Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Risk Based Decision-making for Vaccine Banks

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Presentation outline

1) History of the North American FMD Vaccine Bank (NAFMDVB)

2) NAFMDVB risk based decisions

3) EUFMD and WRLFMD risk based decisions (Pragmatist)

North American FMD Vaccine Bank

1982 — 2002 — 2010 — 2012 — 2013 — 2014 — 2016

- In **1982 a memorandum of understanding was signed** by the Agricultural ministers of Canada, the United States and Mexico that **resulted in the formation of the North American Foot and Mouth Vaccine Bank** (NAFMDVB).

- The **formula for the country contributions** to the annual operating budget of the bank was **originally agreed upon in 1982.**

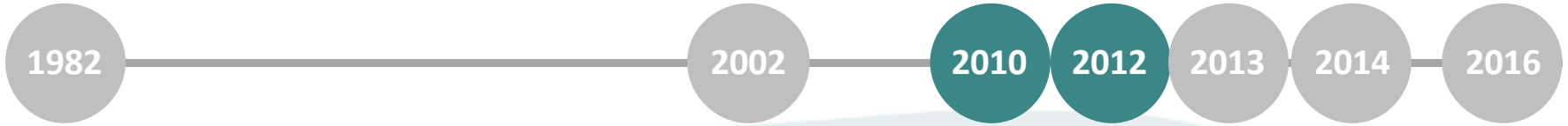
- The **initial proportions were solely base on census of Cattle in each of the countries in 1982** which resulted in a distribution of US - 72%, Mex – 20% and Can – 8%

North American FMD Vaccine Bank

1982 — **2002** — 2010 — 2012 — 2013 — 2014 — 2016

- In **2002 a number of different formulas** were looked at, cattle only, cattle and swine, cattle and sheep and goats.
- The **final decision was US - 70%, Mex – 20% and Can – 10%** which remains in effect today.
- The **NAFMDVB main purpose was to maintain a supply of Vaccine Antigen Concentrates (VAC's)** that could be **rapidly finished** into usable vaccine if an outbreak occurred.
- Originally the bank was designed to **only hold enough vaccine if a stamping out policy alone failed** to halt the spread of the FMD outbreak.

North American FMD Vaccine Bank



- Since **2010 all three countries have included vaccination** as part of their emergency response plans.
- The bank overall **storage strategy was to maintain the individual VAC's in the stockpile until** the yearly stability testing indicated they were **no longer efficacious.**
- In **2012 the bank held VAC's primarily from 2 different companies**, A European company (5 year guarantee), and South American company (12 year guarantee)) with **largest proportion of the VAC's held by** the Bank being provided by the **European Company.**

North American FMD Vaccine Bank

1982 — 2002 — 2010 — 2012 — **2013** — 2014 — 2016

- In **July of 2013** the bank was informed by our **European supplier** that they would **no longer be able to finish VAC's older than 10 years because of changes to the EU good manufacturing requirements** for their facility.
- At the time the NAFMDVB was the **only developed country's FMD vaccine bank that did not store their VAC's at a manufacturer.**
- VACs were stored at **Plum Island from 1982 until 2013** when the decision to store all new VAC's at the manufacturer was made
- VACs purchased **prior to 2013 are still stored at Plum Island**

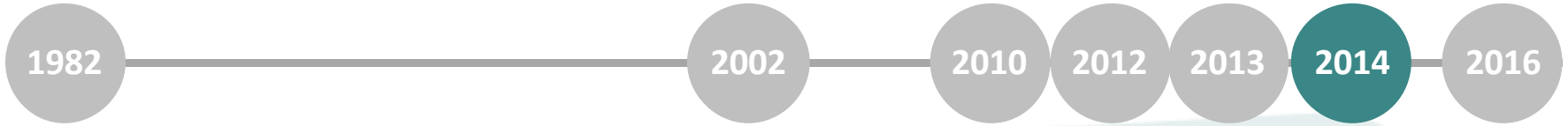
North American FMD Vaccine Bank

1982 — 2002 — 2010 — 2012 — 2013 — **2014** — 2016

At a meeting of the **working group in Mexico in 2014** it was agreed to:

- **Continue** our current **trilateral cooperative agreement**
- Require that the **bank hold a minimum number of antigens** which are;
    - •Capable of being combined into a polyvalent vaccine
    - •Capacity to share directly with other countries banks
    - •Each VAC would be a single formulations.
- **Streamline administrative burden** of the Bank and vaccine use.
- **Examine storage capacity** at present and future facilities.
- **Examine how response strategies** might necessitate increased vaccine amounts, and what those amounts might be.

North American FMD Vaccine Bank



- Each partner is **guaranteed to be allocated vaccine proportionate to their contribution** (USA 70%, Mex 20%, Can 10%)
- The **Commissioners have the discretion at the time of the outbreak** to alter the allocation proportions voluntarily
- The **bank will only supply** the emergency vaccination **needs of each partner** (i.e. the first complete round of vaccination)
- Long-term vaccine needs are the **contractual responsibility of each partner** (i.e. blanket vaccination to live campaigns)

North American FMD Vaccine Bank

1982 — 2002 — 2010 — 2012 — 2013 — 2014 — **2016**

- In **May of 2016** on the fringes of the **OIE meeting the member countries of the NAFMDVB**, Canada, Mexico and the United States **signed an arrangement** with the Foot and Mouth Disease Vaccine bank of Australia and the New Zealand Foot and Mouth Disease Vaccine Bank **to share FMD vaccines in the event of an outbreak** in one or more of the signatory countries.

- All three vaccine banks **store their VACs at the same manufacturer** and rotate stocks on a 5 year cycle.

- The **NAFMDVB would like to pursue sharing agreements with other countries** FMD Banks that use the same manufacturer.

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Four Key Challenges Underlie How are VACs Chosen

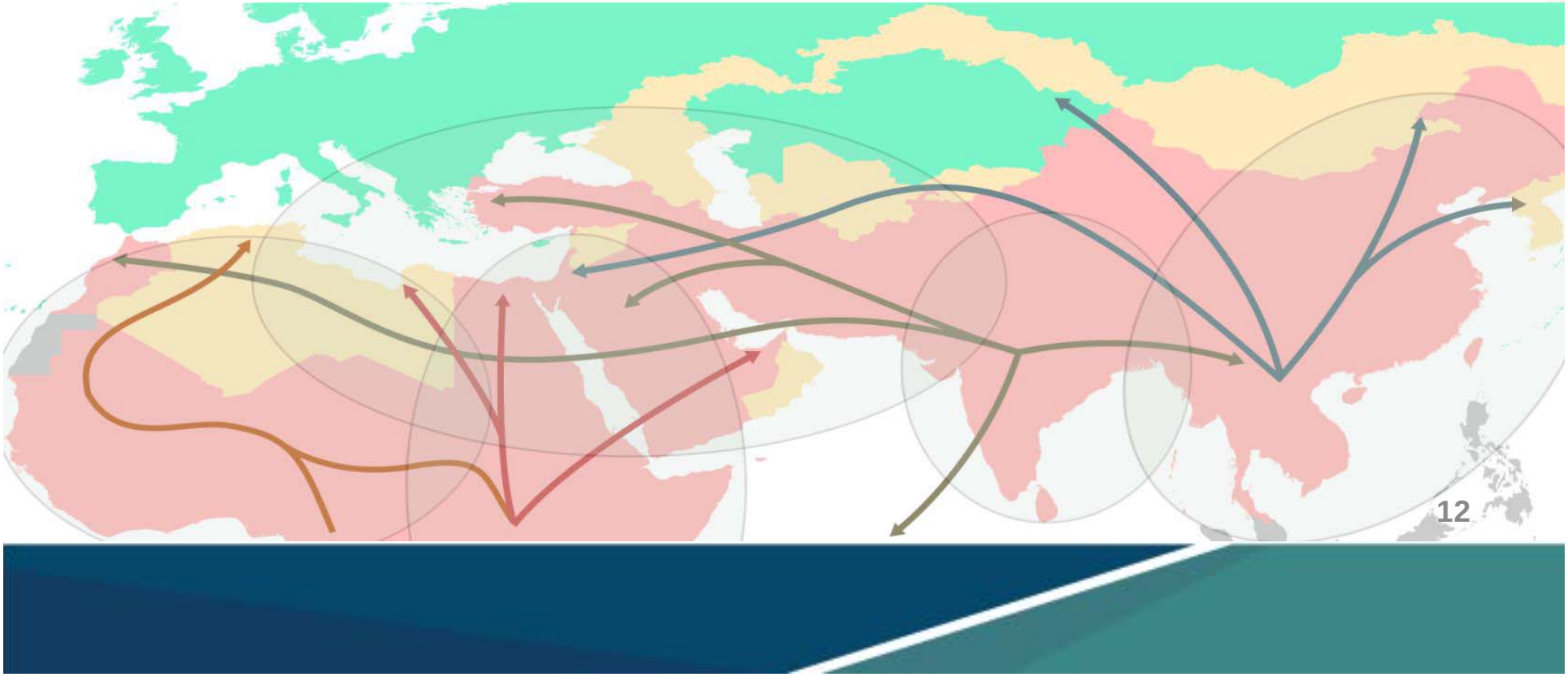
Four Challenges with Choosing VACs:

1. **FMD virus is complex:**
   - 7 (6) serotypes, multiple strains within serotypes.
2. **No cross-protection** between serotypes
   - Variable between strains within serotypes.
3. **Viruses in any region are a potential threat** to all other regions, no matter how far away, and consequently should be considered for inclusion in antigen banks. (Lombard & Füssel, 2007)
4. **Multiple vaccine strains available**

Illustration:

Viruses In Any Region Are A Potential Threat:

- What concerns us the most are the increasing long-distance “trans-pool” FMDV movements
- Multiple Causes are Possible::
  - Escalation of **regional political crises**
  - **Migration** of people in North Africa and the Middle East
  - Increased **demand for animal products** in East Asia.



Vaccine antigen banks must make high stakes decisions but decision criteria are ambiguous

Situation	Challenges	Vaccine Antigen Bank Objective
Antigen bank managers are **faced with difficult decisions** about which strains to maintain in the bank	• 4 challenges already discussed • Risks are **not very well defined** • Significant **financial investment**	An antigen collection should **strive to reflect the major strains involved in recent epidemiological situations** & the **strains expected to be involved in potential epidemiological situations in the next 5 years.** (Lombard & Füssel, 2007)
The **WRLFMD produces quarterly recommendations** that divide antigens into high, medium and low priority	• They are based on the EU perspective: **not "global" (Americas) in nature** • Criteria are **not clearly defined**	

Illustration:

RECOMMENDATIONS FROM WRLFMD® ON FMD VIRUS STRAINS TO BE INCLUDED IN FMDV ANTIGEN BANKS (FOR FMD-FREE COUNTRIES)

December 2017:

Note: Virus strains are NOT listed in order of importance

High Priority	A/ASIA/G-VII(G-18)* O Manisa O PanAsia-2 *(or equivalent)* Asia 1 Shamir A Iran-05 *(or A TUR 06)* A22 Iraq A24 Cruzeiro O BFS or Campos SAT 2 Saudi Arabia *(or equivalent i.e. SAT 2 Eritrea)*
Medium Priority	A Eritrea-98 SAT 2 Zimbabwe SAT 1 South Africa A Malaysia 97 *(or Thai equivalent such as A/Sakolnakorn/97)* A Argentina 2001 O Taiwan 97 *(pig-adapted strain or Philippine equivalent)*
Low Priority	A Iran '96 A Iran '99 A Iran 87 or A Saudi Arabia 23/86 *(or equivalent)* A15 Bangkok related strain A87 Argentina related strain C Noville SAT 2 Kenya SAT 1 Kenya SAT 3 Zimbabwe

Note: Discussions are currently underway to adopt a risk-based approach for different FMD viral lineages to identify priority vaccines for use in Europe and other FMD-free settings.

*Recent *in vitro* data from WRLFMD for serotype A viruses highlights an apparent gap in vaccines supplied by international manufacturers for this viral lineage.

How is the NAFMDVB helping alleviate these issues?

NAFMDVB Risk Prioritization Working Group

Who are they?

- The working group is composed of **4 subject matter experts** from each of the **three countries made** up of at least 1 regulatory, 1 scientific and 1 policy expert.
- Twice a year the working group of the NAFMDVB meets face to face to **prioritize antigen purchases** as well as deal with ongoing Bank operational issues.

What do they do?

- ✓ The group **relies heavily on information** on the spread of different serotypes from the **WRL on FMD** in Pirbright.
- ✓ The group takes into account **the extent of geographic spread**, the frequency of occurrence and the spectrum of protection that the current bank holds.
- ✓ The working group also **sets standards for potency, purity, safety, innocuity, extraneous agents and sterility**.
- ✓ They also **set standards for testing both by the manufacturer and the additional testing** that the Bank performs.
- ✓ Manufacturer is required to submit all test results to the bank for review by the working group.

So how do we choose what to hold in our banks?

WRLFMD recommended list of Vaccines

Serotype	O	A	C	Asia 1	Sat 1	Sat 2	Sat 3
Number	4	12	1	1	2	3	1

The **NAFMDVB working group takes into account all this information** and **produces a list of VAC's** and the order that the WG wishes to purchase them for the next 5 years and presents the list to the CVO's for approval.

NAFMDVB Risk prioritization

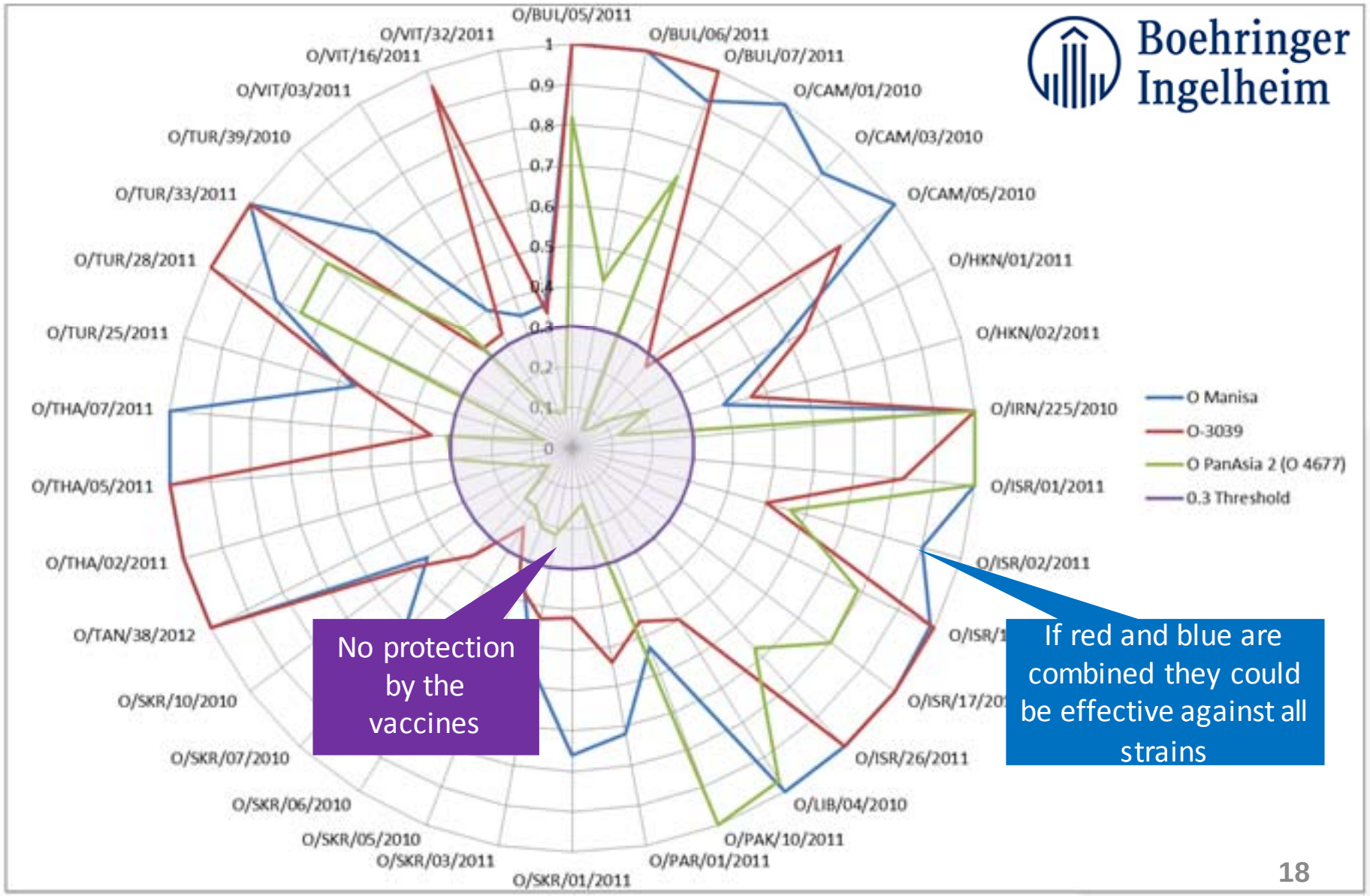
Well Managed Serotypes

Serotype	O	A	C	Asia 1	Sat 1	Sat 2	Sat 3
Number	4	12	1	1	2	3	1

- We feel our **O serotypes provide excellent coverage** when used as a bivalent vaccine.

- **C's have not been seen world** wide for 12 years' while we **do not consider them to be a large risk**, the fact that world stockpiles are being reduced, **concerns us.**
- In fact, because of the progress South America has made towards eradication the Bank feels that there is low risk of the South American strains entering North America, but we are developing agreements with South America vaccine manufactures for just in time delivery of SA serotypes.

- **Asia 1, SAT's 1, 2 and 3 have been relatively stable**, so there is very **little change in our holdings** although recently we have seen some change in the SAT 2.


Boehringer Ingelheim
O/BUL/05/2011
O/BUL/06/2011
O/BUL/07/2011
O/CAM/01/2010
O/CAM/03/2010
O/CAM/05/2010
O/HKN/01/2011
O/HKN/02/2011
O/IRN/225/2010
O/ISR/01/2011
O/ISR/02/2011
O/ISR/17/20
O/ISR/26/2011
O/LIB/04/2010
O/PAK/10/2011
O/PAR/01/2011
O/SKR/01/2011
O/SKR/03/2011
O/SKR/05/2010
O/SKR/06/2010
O/SKR/07/2010
O/SKR/10/2010
O/TAN/38/2012
O/THA/02/2011
O/THA/05/2011
O/THA/07/2011
O/TUR/25/2011
O/TUR/28/2011
O/TUR/33/2011
O/TUR/39/2010
O/VIT/03/2011
O/VIT/16/2011
O/VIT/32/2011
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
O Manisa
O-3039
O PanAsia 2 (O 4677)
0.3 Threshold
No protection by the vaccines
If red and blue are combined they could be effective against all strains

NAFMDVB Risk prioritization

Serotypes Presenting the Greatest Risks

Serotype	O	A	C	Asia 1	Sat 1	Sat 2	Sat 3
Number	4	12	1	1	2	3	1

- The **A serotypes present the largest problem** to any vaccine bank because of their lack of cross protection between strains as well as the large amount of variation. (12 A's on the WRL list).
- In September of 2015 **a new A serotype emerged in the middle East, Saudi Arabia, Turkey, Iran and Armenia**.
- There is **evidence for at least two separate escape events** of this strain from the Indian Sub-continent.
- **Very poor antigenic match to current vaccines** using in vitro tests

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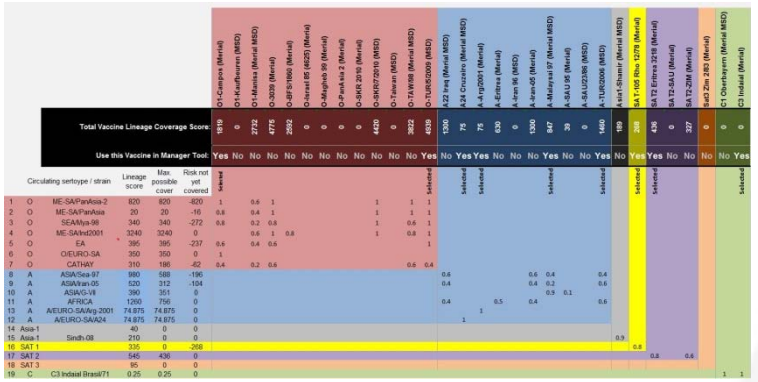
PRAGMATIST: Antigen Priority tool

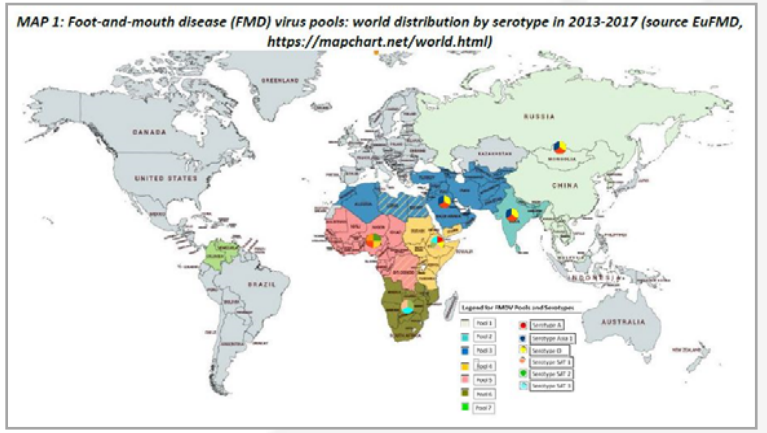
What is Pragmatist?

- The tool **developed by the EUFMD and WRLFMD** takes the form of a **spreadsheet**

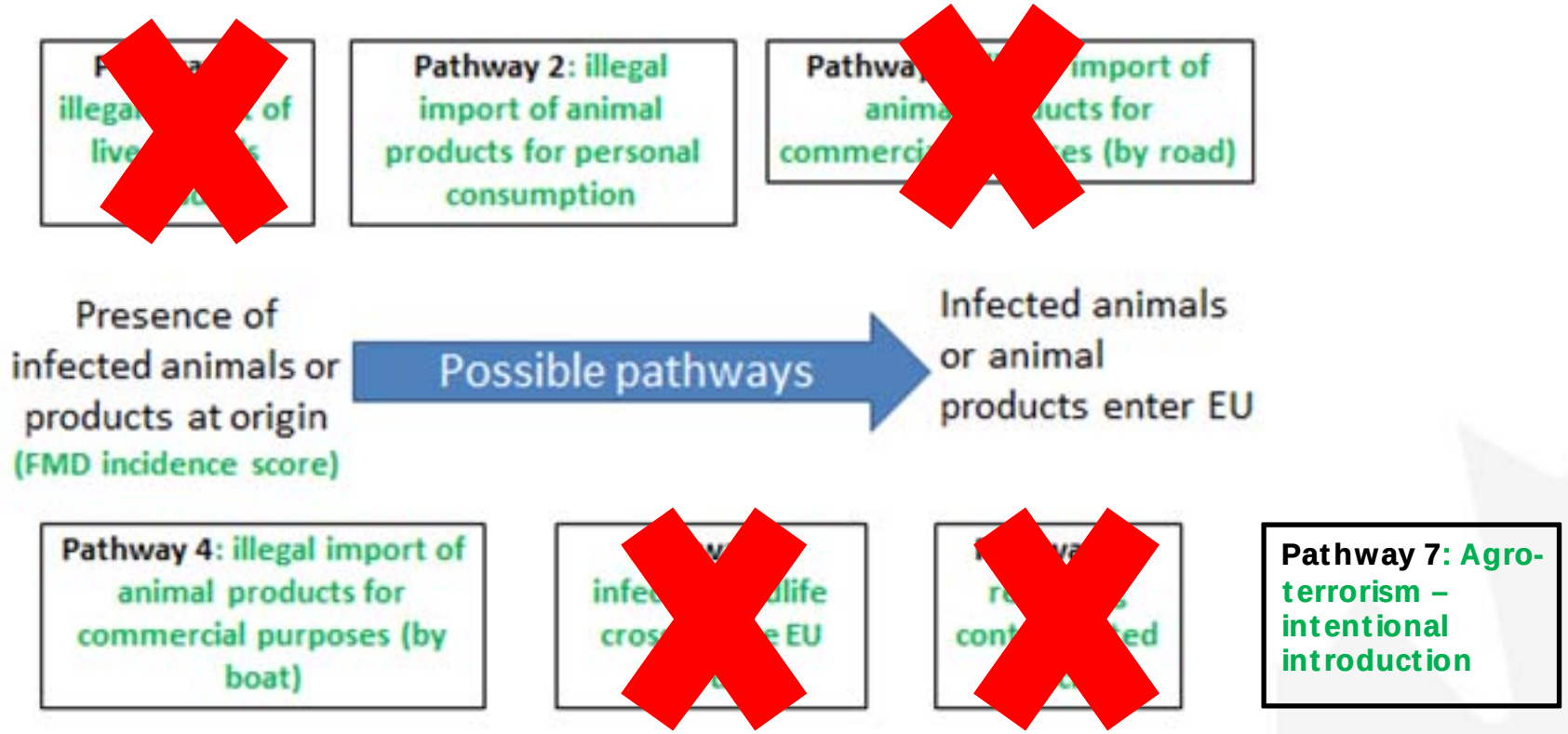


What does it do?

- Serves as an **antigen priority tool** developed to **assist risk managers make decisions about what FMD vaccines** they purchase and/or maintain, **based on present risks** to their country
- The spreadsheet is **primarily EU focused**, but there is **no reason we can not adapt** to North and South America.
- *Little hard data available…need to ask for expert opinion*



PRAGMATIST: Antigen Priority tool

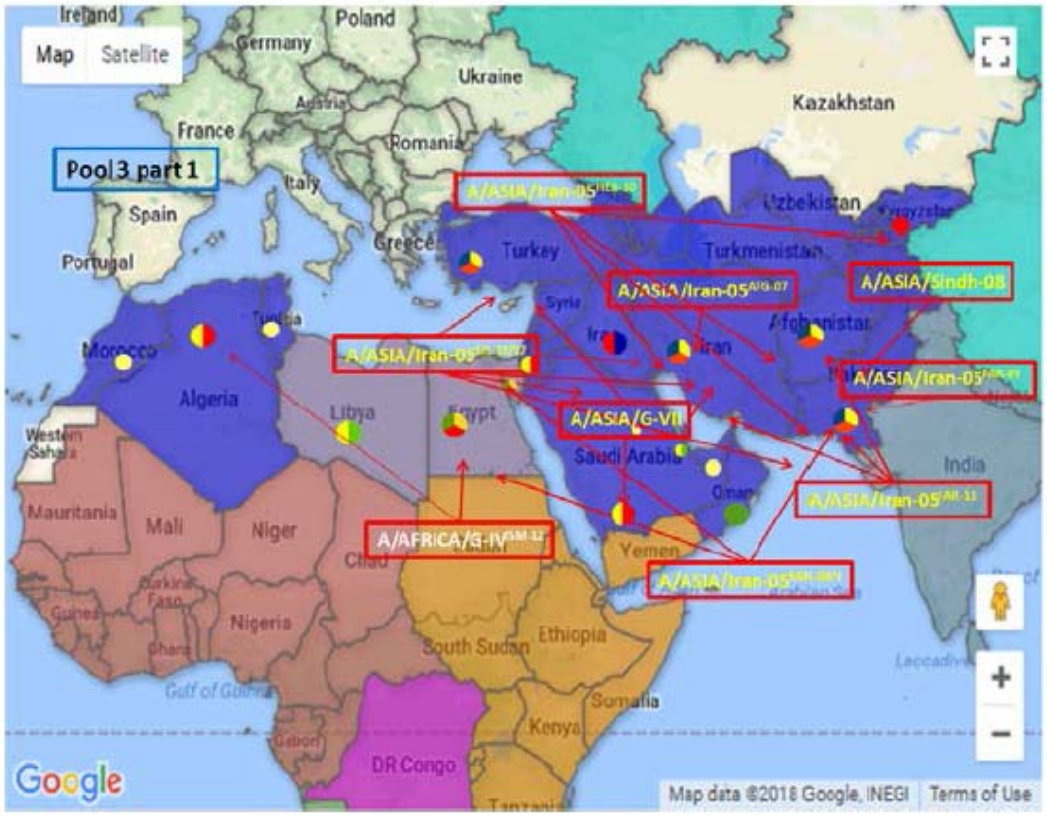


Pragmatists assess risks from viruses entering due to illegal/informal activity. Legal activities are made safe by border and trade restrictions

Case Study – Context: *How could we measure risk from the Middle East?*

High Risk Serotypes: The Middle East currently has numerous A & Asia 1 lineages circulating

The Middle East (pool 3) A & Asia 1 Lineages:



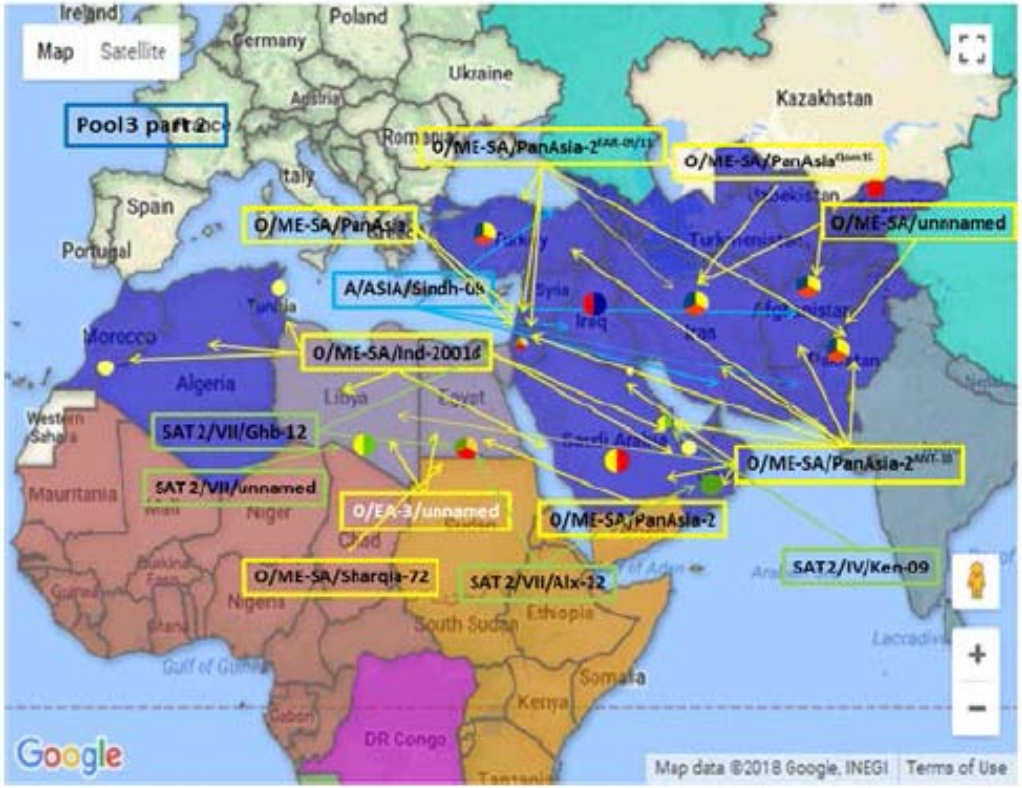
Conjectured circulating FMDV serotype A and Asia 1 lineages:

- A/ASIA/IRAN-05 (from AFG-07, HER 10, SIS-10-13, FAR 11 and BAR-08 sub-lineages)
- A/Asia/G-VII (recent incursion from South Asia)
- A/ASIA/SEA-97
- A/ASIA/Sindh-08
- A/AFRICA/G-IV
- Asia-1 (Sindh-08 lineage)

Case Study – Context: *How could we measure risk from the Middle East?*

Other Serotypes: Various O strains and Sat 2 strains circulate in the region as well.

The Middle East (pool 3) O & Sat 2 Lineages:



Conjectured circulating FMDV serotype O and SAT 2 lineages

- O/ME-SE/PanAsia-2 (predominately from ANT-10 and FAR-09 / 11 sub-lineages)
- O/ME-SA/IND-2001 (recent incursions per 2013/14 from Indian sub-continent)
- New detection during 2016 of O/ME-SA/Sharqia-72 in Egypt and of O/ME-SA/PanAsia-2QOM-15 in Iran
- O/EA-3/unnamed in Egypt, Libya, Israel and Palestine
- SAT 2/IV/Ken-09
- SAT 2/VII/Alx-12 and Ghb-13 sublineages

Pragmatist – A Conceptual Overview

	Inputs	Outputs	
	Relative Risk	**Relative Threat**	**Vaccine Antigen Coverage**
Description	An **assessment of the likelihood of FMD being introduced into your country** from 8 different regions	**Which of 8 different regions** of the world **provides the greatest risk of entry** to your region or country	The portion of lineage score covered by currently available vaccines
Measure	**Source Area Multiplier** • User (Country Expert) **allocates 100 points across each of the 8 different regions** to weight the likelihood of FMD being introduced from that region	**Relative Prevalence:** • Prevalence of a strain **in a given geographic area** **Lineage Score** • Weighted average of risk of each strain to your country (based on relative prevalence from 8 different regions)	**Risk Not Yet Covered:** • The difference between lineage score & max possible coverage • *A manager tool allows user to switch selected vaccines and see impact on a dashboard that outlines % of risk covered*
Source	*Country experts*	*Data from expert opinion: WRLFMD and regional lab/epi networks*	*Table of available vaccines with the coverage that they provide*

Case Study – PRAGMATIST Inputs: *First we can define relative risk from the lens of North America*

- I used some sample values using a **North American Focus** *(typically populated by country experts)*
- Pragmatist splits the **Middle East into region 1 and 3**

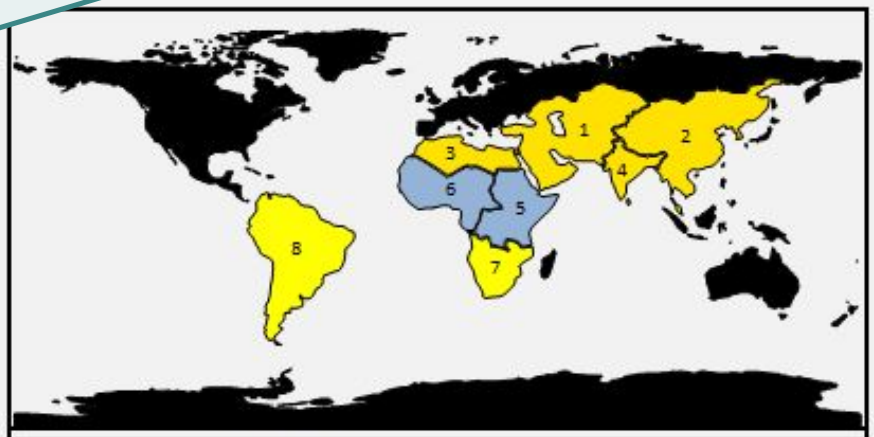
Source Area Multiplier

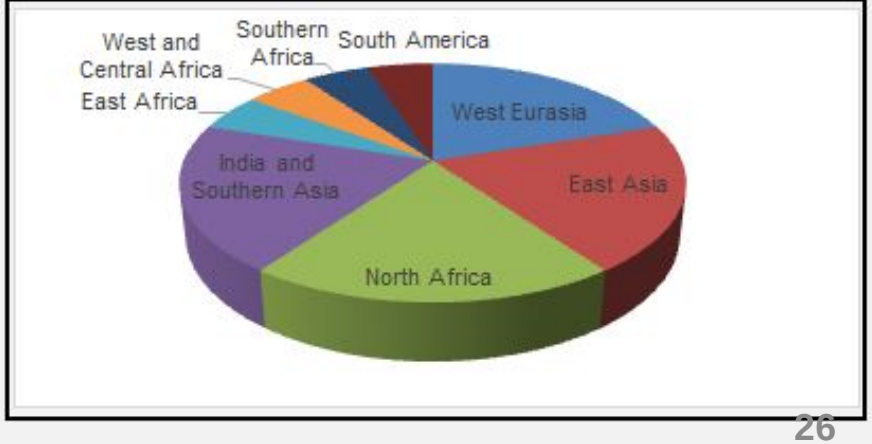
Hit the Return key twice to enter a value

1	West Eurasia	20
2	East Asia	20
3	North Africa	20
4	India and Southern Asia	20
5	East Africa	5
6	West and Central Africa	5
7	Southern Africa	5
8	South America	5
	Total	**100**

All risk has been asigned

Enter the risk of FMD being introduced to your country from the different FMD endemic regions.
You have 100 points to split between all the regions





Case Study – PRAGMATIST Outputs: *A quantified evaluation of relative prevalence*

The **software combines the risk from those 8 areas** with the **relative prevalence** *(estimated based on WRL submission and experts)* of the serotypes circulating in those regions

Relative Prevalence Illustration

		West Eurasia *Total=100*	East Asia *Total=100*	North Africa *Total=100*	India and Southern Asia *Total=100*	East Africa *Total=100*	West and Central Africa *Total=100*	Southern Africa *Total=100*	South America *Total=100*
O	ME-SA/PanAsia-2	41							
O	ME-SA/PanAsia		1						
O	SEA/Mya-98		17						
O	ME-SA/Ind2001	5	16	44	97				
O	EA			6		35	20		
O	O/EURO-SA								70
O	CATHAY		15.5						
A	ASIA/Sea-97		49						
A	ASIA/Iran-05	25.5	0.5						
A	ASIA/G-VII	17.5			2				
A	AFRICA			50		25	27		
A	A/EURO-SA/A24								14.975
A	A/EURO-SA/Arg-2001								14.975
Asia-1			1		1				
Asia-1	Sindh-08	10.5							
SAT 1				0		15	25	27	
SAT 2		0.5		0		22	28	57	
SAT 3						3		16	
C	C3 Indaial Brasil/71								0.05

High relative prevalence of O and A serotypes in **Middle East (region 1 and 3)**

Case Study – PRAGMATIST Outputs: *An overview of lineage scores*

Lineage Scores:

#	Serotype	Strain	West Eurasia	East Asia	North Africa	India and Southern Asia	East Africa	West and Central Africa	Southern Africa	South America	Lineage Score	Relative Lineage Score
1	O	ME-SA/PanAsia-2	820	0	0	0	0	0	0	0	820	8%
2	O	ME-SA/PanAsia	0	20	0	0	0	0	0	0	20	0%
3	O	SEA/Mya-98	0	340	0	0	0	0	0	0	340	3%
4	O	ME-SA/Ind2001	100	320	880	1940	0	0	0	0	3240	32%
5	O	EA	0	0	120	0	175	100	0	0	395	4%
6	O	O/EURO-SA	0	0	0	0	0	0	0	350	350	4%
7	O	CATHAY	0	310	0	0	0	0	0	0	310	3%
8	A	ASIA/Sea-97	0	980	0	0	0	0	0	0	980	10%
9	A	ASIA/Iran-05	510	10	0	0	0	0	0	0	520	5%
10	A	ASIA/G-VII	350	0	0	40	0	0	0	0	390	4%
11	A	AFRICA	0	0	1000	0	125	135	0	0	1260	13%
12	A	A/EURO-SA/A24	0	0	0	0	0	0	0	74.875	74.875	1%
13	A	A/EURO-SA/Arg-2001	0	0	0	0	0	0	0	74.875	74.875	1%

What is a lineage score?

- A lineage score can range **from 0 - 10000 (or 100%)**
- It is calculated by multiplying the relative prevalence x the source area multiplier

Lineage Score Inputs

- Source Area Multiplier:
  - E.g. North Africa was given **20 points (20%)**
- Relative Prevalence
  - E.g. ME-SA/Ind2001 in North Africa was **44**

Lineage Score Calculations

20% Source Area Multiplier * 10,000 Maximum Points

- *Maximum lineage in North Africa = 2,000*

Maximum lineage in North Africa (2,000) * Relative Prevalence (0.44)

- *ME-SA/Ind2001 lineage score of 880*

Case Study – PRAGMATIST Outputs: *Lineage scores as a measure of overall strain risk*

Summing together each of the **lineage scores** across all the regions for an individual strain results in a total lineage score which is used to **assess the overall level of risk**

Lineage Score Illustration:

#	Serotype	Strain	West Eurasia	East Asia	North Africa	India and Southern Asia	East Africa	West and Central Africa	Southern Africa	South America	Lineage Score	Relative Lineage Score
1	O	ME-SA/PanAsia-2	820	0	0	0	0	0	0	0	820	8%
2	O	ME-SA/PanAsia	0	20	0	0	0	0	0	0	20	0%
3	O	SEA/Mya-98	0	340	0	0	0	0	0	0	340	3%
4	O	ME-SA/Ind2001	100	320	880	1940	0	0	0	0	3240	32%
5	O	EA	0	0	120	0	175	100	0	0	395	4%
6	O	O/EURO-SA	0	0	0	0	0	0	0	350	350	4%
7	O	CATHAY	0	310	0	0	0	0	0	0	310	3%
8	A	ASIA/Sea-97	0	980	0	0	0	0	0	0	980	10%
9	A	ASIA/Iran-05	510	10	0	0	0	0	0	0	520	5%
10	A	ASIA/G-VII	350	0	0	40	0	0	0	0	390	4%
11	A	AFRICA	0	0	1000	0	125	135	0	0	1260	13%
12	A	A/EURO-SA/A24	0	0	0	0	0	0	0	74.875	74.875	1%
13	A	A/EURO-SA/Arg-2001	0	0	0	0	0	0	0	74.875	74.875	1%
14	Asia-1		0	20	0	20	0	0	0	0	40	0%
15	Asia-1	Sindh-08	210	0	0	0	0	0	0	0	210	2%
16	SAT 1		0	0	0	0	75	125	135	0	335	3%
17	SAT 2		10	0	0	0	110	140	285	0	545	5%
18	SAT 3		0	0	0	0	15	0	80	0	95	1%
19	C	C3 Indaial Brasil/71	0	0	0	0	0	0	0	0.25	0.25	0%

Several of the higher risk strains have high scores in Middle East (region 1 & 3)

Red = Very **High** Risk

Green = Very **Low** Risk

Case Study – PRAGMATIST Outputs: *How can we understand how well we are currently managing risk?*

Now that we already have our risk quantified, we need to **understand our current coverage**

Inputs Required

Table outlining **available vaccines**

Table outlining **coverage of those vaccines**

Determining Coverage

In every lineage of FMD viruses, **multiple topotypes have been isolated** and **tested using a Virus Neutralization Test**. This test identifies the **estimate of protection**:

- These estimates are given a value between 0 and 1 and are know as **r-values.**
- **r-values greater than or equal to 0.3** confer an antigenic match such that a high potency FMDV vaccines can be **expected to generate a protective response**
- When the **r-values are combined from all the various isolates within a lineage, a per-cent protection level is generated** for a vaccine against that lineage.

Vaccine Antigen coverage	
	no information
0	no matching isolates
0.2	1-20% isolates match
0.4	21-40% isolates match
0.6	41-60% isolates match
0.8	61-80% isolates match
1	81-100% isolates match

Case Study – PRAGMATIST Outputs: *Draft data table identifies the protection of individual vaccines*

Illustrative Draft Data Table:

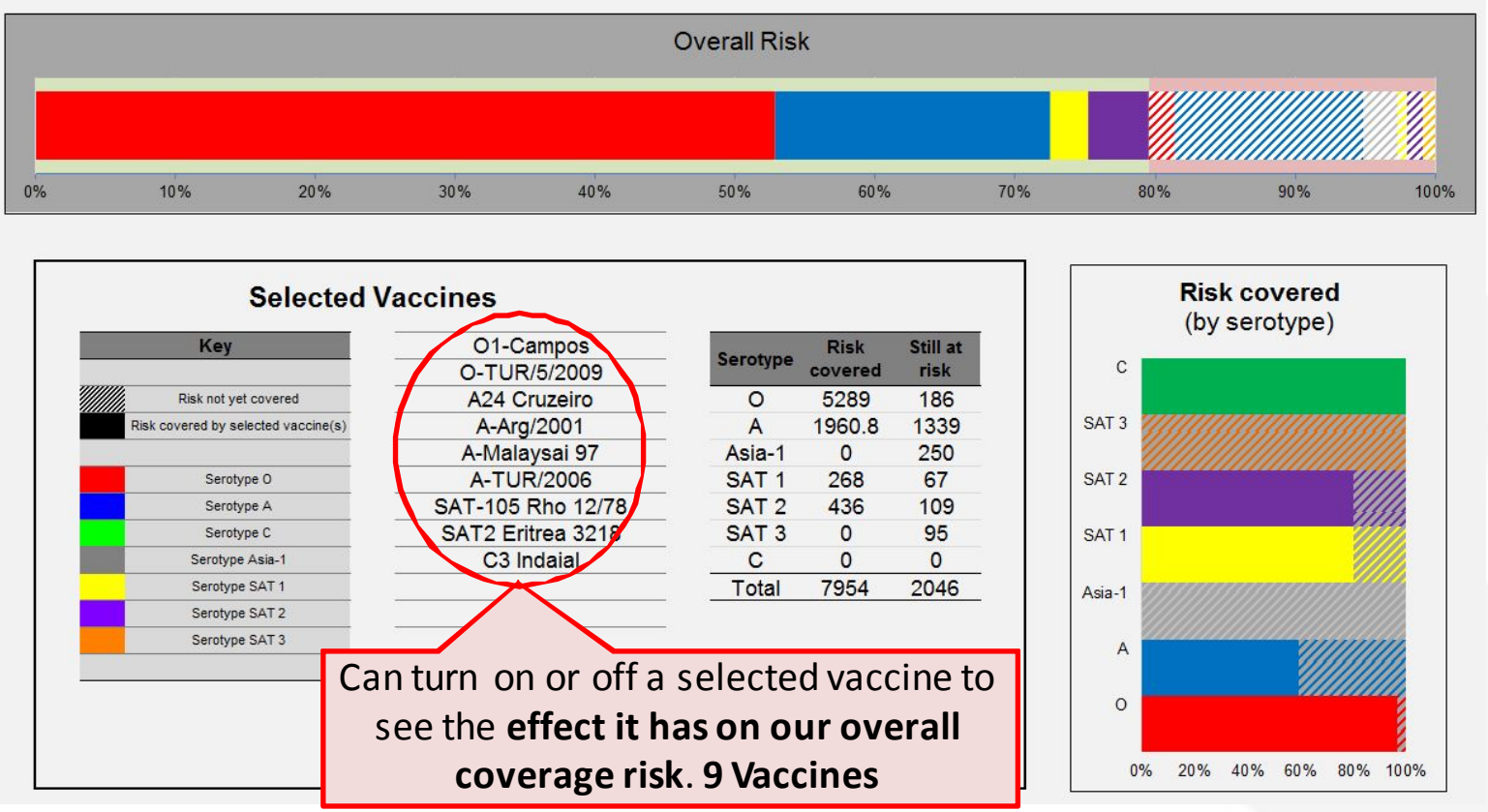
Lineage scores of individual vaccines

		Circulating sertoype / strain	Lineage score	Max. possible cover	Risk not yet covered	O1-Campos (Merial)	O1-Kaufbeuren (MSD)	O1-Manisa (Merial MSD)	O-3039 (Merial)	O-BFS/1860 (Merial)	O-Israel 85 (4625) (Meria)	O-Magheb 99 (Merial)	O-PanAsia 2 (Merial)	O-SKR 2010 (Merial)	O-SKR/7/2010 (MSD)	O-Taiwan (MSD)	O-TAW/98 (Merial MSD)	O-TUR/5/2009 (MSD)	A22 Iraq (Merial MSD)	A24 Cruzeiro (Merial MSD)	A-Arg/2001 (Merial)	A-Eritrea (Merial)	A-Iran 96 (MSD)	A-Iran-05 (Merial)	A-Malaysai 97 (Merial MSD)	A-SAU 95 (Merial)	A-SAU/23/86 (MSD)	A-TUR/2006 (MSD)	Asia1-Shamir (Merial MSD)	SA T-105 Rho 12/78 (Merial)	SA T2 Eritrea 3218 (Merial)	SA T2-SAU (Merial)	SA T2-ZIM (Merial)	Sat3 Zim 2/83 (Merial)	C1 Oberbayern (Merial MSD)	C3 Indaial (Merial)
		Total Vaccine Lineage Coverag				1819	0	2732	4775	2592	0	0	0	0	4420	0	3822	4939	1300	75	75	630	0	1300	847	39	0	1460	189	268	436	0	327	0	0	0
		Use this Vaccine in Manager Too				s	No	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	Yes	No	No	No	Yes	No	No	Yes	No	Yes	Yes	No	No	No	No	Yes
						Selected												Selected		Selected	Selected				Selected			Selected		Selected	Selected					Selected
1	O	ME-SA/PanAsia-2	820	820	-820	1		0.6	1						1		1	1																	
2	O	ME-SA/PanAsia	20	20	-16	0.8		0.4	1						1		1	1																	
3	O	SEA/Mya-98	340	340	-272	0.8		0.2	0.8						1		0.6	1																	
4	O	ME-SA/Ind2001	3240	3240	0			0.6	1	0.8					1		0.8	1																	
5	O	EA	395	395	-237	0.6		0.4	0.6									1																	
6	O	O/EURO-SA	350	350	0	1																													
7	O	CATHAY	310	186	-62	0.4		0.2	0.6								0.6	0.4																	
8	A	ASIA/Sea-97	980	588	-196														0.6					0.6	0.4			0.4							
9	A	ASIA/Iran-05	520	312	-104														0.4					0.4	0.2			0.6							
10	A	ASIA/G-VII	390	351	0																				0.9	0.1									
11	A	AFRICA	1260	756	0														0.4			0.5		0.4				0.6							
13	A	A/EURO-SA/Arg-2001	74.875	74.875	0																1														
12	A	A/EURO-SA/A24	74.875	74.875	0															1															
14	Asia-1		40	0	0																								0.9						
15	Asia-1	Sindh-08	210	0	0																														
16	SAT 1		335	0	-268																									0.8					
17	SAT 2		545	436	0																										0.8		0.6		
18	SAT 3		95	0	0																														
19	C	C3 Indaial Brasil/71	0.25	0.25	0																													1	1

Case Study – PRAGMATIST Outputs: *Manager Tool allows for testing protection based on various baskets of vaccines*

Once we have the protection provided by each of our vaccines entered into the vaccine table **we can begin to choose which vaccines we need to maintain in our bank**.

Managers Tool



Can turn on or off a selected vaccine to see the **effect it has on our overall coverage risk. 9 Vaccines**

Case Study – PRAGMATIST Outputs: *Interpreting amount of "Risk not yet covered"*

Illustrative Coverage Output:

	Circulating sertoype / strain		Lineage score	Max. possible cover	Risk not yet covered
1	O	ME-SA/PanAsia-2	820	820	-820
2	O	ME-SA/PanAsia	20	20	-16
3	O	SEA/Mya-98	340	340	-272
4	O	ME-SA/Ind2001	3240	3240	0
5	O	EA	395	395	-237
6	O	O/EURO-SA	350	350	0
7	O	CATHAY	310	186	-62
8	A	ASIA/Sea-97	980	588	-196
9	A	ASIA/Iran-05	520	312	-104
10	A	ASIA/G-VII	390	351	0
11	A	AFRICA	1260	756	0
13	A	A/EURO-SA/Arg-2001	74.875	74.875	0
12	A	A/EURO-SA/A24	74.875	74.875	0
14	Asia-1		40	0	0
15	Asia-1	Sindh-08	210	0	0
16	SAT 1		335	0	-268
17	SAT 2		545	436	0
18	SAT 3		95	0	0
19	C	C3 Indaial Brasil/71	0.25	0.25	0

Note that there are some negative values in the risk not yet covered

- This is because the vaccines chosen provide **more than 100% coverage.**
- We also found some errors in the formula, and We will be correcting this in the next version.

Case Study 2 – PRAGMATIST Inputs: *Through the lens of South America*

So what if we modify the spreadsheet to focus on an example of a perceived risk to South America.

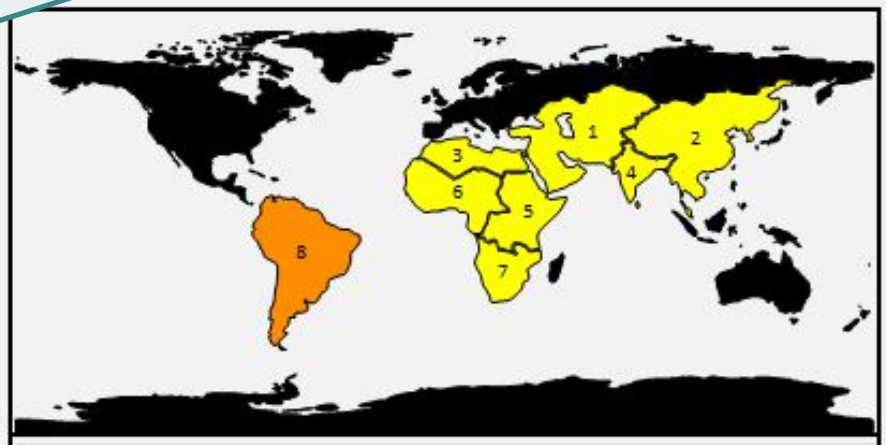
Source Area Multiplier

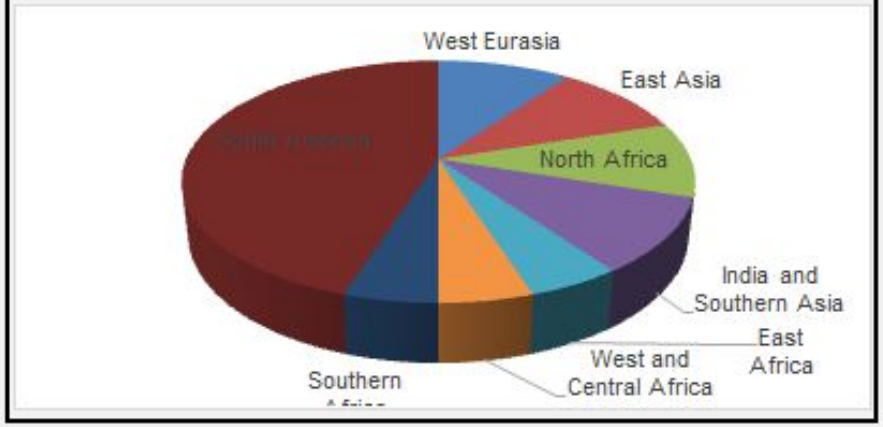
Hit the Return key twice to enter a value

1	West Eurasia	10
2	East Asia	10
3	North Africa	10
4	India and Southern Asia	10
5	East Africa	5
6	West and Central Africa	5
7	Southern Africa	5
8	South America	45
	Total	**100**

All risk has been asigned

Enter the risk of FMD being introduced to your country from the different FMD endemic regions.
You have 100 points to split between all the regions





Case Study 2 – PRAGMATIST Outputs: *Through the lens of South America*

- So I have changed the distribution in South America to reflect the most risk.
  - **Normally Lineage distribution is given for a whole region**, but what if a country feels there are **regional differences**.
  - A has not been seen in some years (lowered value) , O in June 2017

		West Eurasia *Total=100*	East Asia *Total=100*	North Africa *Total=100*	India and Southern Asia *Total=100*	East Africa *Total=100*	West and Central Africa *Total=100*	Southern Africa *Total=100*	South America *Total=100*
O	ME-SA/PanAsia-2	41							
O	ME-SA/PanAsia		1						
O	SEA/Mya-98		17						
O	ME-SA/Ind2001	5	16	44	97				
O	EA			6		35	20		
O	O/EURO-SA								85
O	CATHAY		15.5						
A	ASIA/Sea-97		49						
A	ASIA/Iran-05	25.5	0.5						
A	ASIA/G-VII	17.5			2				
A	AFRICA			50		25	27		
A	A/EURO-SA/A24								7.475
A	A/EURO-SA/Arg-2001								7.475
Asia-1			1		1				
Asia-1	Sindh-08	10.5							
SAT 1				0		15	25	27	
SAT 2		0.5		0		22	28	57	
SAT 3						3		16	
C	C3 Indaial Brasil/71								0.05

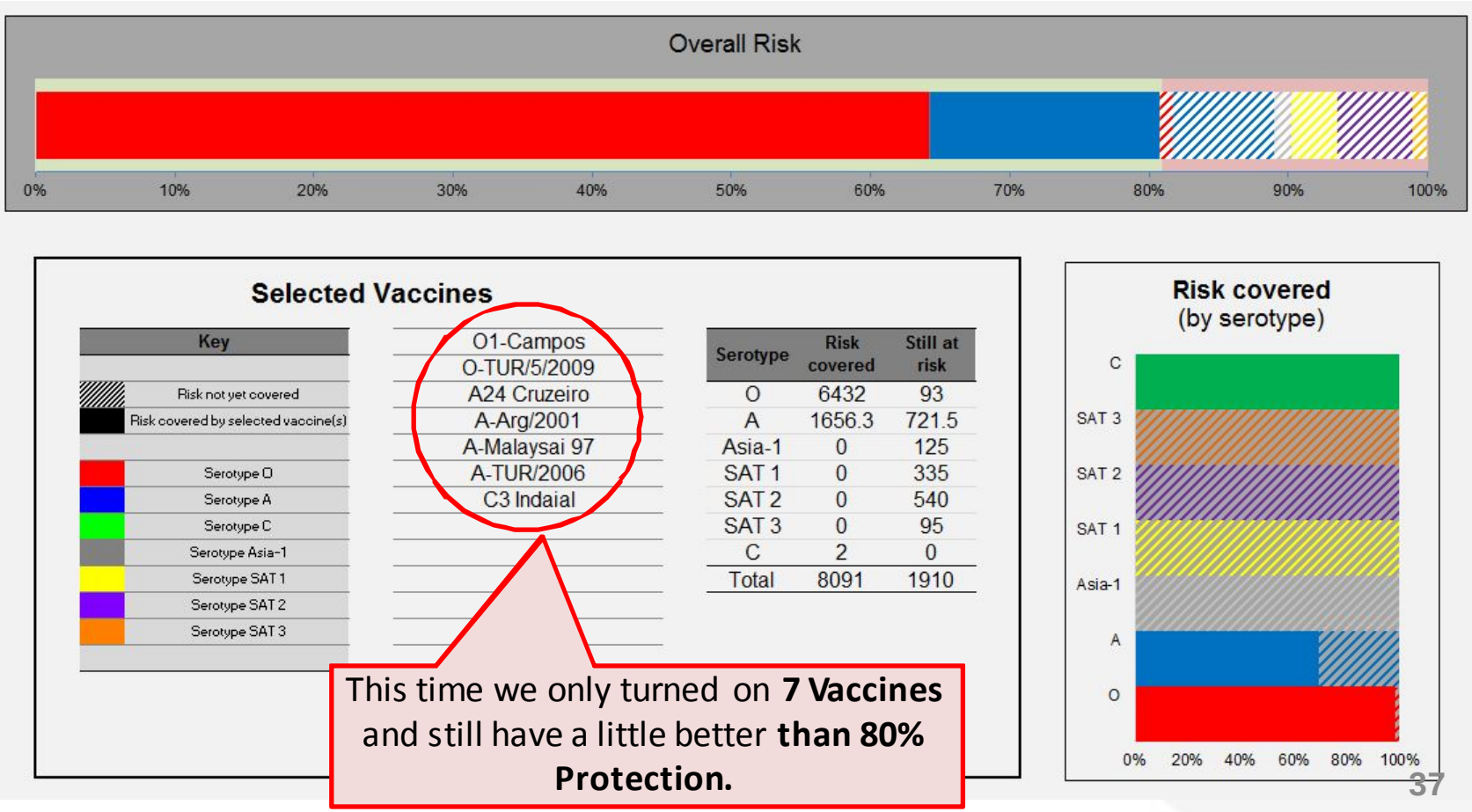
Case Study – PRAGMATIST Inputs: *Allows for insight into comparisons of regional risk variations*

			North American View		South American View	
			Lineage Score	Relative Lineage Score	Lineage Score (total=10000)	Relative Lineage Score (total=100%)
1	O	ME-SA/PanAsia-2	820	8%	410	4%
2	O	ME-SA/PanAsia	20	0%	10	0%
3	O	SEA/Mya-98	340	3%	170	2%
4	O	ME-SA/Ind2001	3240	32%	1620	16%
5	O	EA	395	4%	335	3%
6	O	O/EURO-SA	350	4%	3825	38%
7	O	CATHAY	310	3%	155	2%
8	A	ASIA/Sea-97	980	10%	490	5%
9	A	ASIA/Iran-05	520	5%	260	3%
10	A	ASIA/G-VII	390	4%	195	2%
11	A	AFRICA	1260	13%	760	8%
12	A	A/EURO-SA/A24	74.875	1%	336.375	3%
13	A	A/EURO-SA/Arg-2001	74.875	1%	336.375	3%
14	Asia-1		40	0%	20	0%
15	Asia-1	Sindh-08	210	2%	105	1%
16	SAT 1		335	3%	335	3%
17	SAT 2		545	5%	540	5%
18	SAT 3		95	1%	95	1%
19	C	C3 Indaial Brasil/71	0.25	0%	2.25	0%

- O1-Campos critical risk in South America
- ME-SA/Ind2001 critical risk in North America

Case Study 2 – PRAGMATIST Outputs: *Through the lens of South America*

Managers Tool



Conclusions

- **NAFMDVB** has recently signed sharing arrangements with Australia & New Zealand and **would like to pursue sharing arrangements with other countries**
- **Managing risk is very complex** due to constant viral change, no cross-protection between serotypes, threats from around the globe, and multiple vaccines stains available.
  - Current **WRLFMD guidelines** are EU focused and **not sufficient to objectively manage risks across multiple countries & stakeholders**
- Pragmatist can be adapted to the South American situation to provide a **more objective method of assessing risk** and choosing the vaccines that a bank needs to hold.
  - **Adapting PRAGMATIST** to include additional vaccines available from South American suppliers is not difficult.

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Questions ??