeid shrimp/prawn
Aerococcus viridans	Gaffkemia, red tail	American lobster
"Candidatus hepatobacter penaei"	Necrotising hepatopancreatitis	Penaeid shrimp/prawn
Rickettsia spp.	Rickettsiosis	Penaeid shrimp/prawn
Vibrio spp. (V. harveyi, V. alginolyticus)	Vibriosis	Penaeid shrimp/prawn



### **Antibiotics authorized for FINFISH diseases**



Antimicrobial agents	Aeromonas spp. (A. caviae, A. hydrophila, A. veronii) – Mobile aeromonas septicaemia	Aeromonas salmonicida - Furunculosis	Chlamydia sp Epitheliocystis	Edwardsiella ictalurid – Enteric septicaemia of catfish	Edwardsiella piscida - Edwardsiellosis	Flavobacterium branchiophilum – Bacterial gill disease	Flavobacterium psychrophilum – Cold water disease, rainbow trout fry syndrome	Francisella spp. – Francisellosis	Lactococcus garvieae, L. petauri – Lactococcosis	Nocardia sp. – Nocardiosis	Photobacterium damselae piscicida, P. damselae damselae – Photobacteriosis, pseudotuberculosis, pasteurellosis
AMINOGLYCOSIDES + 2 DEOXYSTREPTAMINE: Neomycin	Х	Х		X	Х						
AMPHENICOLS: Florfenicol, thiamphenicol	Х	Χ		Χ	X	Х	X	Х	Χ		Х
LINCOSAMIDES: Lincomysin									Х		
MACROLIDES: Erythromycin, Kitasamycin, Tilmicosin			Х			Х	Х	Х	Х		
PENICILLINS: Amoxicillin, Ampicillin	Х	Х			Х						Х
PHOSPHONIC ACID DERIVATIVES: Fosfomycin											Х
PLEUROMUTILINS: Tiamulin	Х	Χ			Х						
QUINOLONES 1st Gen: Flumequine, Oxalinic acid	Х	Х			Х						Х
QUINOLONES 2ND G (FLUOROQUINOLONES): Ciprofloxacin, Enrofloxacin	X	X					X		Х		X
SULFONAMIDES: Sulfadiazine, Sulfadimethoxine, Sulfamerazine, Sulfamonomethoxine, Sulfisozole sodium	Х	Х					Х			Х	Х
SULFONAMIDES + DIAMINOPYRIMIDINES: Ormetoprim + sulfonamide	Х	Х		Χ	Х		X				Х
TETRACYCLINES: Chlortetracycline, Doxycycline, Oxytetracycline, Tetracycline	Χ	X	Χ		X	Χ	Χ	Х	X		X



#### **Antibiotics authorized for FINFISH diseases**



Antimicrobial agents	Piscirickettsia salmonis – Piscirickettsiosis	Pseudomonas spp. – Pseudomoniasis, Pseudomonas septicaemia	Pseudomonas anguilliseptica – Red spot disease, pseudomoniasis	Renibacterium salmoninarum – Bacterial kidney disease	Streptococcus spp. (S. agalactiae, S. iniae) – Streptococcosis	Tenacibaculosis dicentrarchi – Tenacibaculosis	Tenacibaculum maritimum – Marine flexibacteriosis, tenacibaculosis	Vibrio anguillarum – Vibriosis	Vibrio spp. (V. harveyi, V. ordalii) – Atypical vibriosis	Aliivibrio salmonicida – Cold water vibriosis	Yersinia ruckeri – Redmouth disease
AMINOGLYCOSIDES + 2 DEOXYSTREPTAMINE: Neomycin								Х			
AMPHENICOLS: Florfenicol, thiamphenicol	Χ			Χ	Χ		Χ	Χ	Χ	Χ	Х
LINCOSAMIDES: Lincomysin					Х						
MACROLIDES: Erythromycin, Kitasamycin, Tilmicosin				Х	Х						
PENICILLINS: Amoxicillin, Ampicillin					Х						
PHOSPHONIC ACID DERIVATIVES: Fosfomycin					Х						
PLEUROMUTILINS: Tiamulin						Х					
QUINOLONES 1st Gen: Flumequine, Oxalinic acid	Х		Х				Х	Х	Х		Х
QUINOLONES 2ND G (FLUOROQUINOLONES): Ciprofloxacin, Enrofloxacin		Х		Х	Х		Х	Х		Х	Х
SULFONAMIDES: Sulfadiazine, Sulfadimethoxine, Sulfamerazine, Sulfamonomethoxine, Sulfisozole sodium					Х			Х	Х	Х	
SULFONAMIDES + DIAMINOPYRIMIDINES: Ormetoprim + sulfonamide					Х		Х	Х			Х
TETRACYCLINES: Chlortetracycline, Doxycycline, Oxytetracycline, Tetracycline	Х	Х		Х	Х		Х	Х	Х	Х	Х



### Antibiotics authorized for CRUSTACEAN diseases



Antimicrobial agents	Aeromonas spp. – Aeromoniasis	Aerococcus viridans – Gaffkemia, red tail	Candidatus Hepatobacter vanamei – Necrotising hepatopancreatitis	Rickettsia spp. – Rickettsiosis	Vibrio spp. – Vibriosis
AMINOGLYCOSIDES + 2 DEOXYSTREPTAMINE: Neomycin	Χ				X
AMPHENICOLS: Florfenicol, thiamphenicol			X		Х
QUINOLONES 2ND G (FLUOROQUINOLONES): Ciprofloxacin, Enrofloxacin	Х			Х	Х
TETRACYCLINES: Chlortetracycline, Doxycycline, Oxytetracycline, Tetracycline	Х	Х	Х	Х	Х

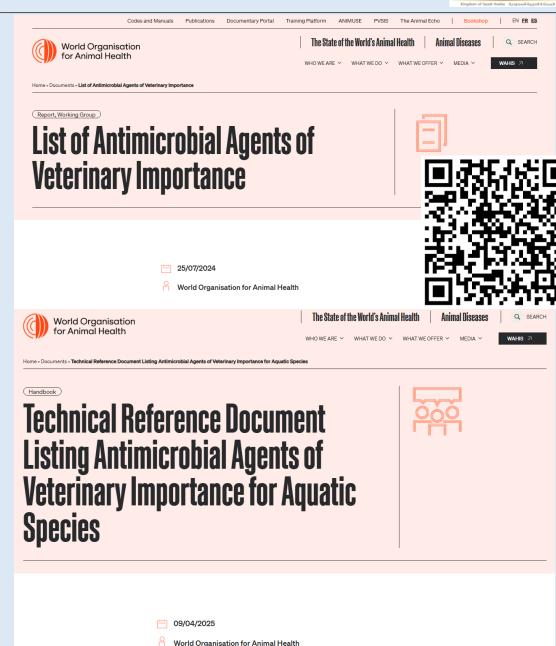


## It was developed for you!



The WOAH List / TRD-AS can support Members when

- evaluating access to veterinary medicinal products needed to treat common infectious diseases, taking into consideration their importance for animal and public health;
- developing and updating national guidelines for responsible antimicrobial use and advice for best practice management;
- conducting risk management on AMU and AMR, and risk prioritisation to minimise and contain AMR;
- conducting the selection of antimicrobial agents and classes in national surveillance systems for AMU and AMR in animals



## Thank you!

#### d.mateo@woah.org

12, rue de Prony, 75017 Paris, France T. +33 (0)1 44 15 19 49 F. +33 (0)1 42 67 09 87

woah@woah.org www.woah.org <u>Facebook</u>

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## Substandard and Falsified Veterinary Products (SFVPs) Programme s

Workshop on enhancing aquatic animal health and biosecurity

**Dr Andrés García Campos** 

26-29 October 2025, Jeddah, Saudi Arabia

Senior Programme Manager Antimicrobial Resistance and Veterinary Products Department, WOAH



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#### Why do we need to tackle Substandard & Falsified Veterinary Products (SFVP)?



#### **Animal Health management**





**51.90%** (n=308) substandard

#### **Animal Safety**

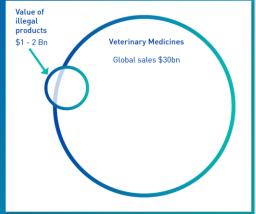


#### **Global programmes**



#### **Economy**









#### Alert summary

This WHO Medical Product Alert concerns six lots of substandard FENTANILO HLB (fentanyl citrate) detected in Argentina

Fentanyl citrate injections are opioid analgesics used to relieve pain during and after surgery. It is also used to reduce the rate of breathing in patients who are on a ventilator. It is also used to manage severe pain in patients with chronic conditions.

In May 2025, WHO identified reports of a fatal outbreak of bacterial infections in Argentina linked to a contaminated lot (Lot 31202) of injectable FENTANILO HLB. The contamination involves drug-resistant strains of bacteria: Klebsiella pneumoniae and Ralstonia Picketti.

Information now available to WHO indicates that multiple lots of FENTANILO HLB are contaminated and are therefore subject to

#### **Security**







#### Why do we need to tackle Substandard & Falsified Veterinary Products (SFVP)?





**Caution with interpretation !!** 

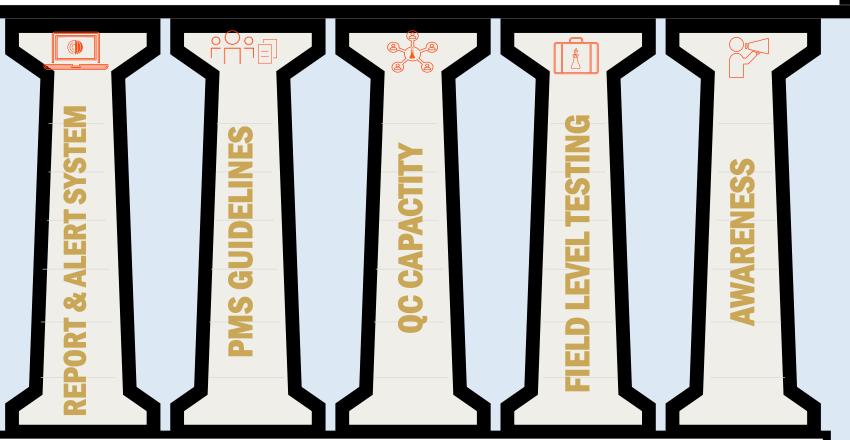
No Geographical regions exempt of SFVP

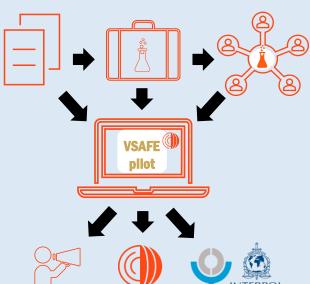
All Terrestrial and Aquatic species at risk

48 % of antibiotics tested in aquaculture <80% API



### **Theory of Change**





**WOAH International Standards, resolutions & recommendations** 













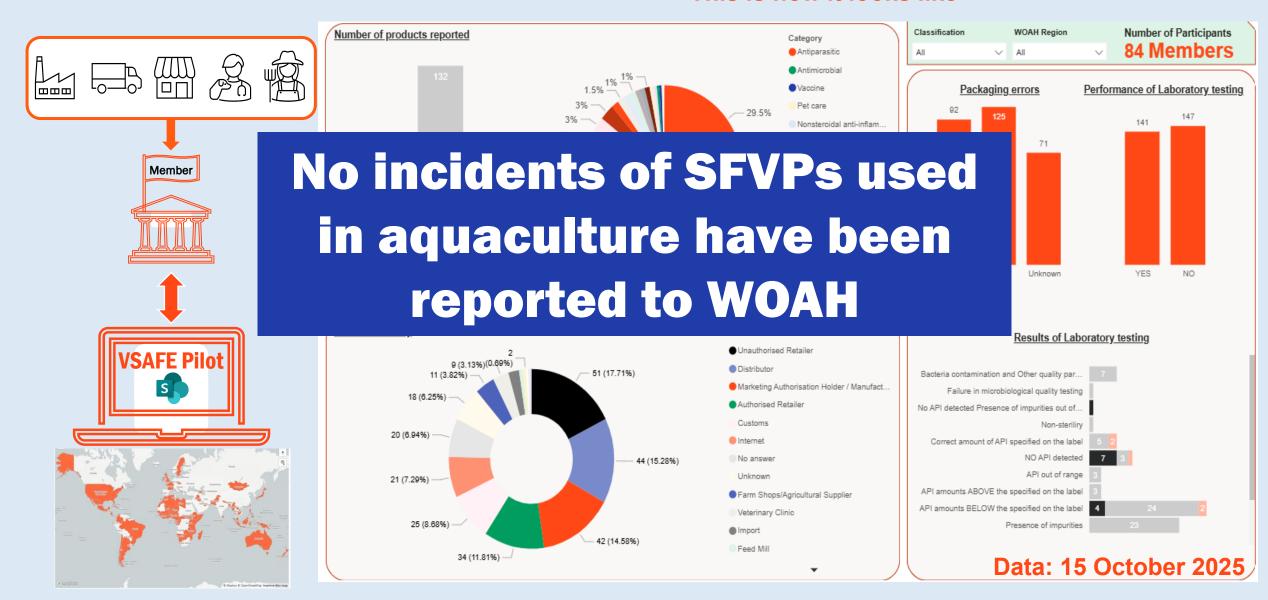




#### **VSAFE pilot – Veterinary monitoring & surveillance system for Substandard And Falsified vEterinary products**

#### What is it? How is it fed?

#### This is how it looks like





#### **TRUVET - Track and Report Unsafe VETerinary products**



#### What is the ADDED VALUE?



Helps countries to develop their monitoring and reporting systems



Data interoperability with existing tools



Analysis of the global situation, globally and regionally



Database accessible, with transparent information at global and regional level



Links to WCO and Interpol for law enforcement



Alerts and recommendations to countries



#### **WOAH International Standards, recommendation and resolutions addressing SFVPs**





## Article 3.4.11.5 : Retailing, use and traceability of VMP

"Veterinary legislation should provide a basis for actions to address ...

a system of surveillance of the quality of veterinary medicinal products marketed in the country, including a system of surveillance for falsification"



## Article 6.10.3.10 : Distribution & administration of antimicrobials...

"The Competent Authority should ensure that all antimicrobial agents and VMPs containing antimicrobial agents are ...

not illegal, substandard, falsified medicines or unapproved formulations and that these are prevented from entering distribution systems"



?



#### Resolution No. 26 Adopted on 26 May 2015

10. The OIE strengthen its collaboration with international organisations, such as the World Customs Organisation and Interpol, and stakeholders to combat counterfeit products with the aim of ensuring access to antimicrobial agents of proven quality.



#### 6<sup>th</sup> recommendation Adopted in March 2018

Explore the possibility of building an information system of falsified and substandard drugs in the animal sector illegally circulating within and between countries and building on the experience of the monitoring systems set up by WHO for drugs designed for human use taking a 'One Health' approach"



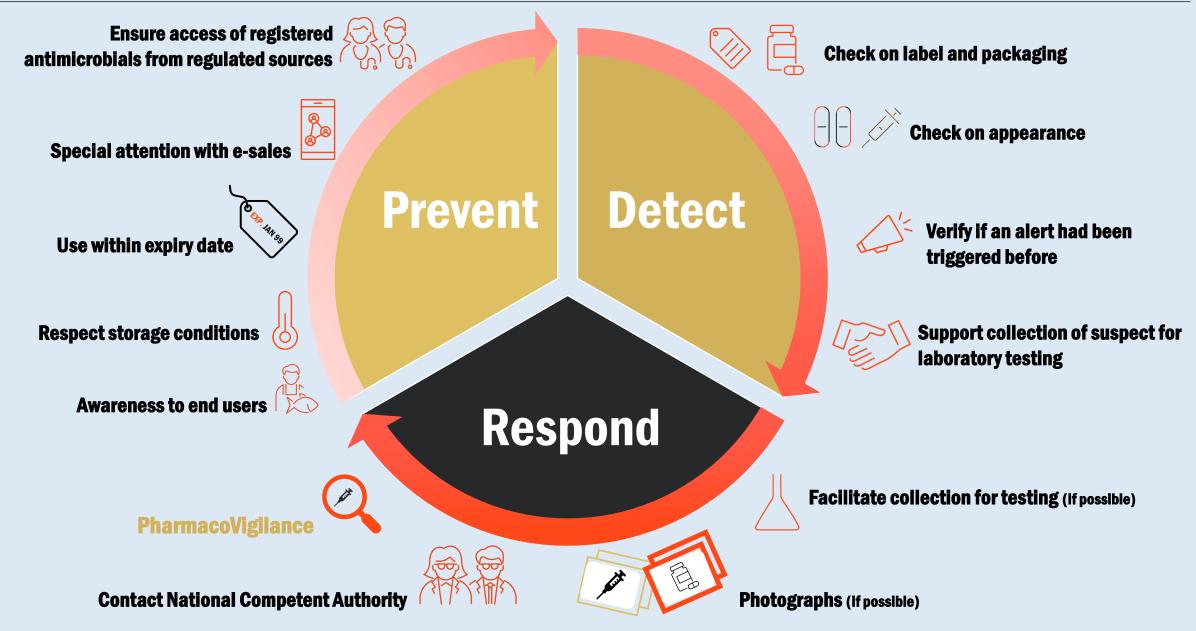
#### Resolution No. 29 Adopted on 29 May 2025

6. WOAH completes the deployment of the global alert system on substandard and falsified veterinary products to strengthen vaccine quality oversight and support the removal of these vaccines from circulation, and WOAH Members to actively report to WOAH incidents of substandard and falsified vaccines encountered in their territories;



#### **Role of Veterinarians/Aquatic Animal Health Professionals, Professionals Associations**









## Take home

## messages

The role of competent national authorities (NCAs), Aquatic Animal Health Services (AAHS) and the private sector in ensuring the high quality of veterinary medicinal products and taking action against substandard and falsified products is of vital importance.

**WOAH** has launched the program against substandard and falsified veterinary medical products (SFVP programme) which includes VSAFE pilot with the aim of:

- Analyse the dimension of the problem and impact on AMR
- Understand the vulnerabilities and drivers for their presence
- Recommend actions towards the prevention, detection and response

Whilst no incidents of SF antimicrobials for aquaculture have been reported, scientific literature shows that the Aquatic sector is not exempt of this problem.

Should you suspect to encounter a substandard or falsified antimicrobial please contact your NCA.

WOAH expects to launch the TRUVET platform—the Track and Report Unsafe Veterinary Products system— in 2026. In the meantime, we recommend:

- Collaboration of Aquatic Animal Health Services through the reporting of known cases
- Adherence to the VSAFE pilot phase by Members

Contact us <a href="mailto:sfvp@woah.org">sfvp@woah.org</a>

## Thank you!

#### a.garcia@woah.org

12, rue de Prony, 75017 Paris, France T. +33 (0)1 44 15 19 49 F. +33 (0)1 42 67 09 87

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