

"The right tools for real impact - why quality matters"

TAFS Workshop: "Right Tools, Real Impact: Evaluation and Use of FMD Vaccines and Diagnostics in the Field"

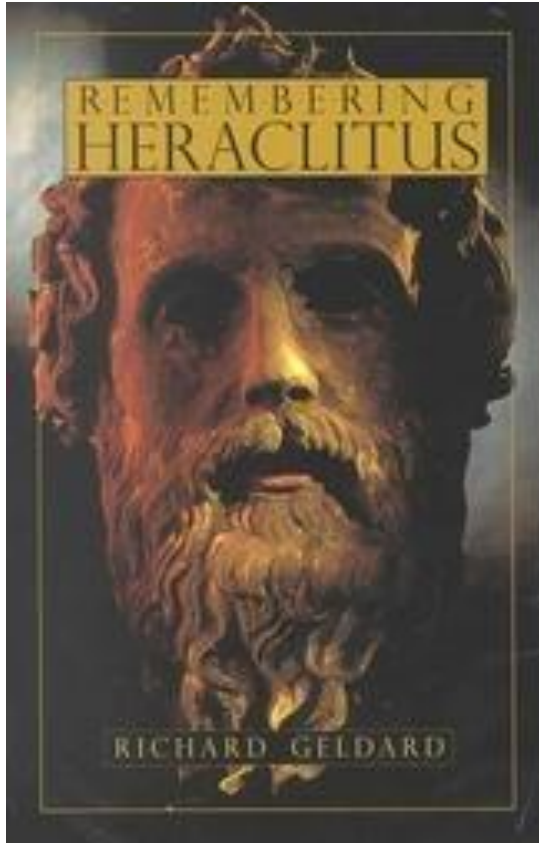
Nadav Galon

former CVO and FAO/WOAH expert

November 2025, Bangkok

TAFS Bangkok 2025





Ancient Greek philosopher

"PANTA REI"
everything flows

*"You could not step twice
into the same river"*

HPAI

ASF

LSD

BT

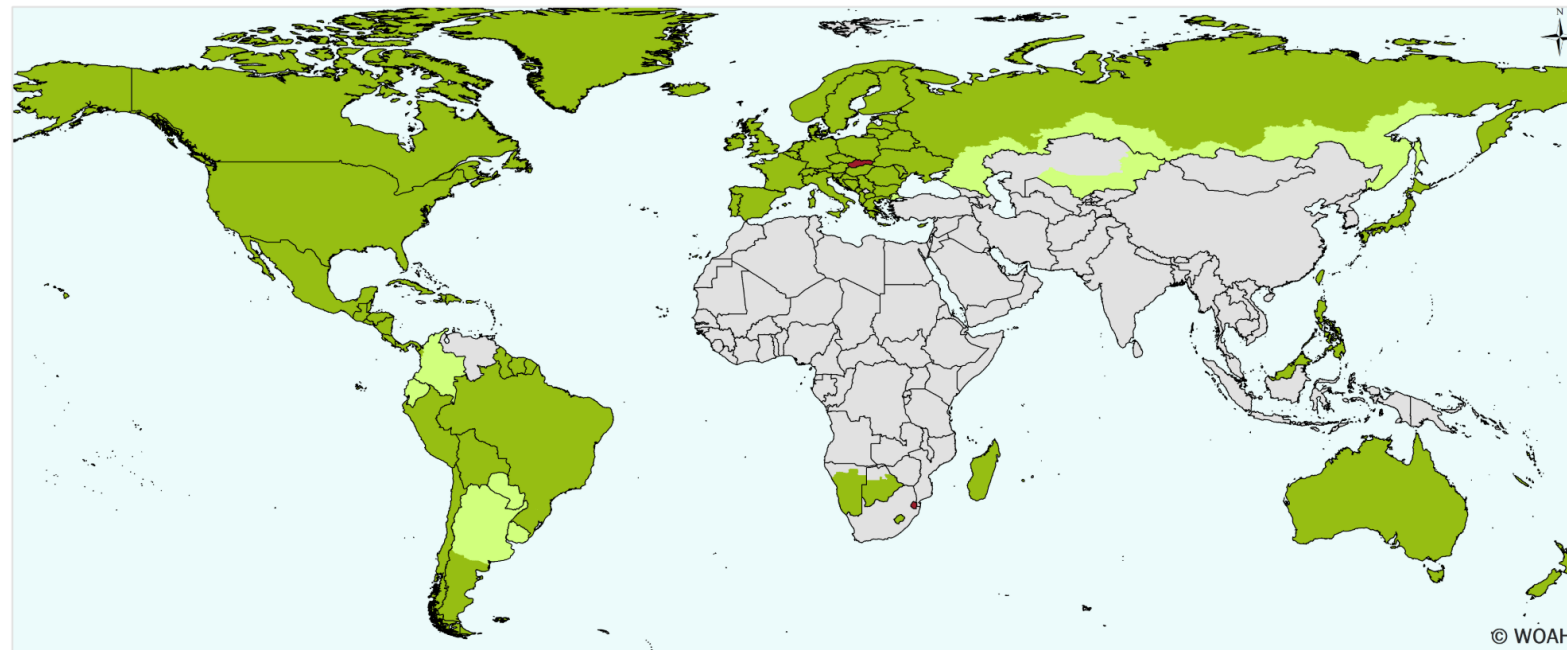
FMD

WOAH global map - “Grey zones”

Sept-2025

WOAH Members' official FMD status map

Last update September 2025



■ Members and zones recognised as free from FMD without vaccination

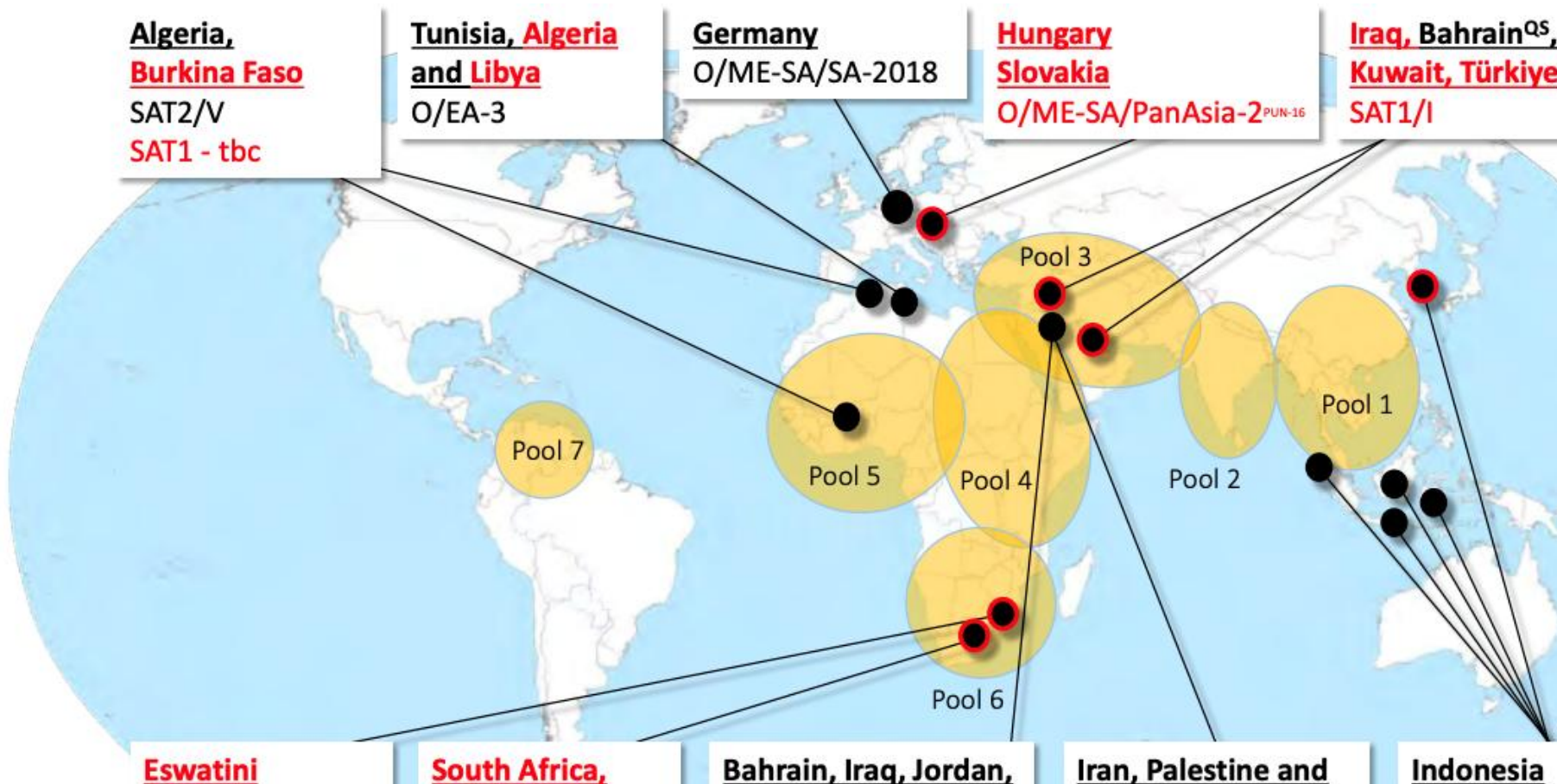
■ Members and zones recognised as free from FMD with vaccination

■ Suspension of FMD free status

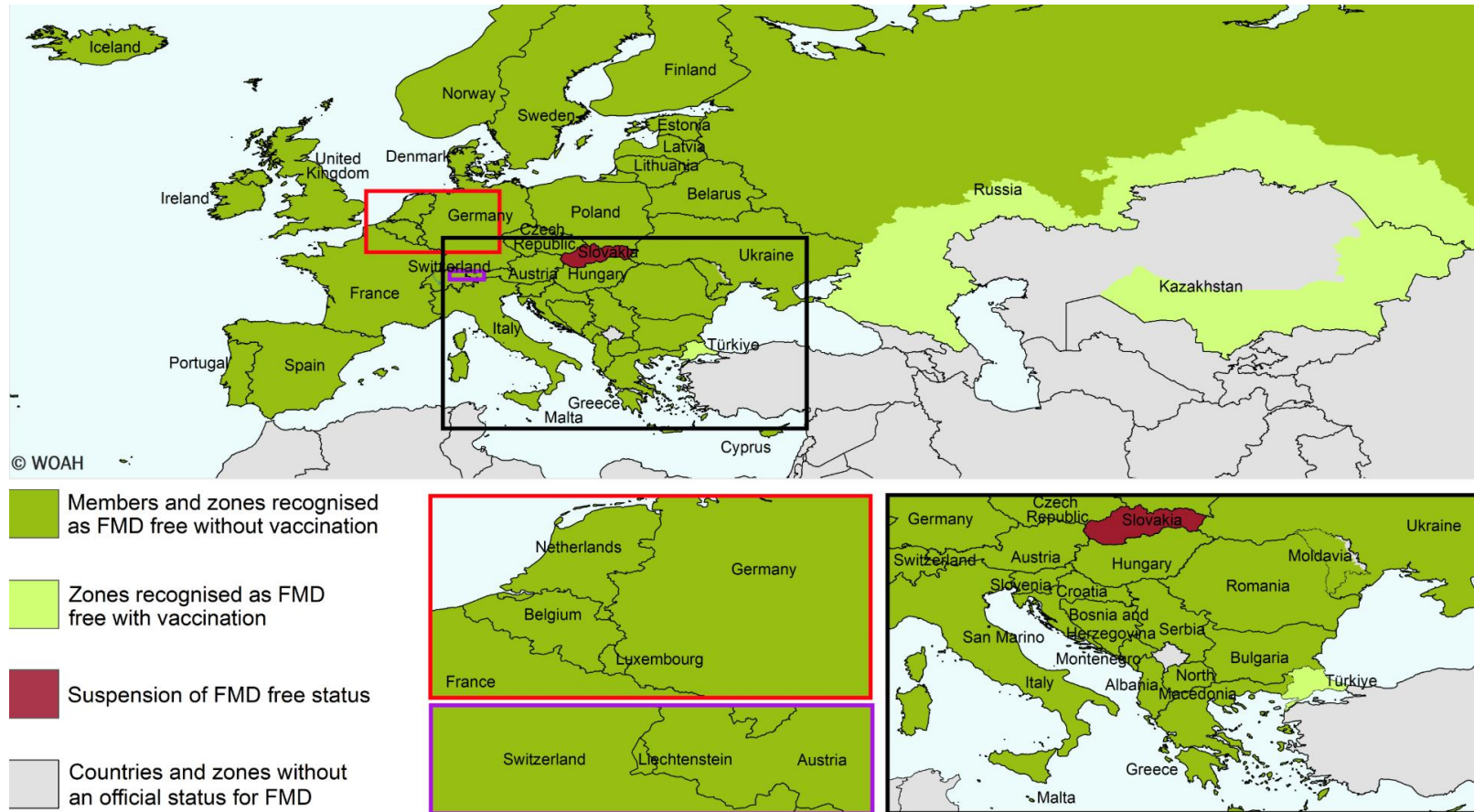
■ Countries and zones without an official status for FMD

FMD epidemiological significant outbreaks

July 2025

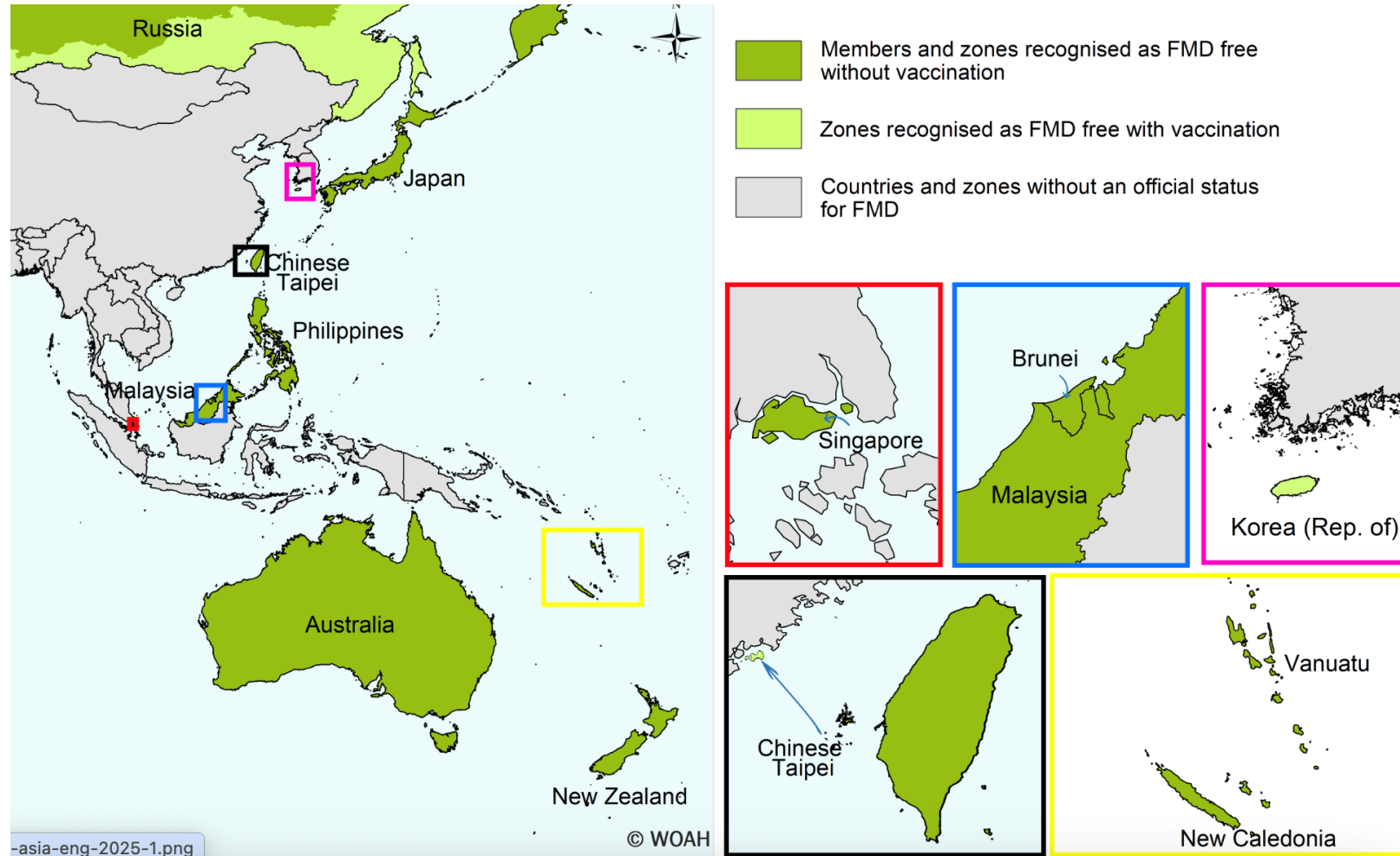


FMD in Europe



Asia and Pacific

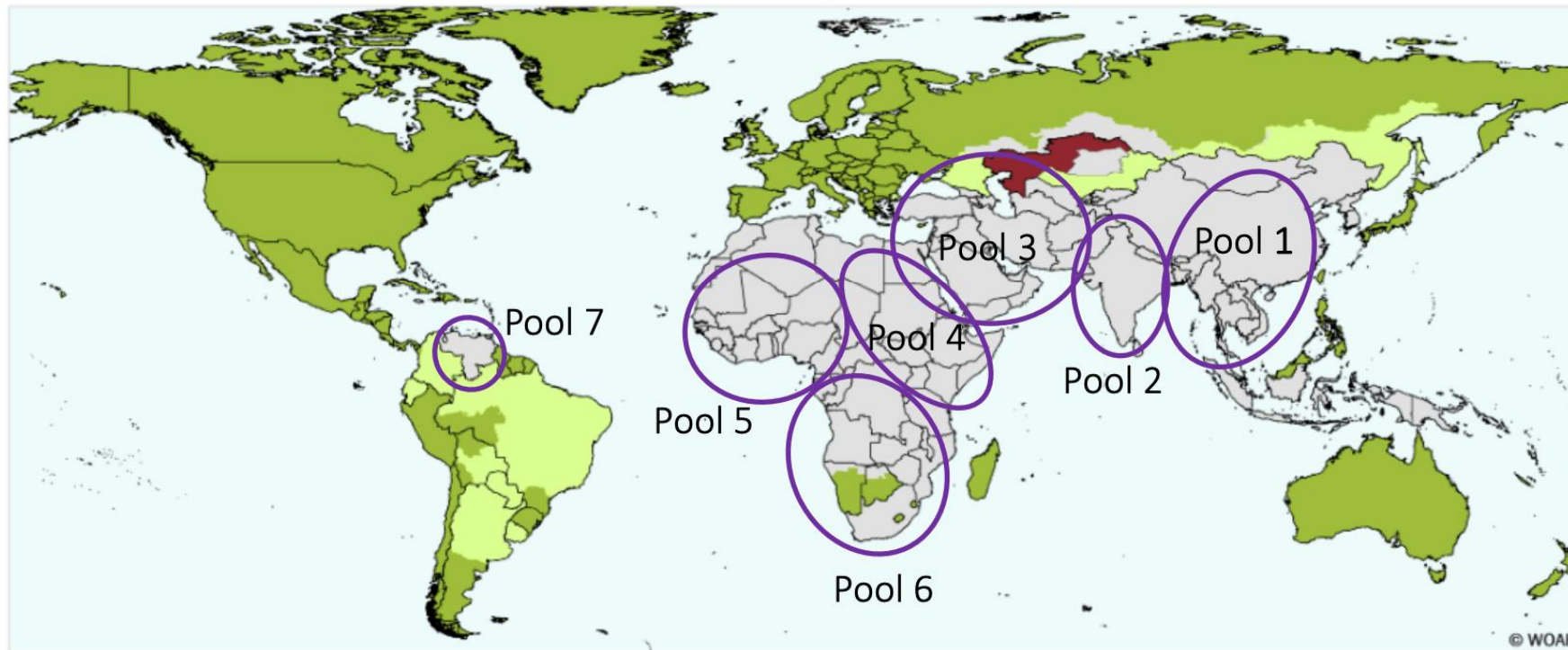
June-2025



FMD pools

WOAH Members' official FMD status map

Last update April 2024



Members and zones recognised as free from FMD without vaccination

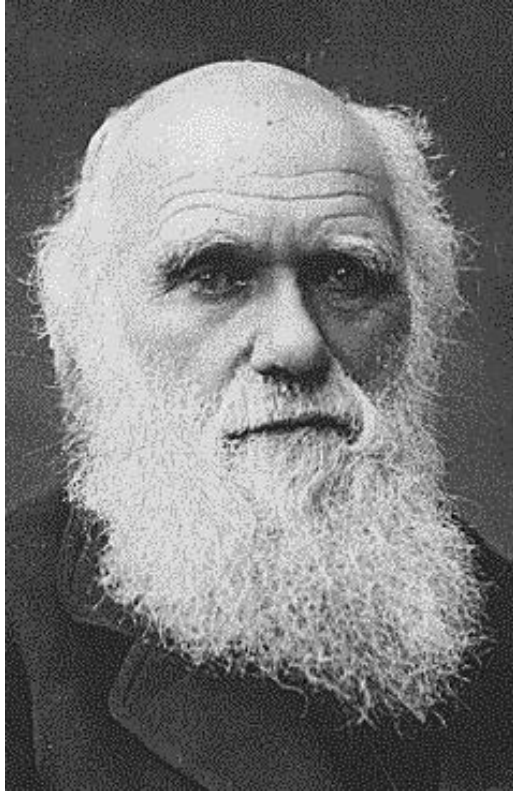
Members and zones recognised as free from FMD with vaccination

Suspension of FMD free status

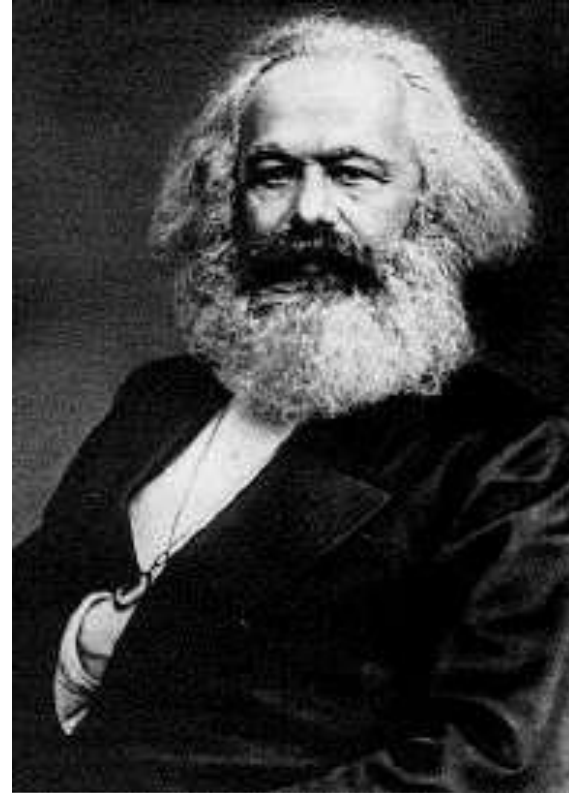
Countries and zones without an official status for FMD

“Change is the only constant”

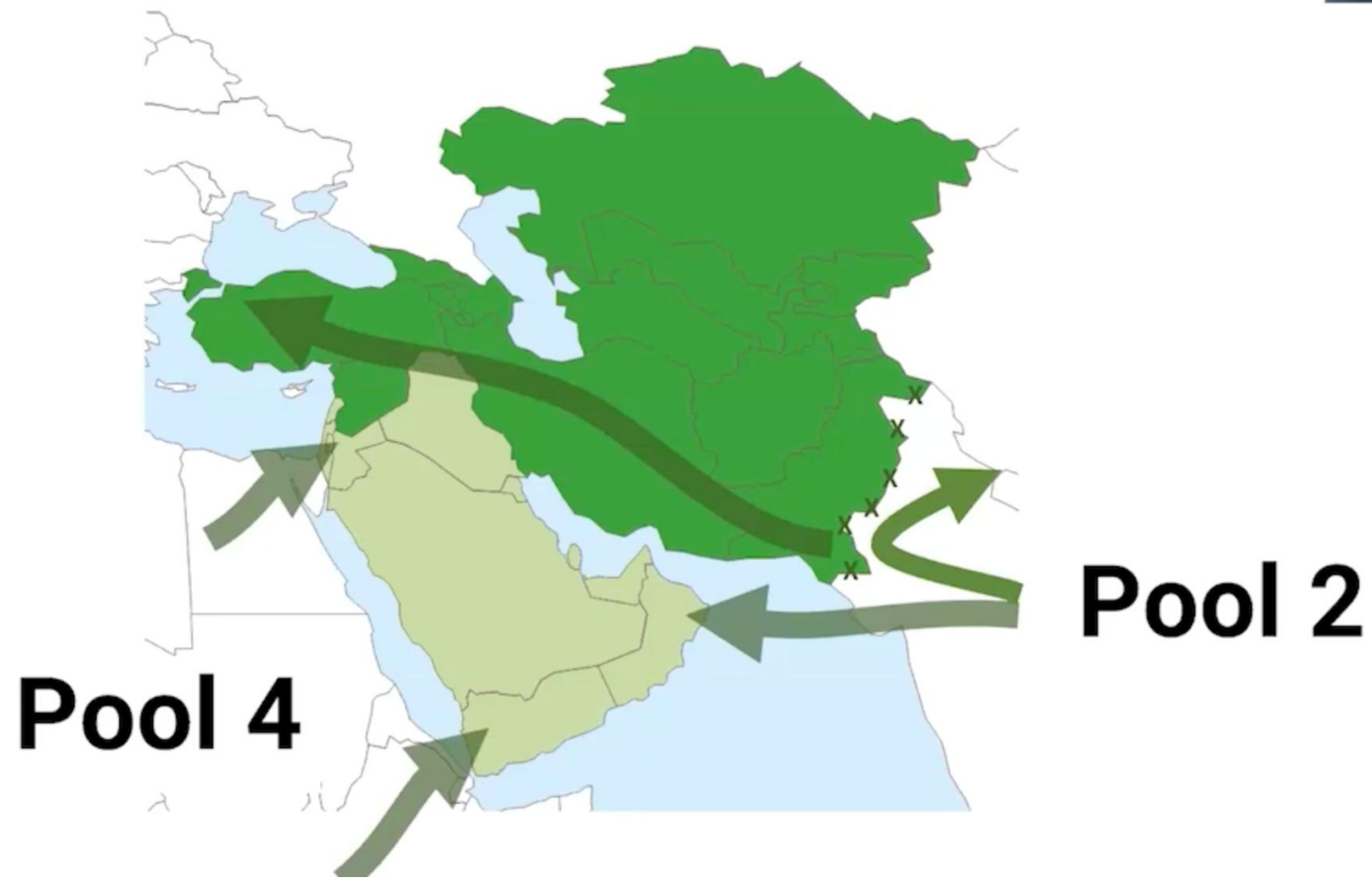
Evolution or Revolution



Charles Darwin



Karl Marks



FMD SAT1: Situation Update & Recommendations for Prevention and Response in the Near East and beyond



Food and Agriculture Organization of the United Nations ✓

220K subscribers

Subscribe

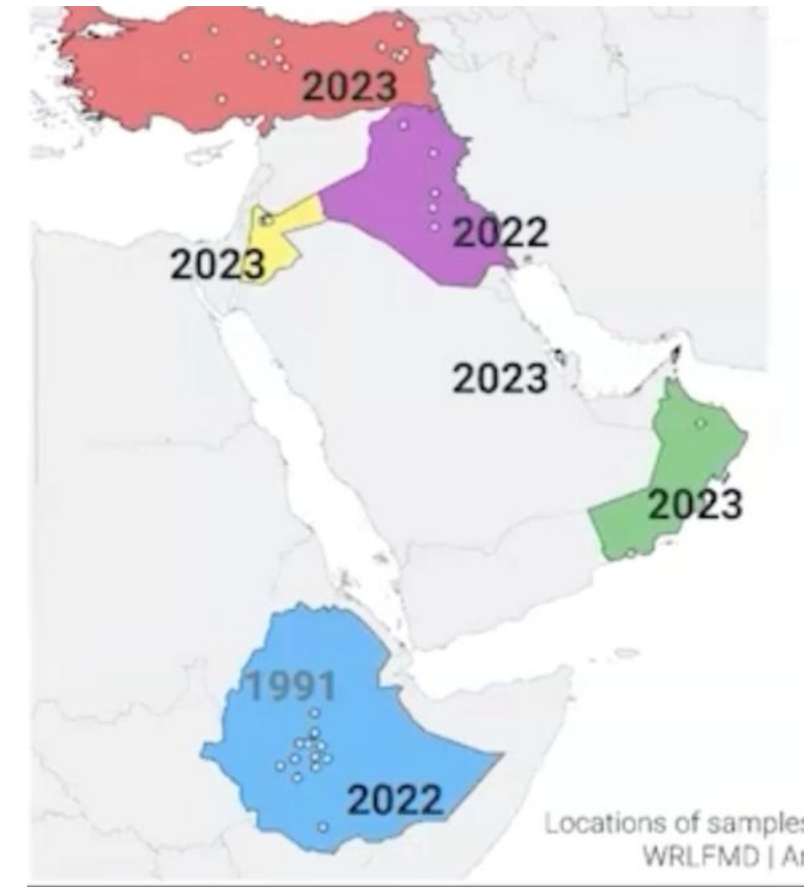
May 2025

TAFS Bangkok 2025

FMD strains (“inter-pool”) mobility

- Escapes of FMDV lineages endemic in East Africa have been historically recorded for serotypes A, O, SAT1 and SAT2 viruses, with documented examples including:

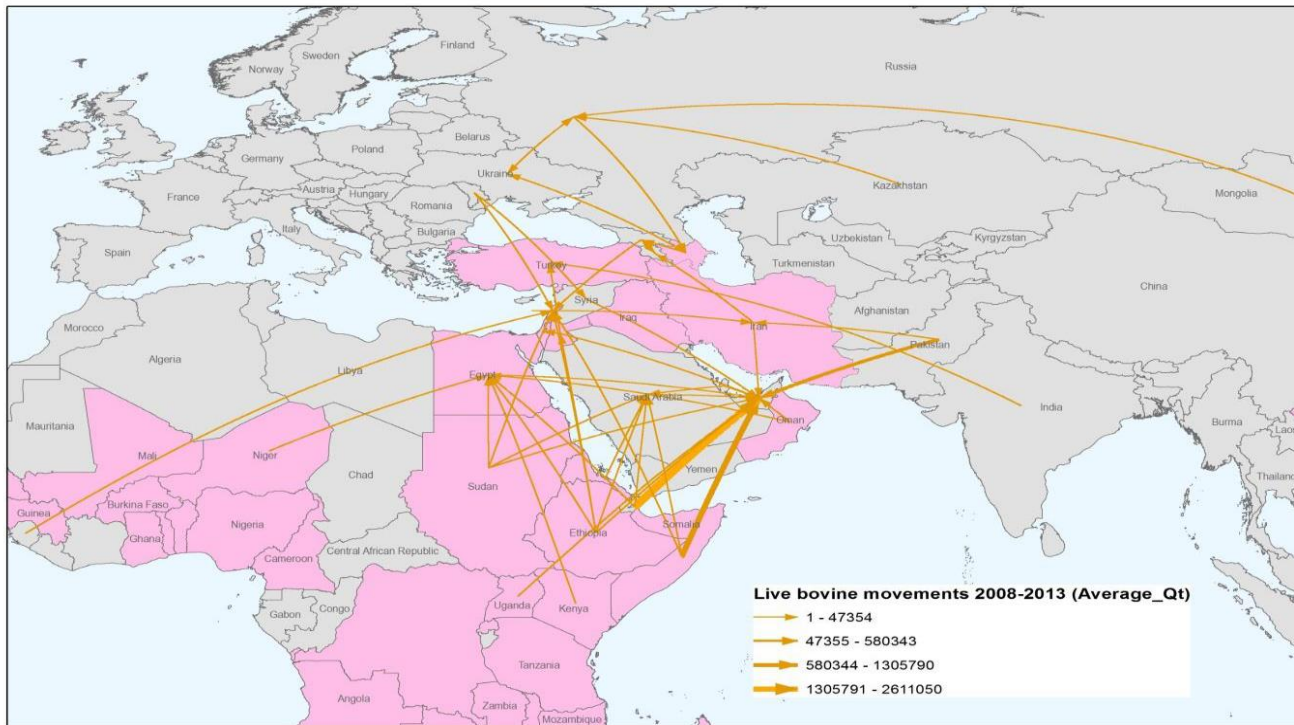
O	O/EA-2 [2019]	O/EA-3 [1974]	
A	A/G-I [2018]	A/G-II [1985]	A/G-VII [1989]
SAT1	SAT1/? [1970]	SAT1/I [2023]	SAT1/VI [1962]
SAT2	SAT2/IV [1990]	SAT2/VII [2012]	



FAO update May 2025

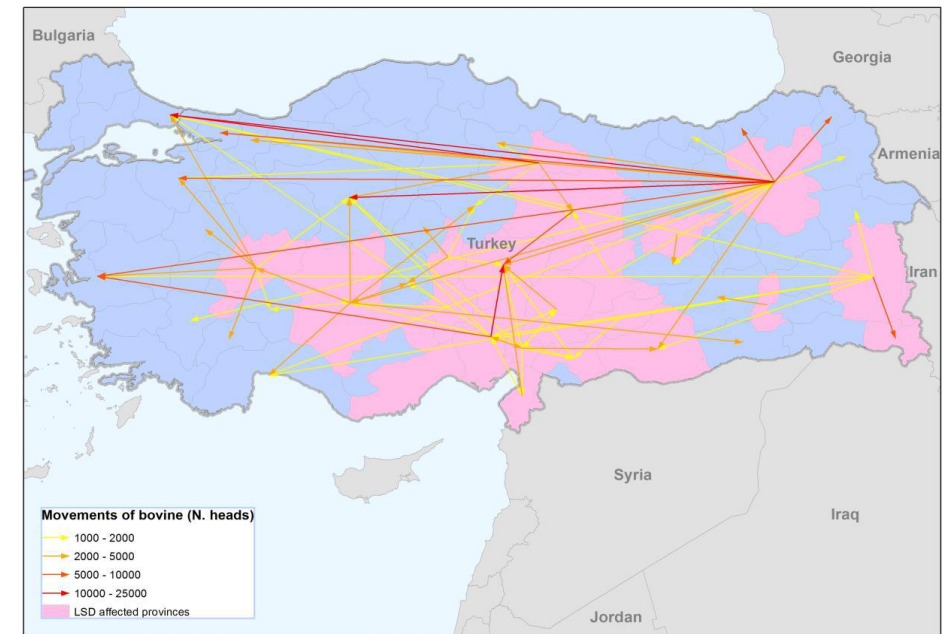
Inter-regional animal trade “formal and non-formal”

Cattle movements out of Africa 2008-2013



Pink- Countries reporting LSD in 2011-2014 according to OIE

Cattle movements in Turkey



FMD - Mediterranean 2022- 23



Map Prepared by IDM
Date: 08/02/2023
Absolute Scale: 1:26,000,000

Foot and Mouth Disease
March 2022 to February 2023
(WOAH Data Only)

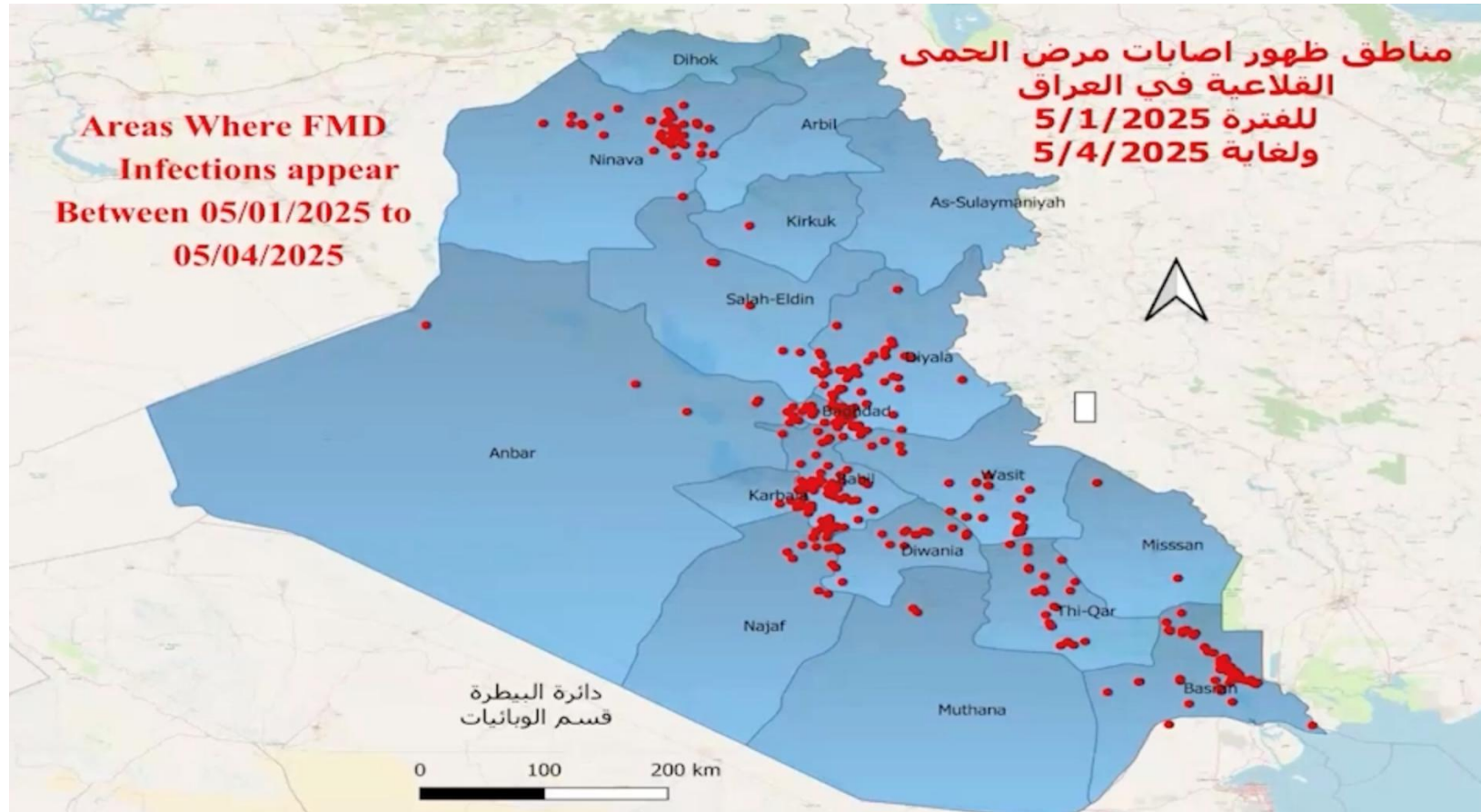
0 490 980 1,470 Km

Source: FMD outbreaks in the Middle East and North Africa between Mar 2022 - Feb 2023

Department for Environment, Food and Rural Affairs (DEFRA UK)

TAFS Bangkok 2025

Iraq FMD SAT-1 in 2025



FMD SAT1: Situation Update & Recommendations for Prevention and Response in the Near East and beyond
FAO 2025

Azerbaijan reporting SAT-1 FMD 10-2025



World Organisation
for Animal Health

WAHIS



Azerbaijan – Foot and mouth disease virus (Inf. with) – Immediate notification

GENERAL INFORMATION

COUNTRY/TERRITORY OR ZONE	ANIMAL TYPE	DISEASE CATEGORY	EVENT ID
ZONE	TERRESTRIAL	Listed disease	6951
DISEASE	CAUSAL AGENT	GENOTYPE / SEROTYPE / SUBTYPE	START DATE
Foot and mouth disease virus (Inf. with)	Foot and mouth disease virus	SAT 1	2025/10/25

<https://wahis.woah.org/#/in-review/6951>

SAT 1 strain



SAT1 strains have shown limited circulation in recent decades

- Many manufacturers have discontinued production of SAT1 vaccines
- The SAT1 strains available for vaccine production are outdated and matching data are missing

Sharing of the actual SAT1 strains

- Biosafety/biosecurity issues (live virus to be shared)
- FAO/WOAH/WRL Ref centres/labs to be involved
- Must be coordinated on the international level

FMD SAT1: Situation Update & Recommendations for Prevention and Response in the Near East and beyond FAO 2025

Production of FMD vaccine from an isolate

- Adaptation to cell culture
- Strain characterization
 - Biological
 - Antigenic
 - Molecular
- Vaccine production and quality control
- Vaccine registration/licensing in the country of origin

FAO: Situation Update & Recommendations for Prevention and Response in the Near East and beyond 2025

FMD vaccines production

- National / Regional / Global
- Public / Private / PPP
- Autogenic
- Capability
- Investments
- Updating
- Dossier
- Transparency



National FMD vaccine production

- Expensive and ever-growing demands
 - R&D
 - Production facilities
 - Quality Assurance (GMP)
 - Documentation and record keeping
 - Production process
 - Process validation
 - Stability tests
 - Tests to demonstrate safety and efficacy
 - Safe for user, environment

- Difficult in small scale
- Country or Business
- Fewer players
- Global players

BSL-3 facility KVI VS Israel



Technical Item

**VETERINARY VACCINES AND VACCINATION:
from science to action – reflections for change**

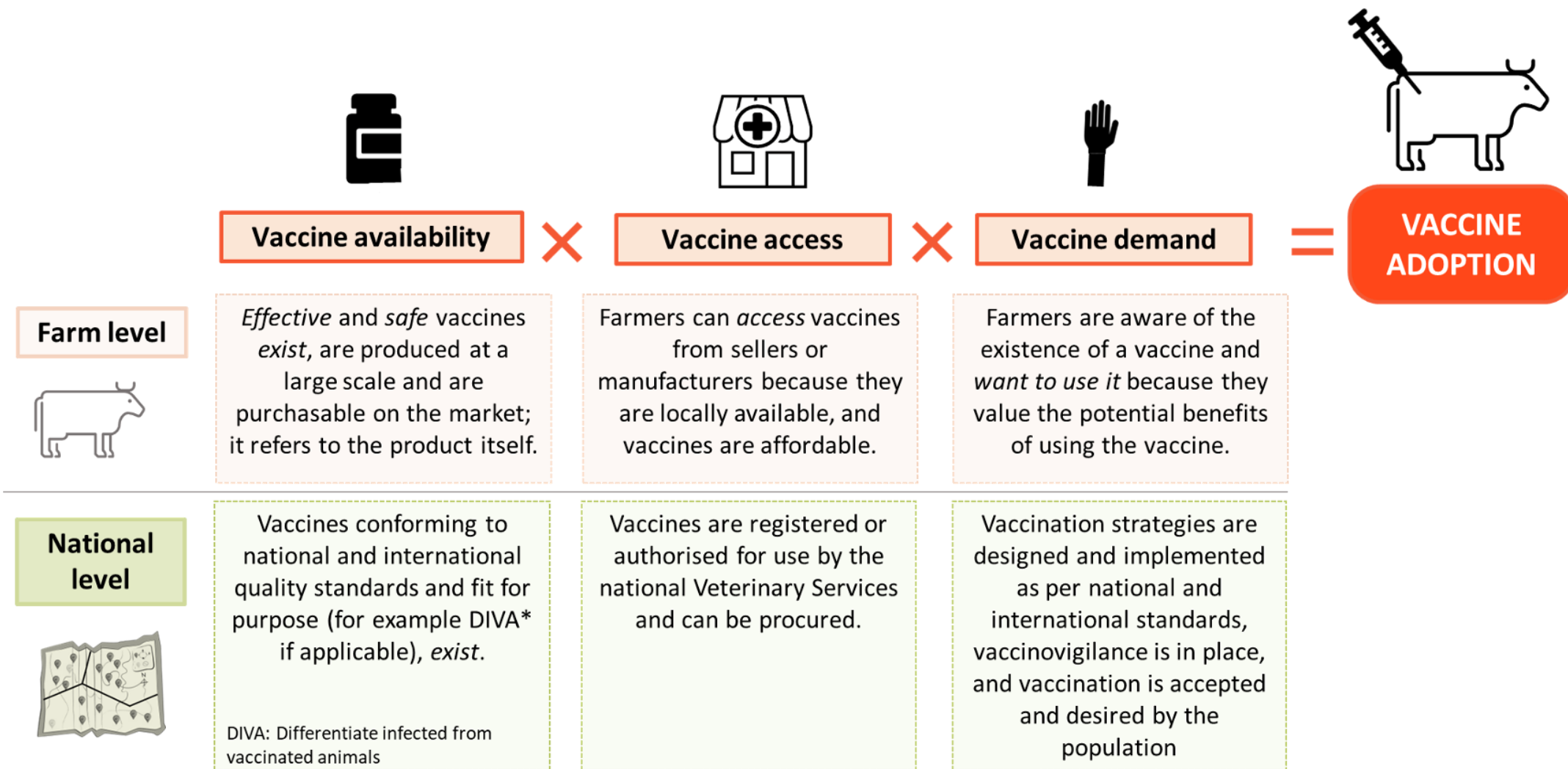
Authors: Baptiste Dungu¹, Meritxell Donadeu²

¹ Bonisa Solutions Ltd.; Initiative for Neglected Animal Diseases (INAND)

² Independent consultant; Initiative for Neglected Animal Diseases (INAND)

With support from: Gregorio Torres³, Javier Yugueros-Marcos³, Andrés García-Campos³, Rachel Tidman³, Charmaine Chng³, Mariana Delgado³, Francisco D'Alessio³ and Ramanan Laxminarayan⁴

³ World Organisation for Animal Health (WOAH); ⁴ One Health Trust



WOAH on vaccine production

Potential WOAH contribution:

- WOAH to encourage Members to reassess and evaluate vaccine supply structures and governance.

Potential Member contributions:

- Members without adequate facilities or expertise to produce all necessary veterinary vaccines with the quality recommended by international standards to consider different technical and commercial options before engaging in national manufacturing.

Potential Pharmaceutical company contributions:

- Local vaccine producers that are faced with challenges to produce the right vaccines in enough quantity or quality to develop collaborations with other companies including PPP approaches.



FMD vaccine producers - 29 facilities

Company	Location of production sites
Biogénesis Bagó	Argentina/ Brazil
Biovet Private Ltd	India
Boehringer-Ingelheim (BI)	France/UK/ Brazil
Botswana Vaccine Institute (BVI)	Botswana
Brilliant Bio Pharma	India

BWAT Bio. Science and Technology (website says Inner Mongolia Bigvet Biotech Co., Ltd.)	China
China Agricultural Vet. Bio. Science and Technology	China
Department of Livestock Development (DLD)	Thailand
Dollvet	Türkiye

FMD vaccine – Formulation plants

Company	Location of production sites	Antigen source
Biopharma	Morocco	
FVC Co. Ltd	South Korea	Biogenesis Bago
Dong Bang	South Korea	FGBI-ARRIAH
Navetco	Vietnam	
Vetvaco	Vietnam	BI

The European Commission for the Control of Foot-and-Mouth Disease (EuFMD)



Food and Agriculture
Organization of the
United Nations



	Who we are	Global situation	What we do	Progressive Learning Pathway	Meetings and Events	Tools	Resources
--	------------	------------------	------------	------------------------------	---------------------	-------	-----------

Public Summary Report (PSR)

Committee for Prequalification (SCPQv)

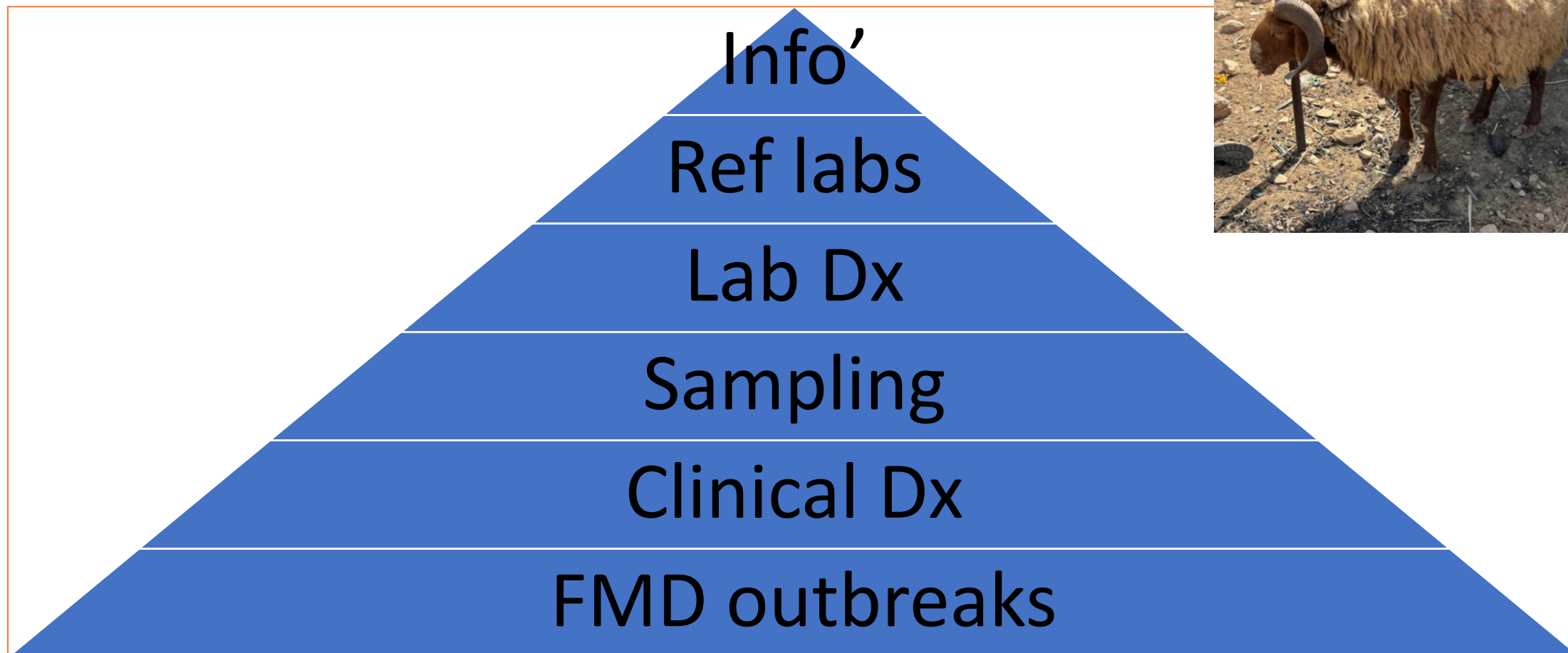
Vaccine Prequalification

PQv list

- BIOAFTOGEN**
- AFTOPOR**
- DECIVAC FMD DOE**
- AFTOVAXPUR**

Source: WRLFMD

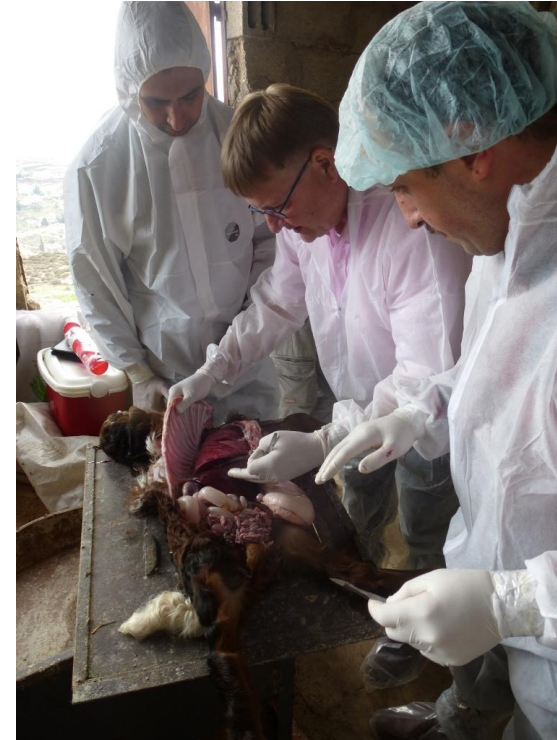
FMD diagnosis



Diagnosis and sampling capacity



Expertise
Training
Experience
Resources



Sampling training and research

News

Field study reveals the best way of sampling for foot-and-mouth disease in endemic settings

04 April 2025

Scientists from The Pirbright Institute have led a longitudinal study of foot-and-mouth disease (FMD) in collaboration with the National Veterinary Research Institute (NVRI) in Northern Nigeria.



www.pirbright.ac.uk/news/field-study-sampling-foot-and-mouth-disease

FMD lesion sampling

- Incubation period is highly variable
- Depends on strain, dose, route, species
- Physiology, immunology, husbandry conditions
- Field- typically 2 to 5 days
- WOAAH -Terrestrial Code -14 days incubation



Testing site – field or lab

- WOAHA certified kit 2023
- VDRG® FMDV 3Diff/PAN Ag Rapid kit
- Pen-side test
- Serotypes A, O and Asia-1
- Cattle or pig samples
- Tissue /fluid samples

MEDIAN Diagnostics Inc.

VDRG® FMDV 3Diff/PAN Ag Rapid kit

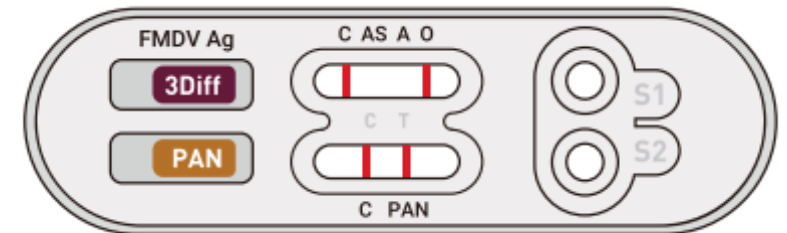
Cat. No. PM-FMD-16

For *in-vitro* veterinary diagnostic use only



World Organisation
for Animal Health
Founded as OIE

Validated and certified by WOAHA as fit for the purposes
defined in this instruction manual.
Registration number: WOAHA 022029



Both control and test lines are red

FMD sampling and reporting

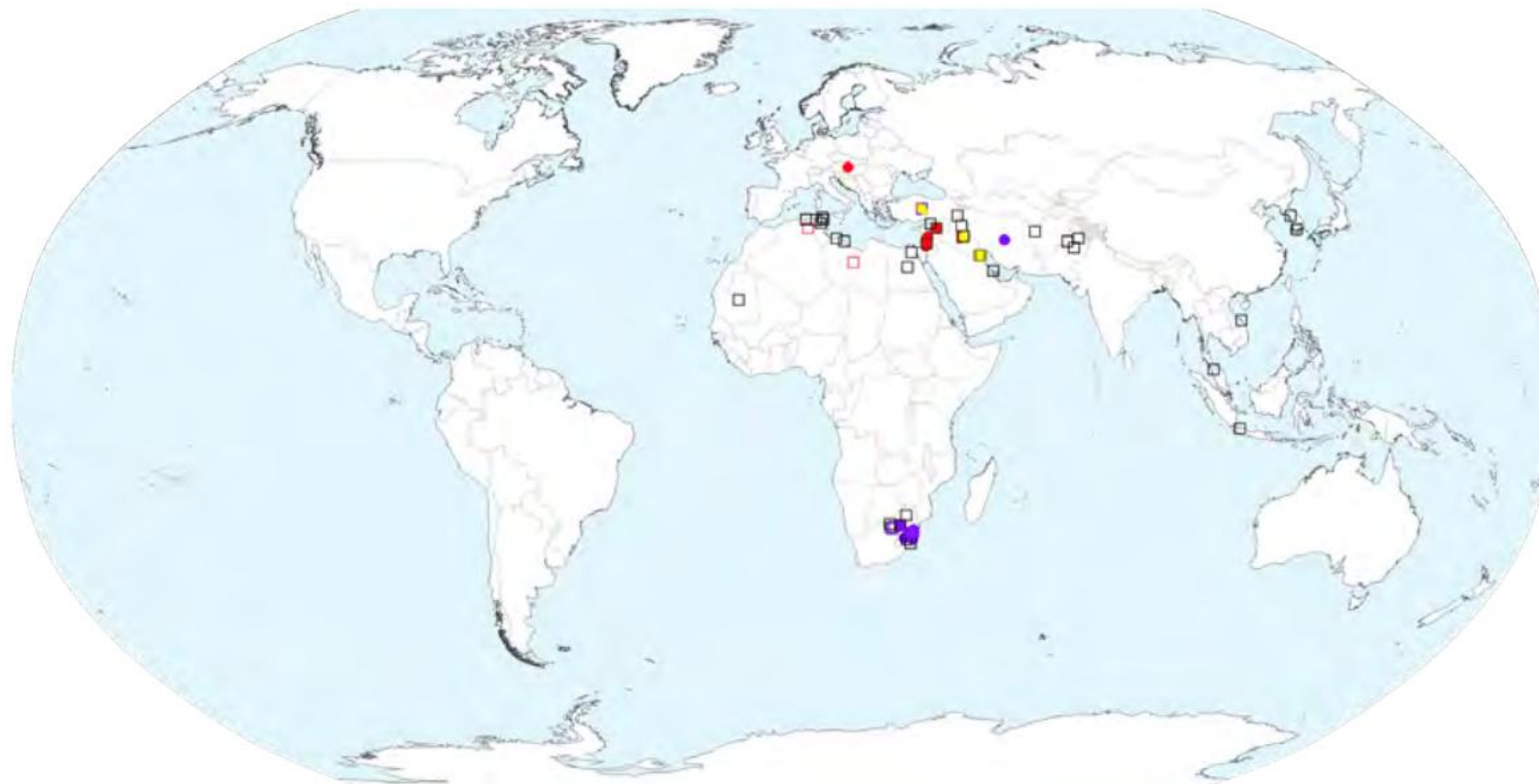


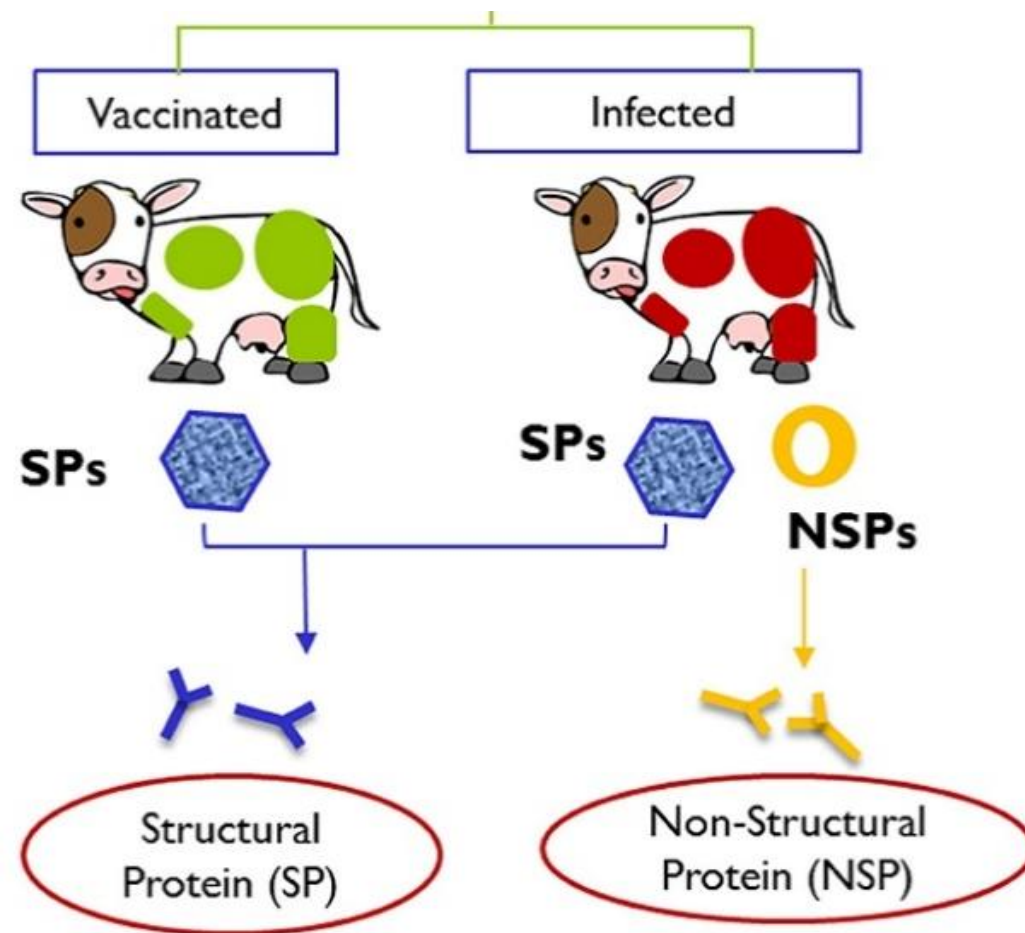
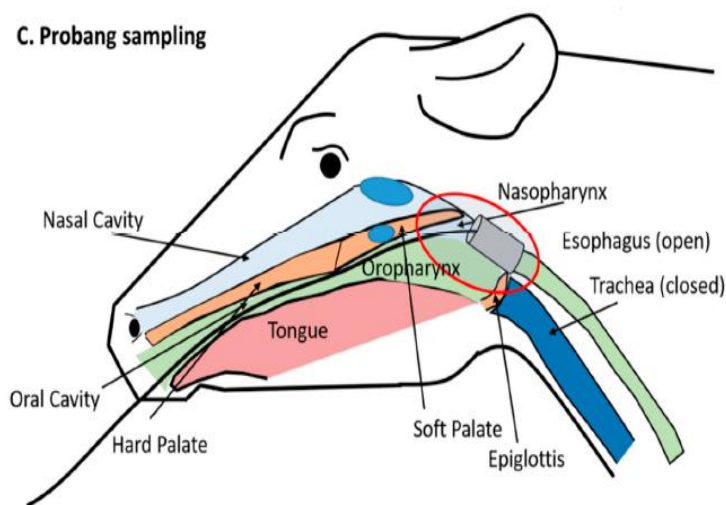
Figure 1: Samples tested by WRLFMD or reported in this quarter. ● indicates samples analysed; × indicates outbreaks reported/updated to the WOAH this quarter; □ indicates reports of FMD from other sources. Shape colours define the serotype detected ● O; ● A; ● C; ● Asia1, ● SAT1, ● SAT2, ● SAT3, ● serotype undetermined/not

Source: WRLFMD. Map conforms to the United Nations World map, June 2020

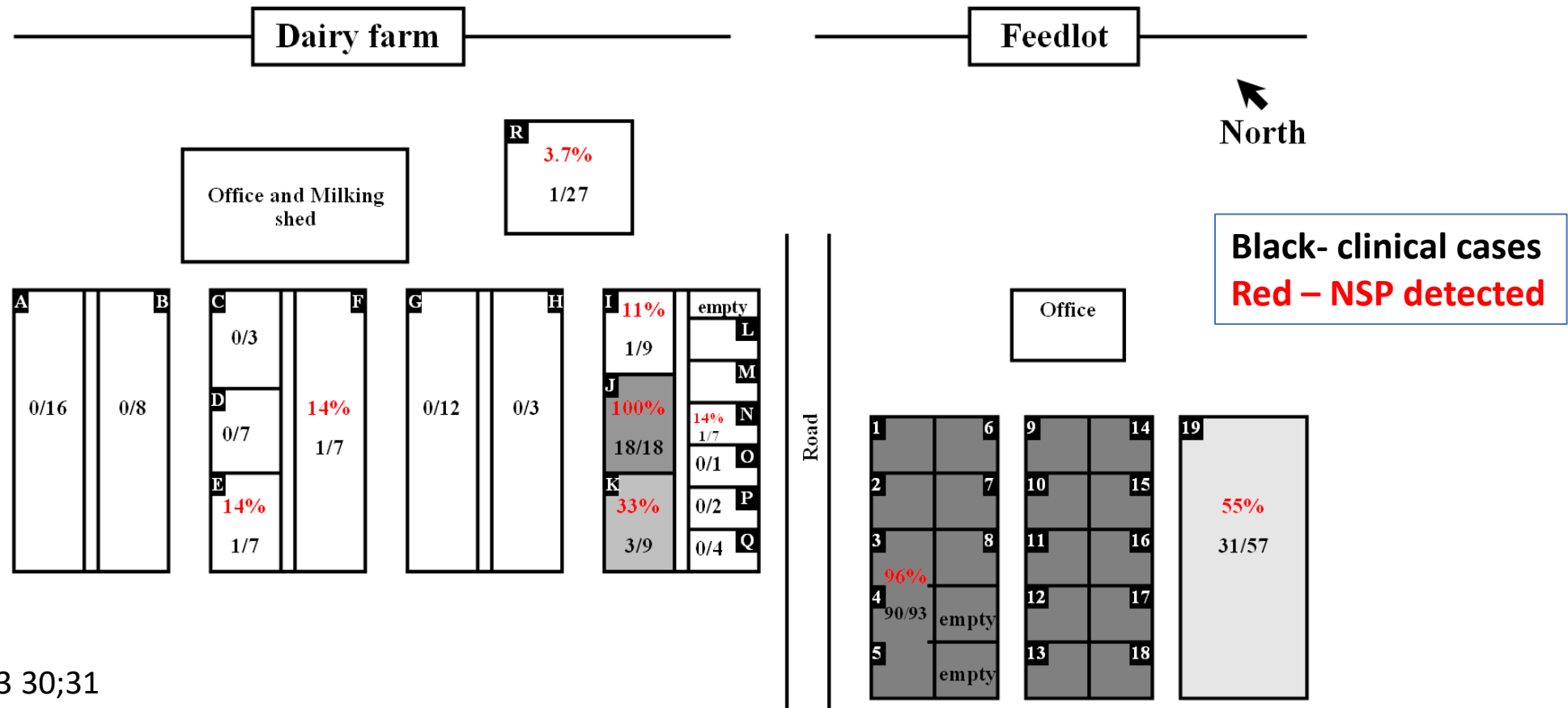
Traceability and Sero-surveillance

Samples collected from suspected herds

- Nasopharynx
- Serology



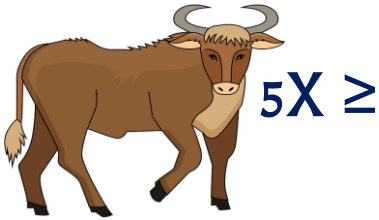
NSP sero-surveillance – RM farm 2011 IL



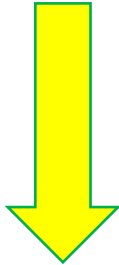
Elnekave et al vaccine 2013 30;31

NSP-free vaccine is crucial for NSP- sero-surveillance

Testing vaccine strain efficacy



d21-30



Vaccinated sera



- Optimal combination
 $VNT \geq 1.42$
and
 $r1 \geq 0.3$

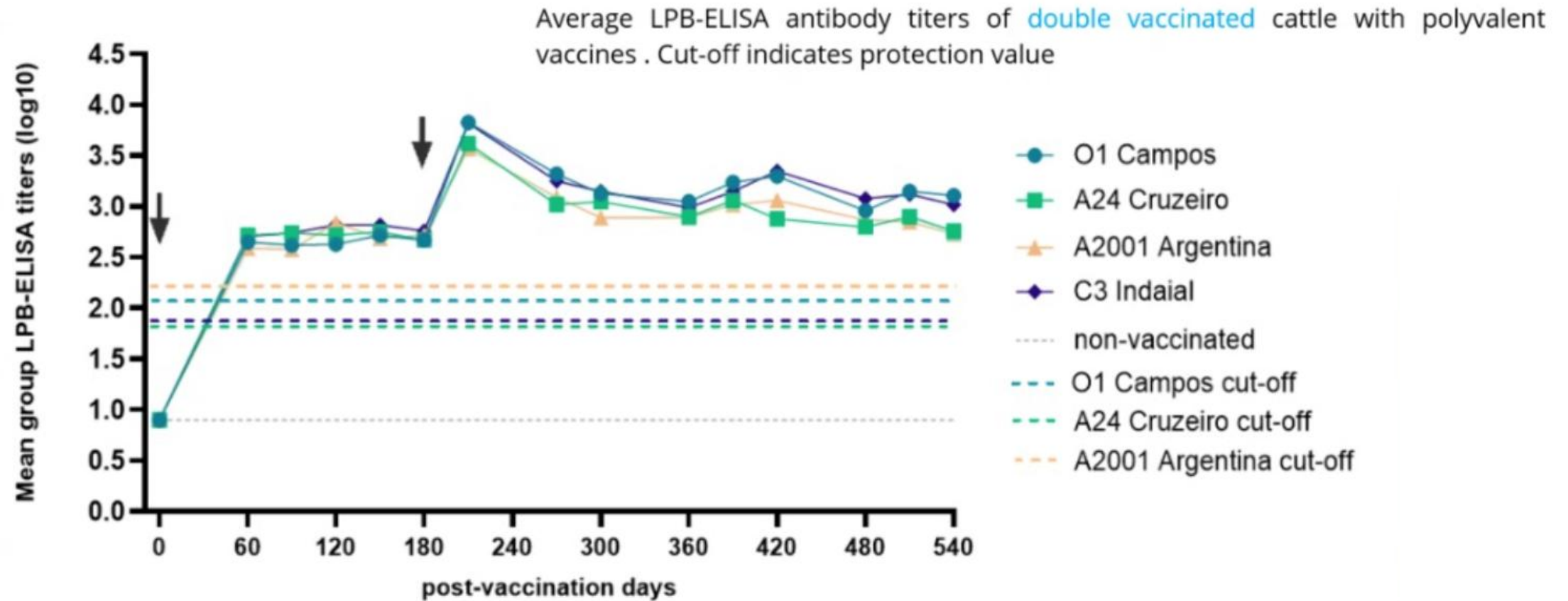
- 5 calves
- Vaccinated \geq once
- 21-30 after last vaccination

Matching vaccine field strains results

	BI			MSD	BB	BI	
	O3039	O-PanAsia02	O-Manisa	O-TUR/5/09	O1-Campos (biogenesis)	O1-Campos (Boehringer)	
Isolate: O/JOR/10/2021	0.37 (1.53)	0.23 (1.84)	0.11 (1.61)	0.35 (1.92)	0.18 (2.09)	0.22 (1.85)	r1 VNT
Isolate: O/JOR/6/2021	0.36 (1.54)	0.30 (1.95)	0.19 (1.82)	0.56 (2.12)	0.25 (2.24)	0.17 (1.73)	r1 VNT

Vaccines originating from other pools may protect

Duration of immunity



“Vaccines don’t protect, vaccination does”

The Lancet Regional Health - Western Pacific 6 (2021) 100099



ELSEVIER

Contents lists available at [ScienceDirect](#)

The Lancet Regional Health - Western Pacific

journal homepage: www.elsevier.com/locate/lanwpc

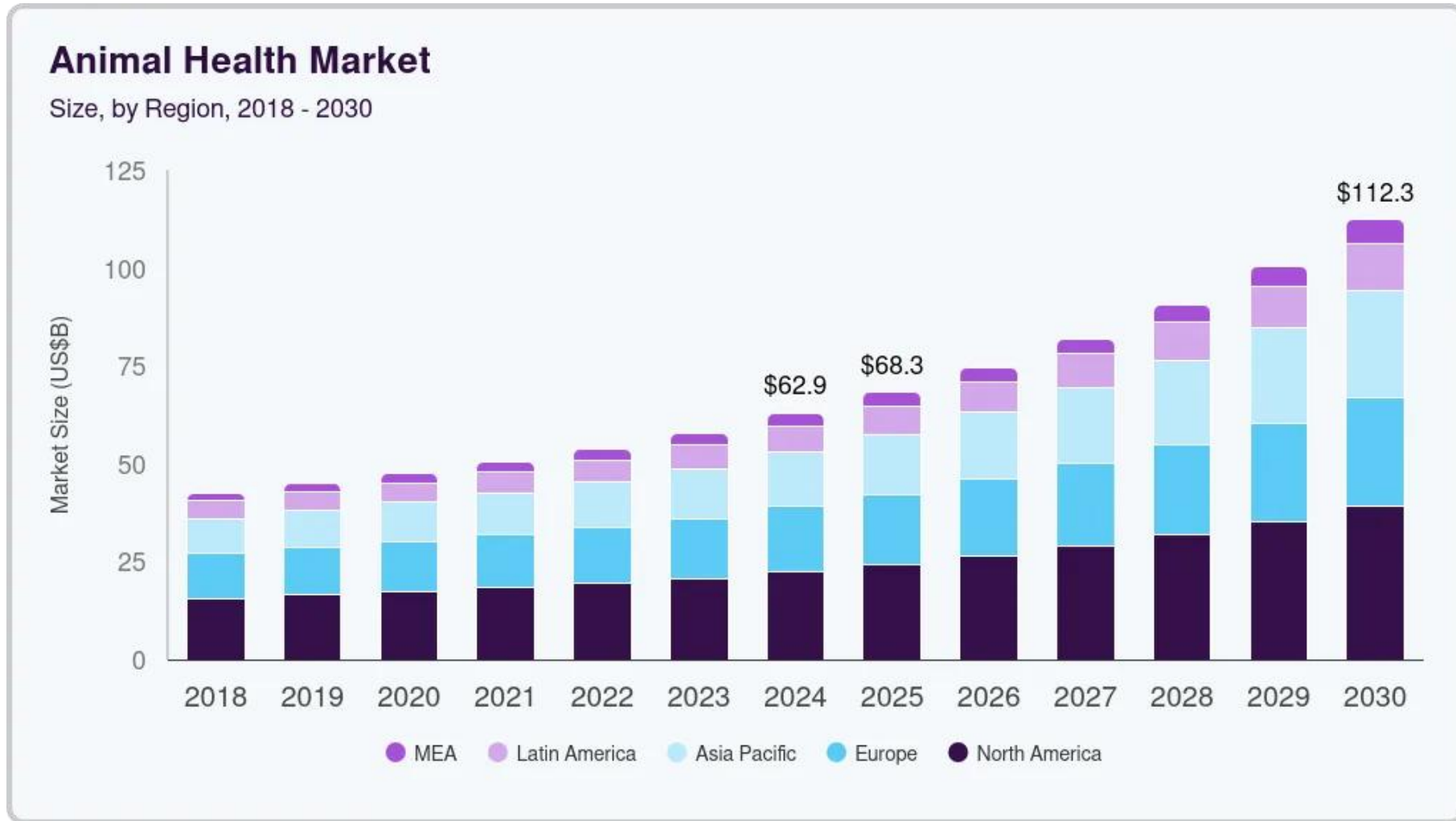


Editorial

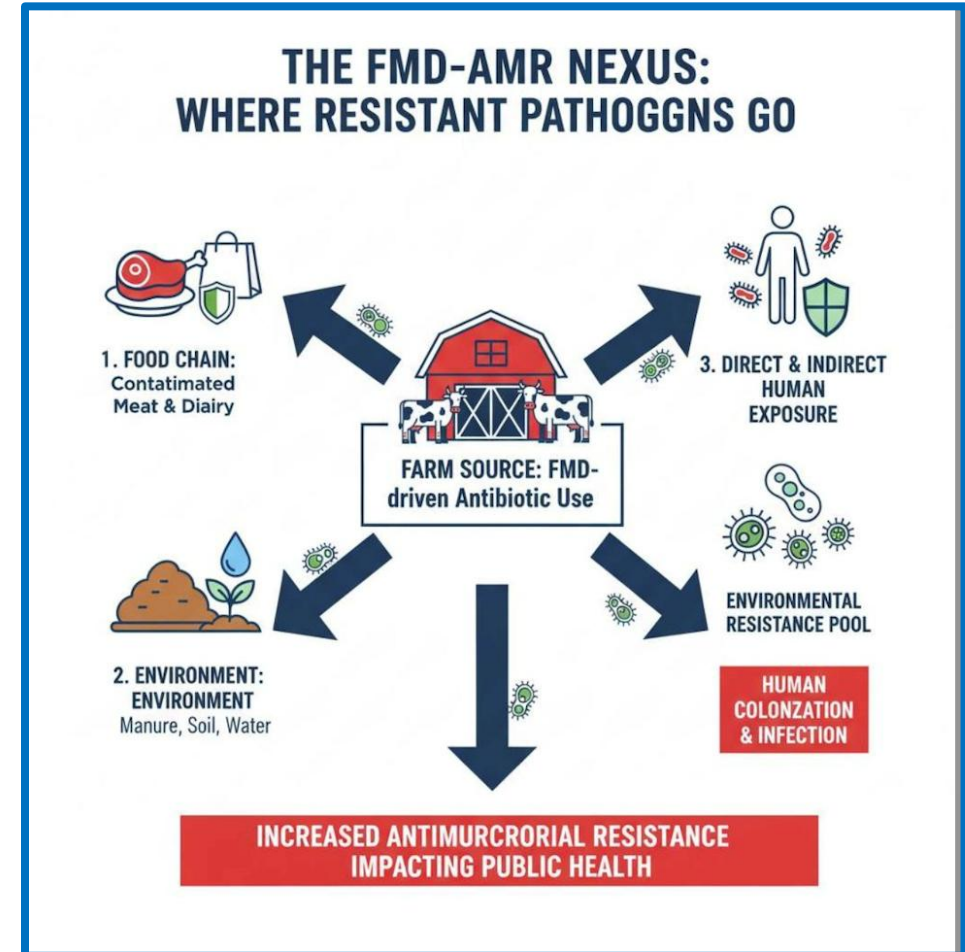
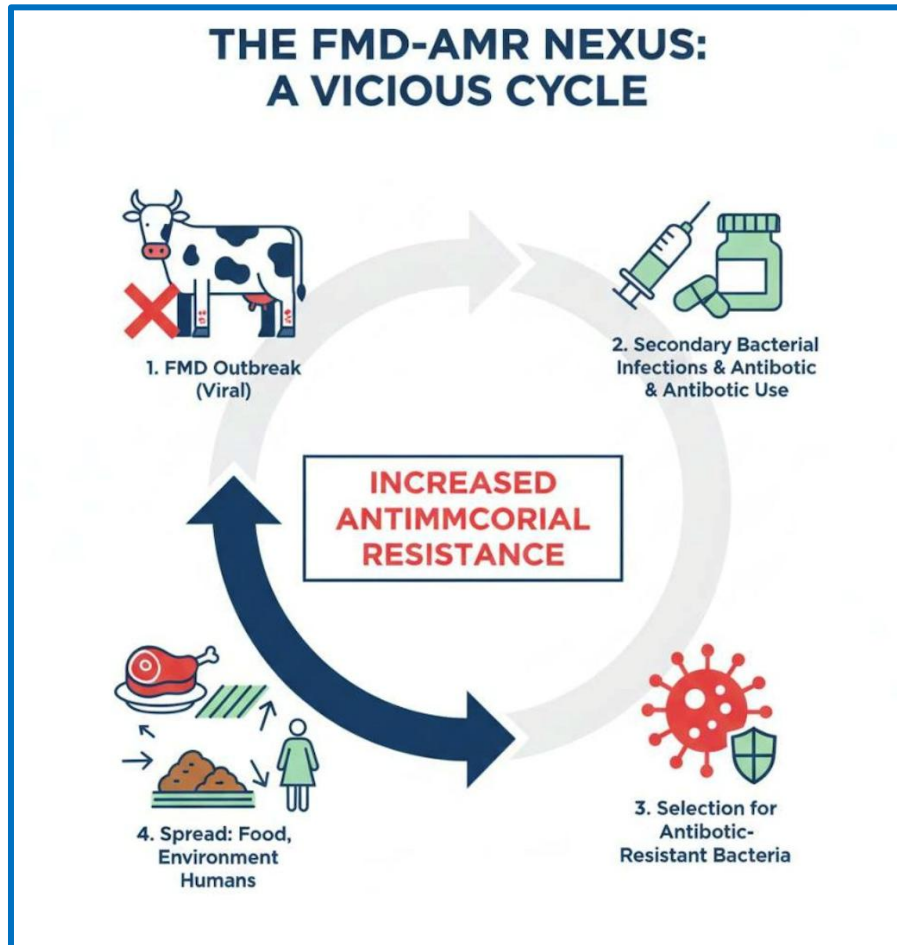
Vaccines don’t save lives, vaccination does

[www.thelancet.com/journals/lanwpc/article/PIIS2666-6065\(21\)00008-0/fulltext](http://www.thelancet.com/journals/lanwpc/article/PIIS2666-6065(21)00008-0/fulltext)

More livestock - more investments - better protection



FMD AMR One-Health



Summary

- Valuable animals - quality vaccines
- Cost-Benefit
- Efficacy & effectiveness
- NSP free vaccines
- Traceability & surveillance
- Vaccines and vaccination

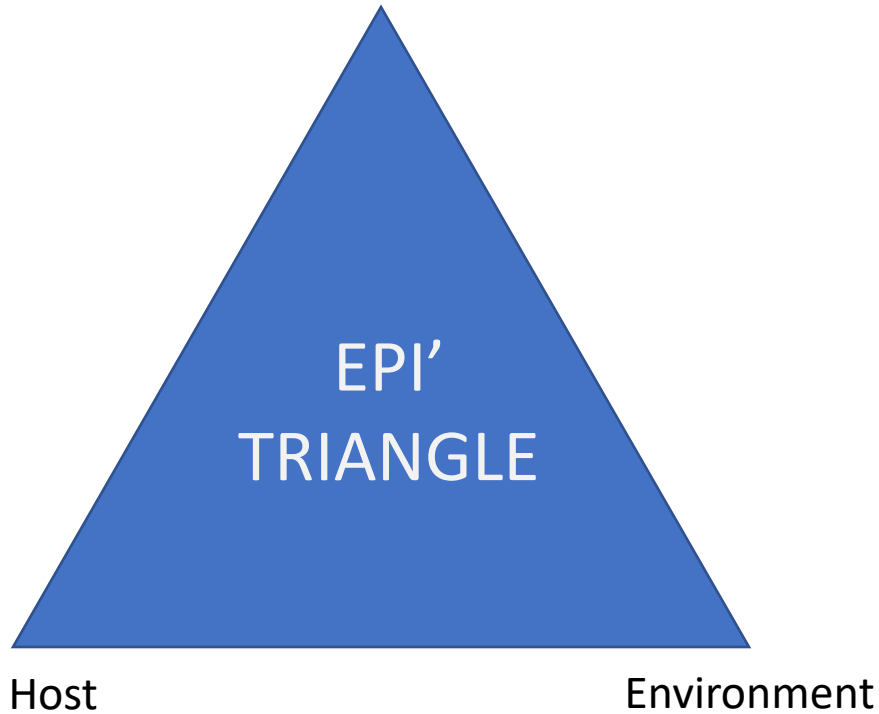




Human era - Paradigm shift

HOLOCENE

Agent



Agent

Human factor



Host

Environment

“Very Few Things are Simple Black and White”



Thank You
Nadav.galon@gmail.com