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## Faculty of Veterinary Science

Fakulteit Veeartsenykunde  
Lefapha la Diseanse tša Bongakadiriwa

# The Role of Risk Analysis in Meeting International Standards of Equivalence: A Case Study from the Zambezi Region

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ESSENTIALS OF RISK MANAGEMENT:  
1. DON'T DO ANYTHING WRONG TODAY.  
2. DON'T DO ANYTHING WRONG TOMORROW.  
3. REPEAT.



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## Outline

- Risk and risk analysis
- Equivalence
- Quantitative risk assessment case study
- Model results
- Sensitivity analysis
- Conclusions



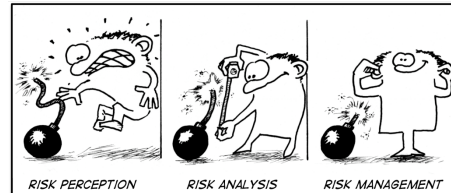
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# Risk analysis

- Risk is the probability that an event will occur
- Hazard (lay interpretation of risk) is the probability of an event weighted by the severity of negative consequences

- Risk analysis
  - Risk identification
  - Risk assessment
  - Risk management
  - Risk communication



<http://quotesgram.com/risk-management-funny-quotes/>

		Event severity			
		Negligible	Marginal	Critical	Catastrophic
Event probability	Certain	High	High	Extreme	Extreme
	Likely	Moderate	High	High	Extreme
	Possible	Low	Moderate	High	Extreme
	Unlikely	Low	Low	Moderate	Extreme
	Rare	Low	Low	Moderate	High

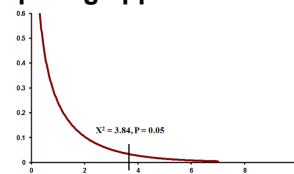
- Qualitative versus quantitative risk assessment



# Equivalence



- According to the Codex Alimentarius
  - Equivalence is the capability of different inspection and certification systems to meet the same objectives
  - The “same objective” can be an (unspecified) level of risk
  - Determination of equivalence often based on subjective expert opinion
- Statistical interpretation
  - Must define an equivalence margin (what is close enough?)
  - Noninferiority testing employs a 1-tailed statistical test
  - Provides an objective criterion for comparing approaches



# Exposure scenario

- **Exposure quantification**
  - Amount of FMD virus in a box of processed product
  - Varied by cut due to proportion of carcass and likelihood of contamination with lymphoid tissue
  - Possibility of incomplete inactivation of FMDV in muscle
  - Possibility of microlesions in muscle protected from maturation
  - Possible contamination with bone marrow excluded
- **Exposure scenario**
  - Swine herd exposed to
  - Product fed as improperly treated swill

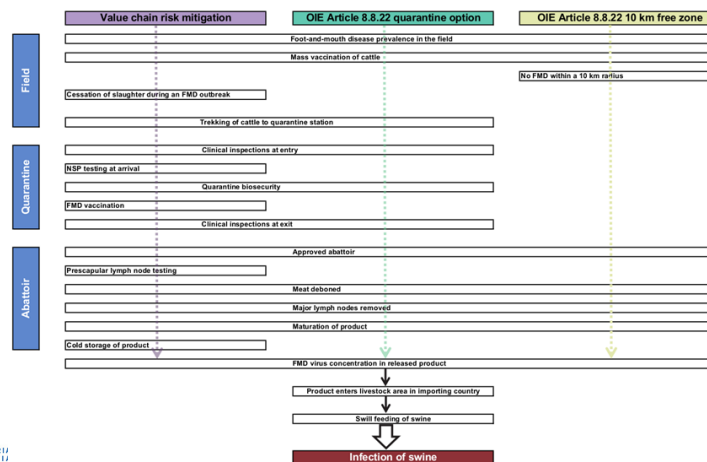


[http://asforce.org/course/assets/img/module3/swill\\_feeding.jpg](http://asforce.org/course/assets/img/module3/swill_feeding.jpg)

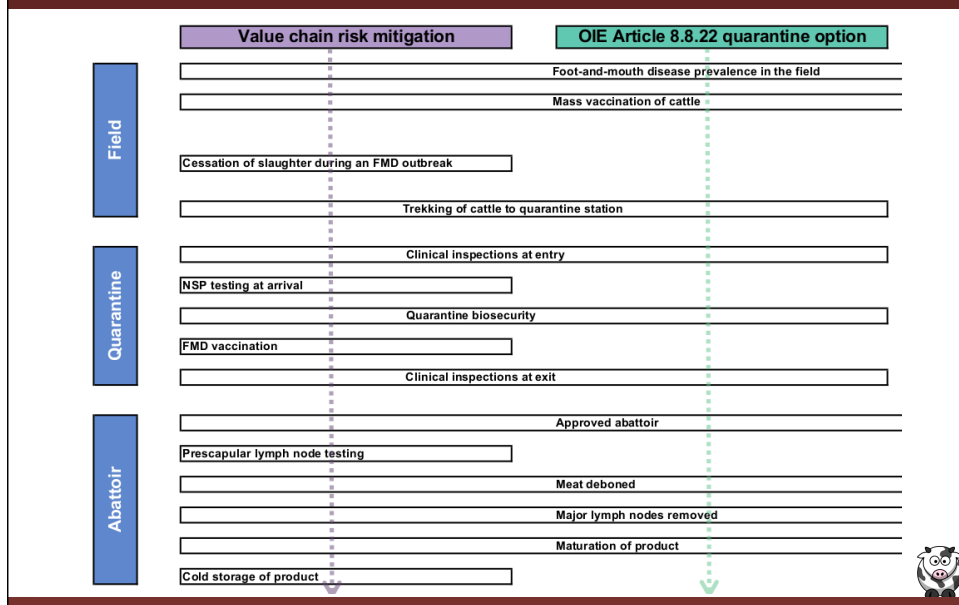


# Analytical approach

- Study area is the Zambezi region of Namibia
- Three risk mitigation approaches simultaneously modelled based on the same assumptions



# Quantitative risk assessment

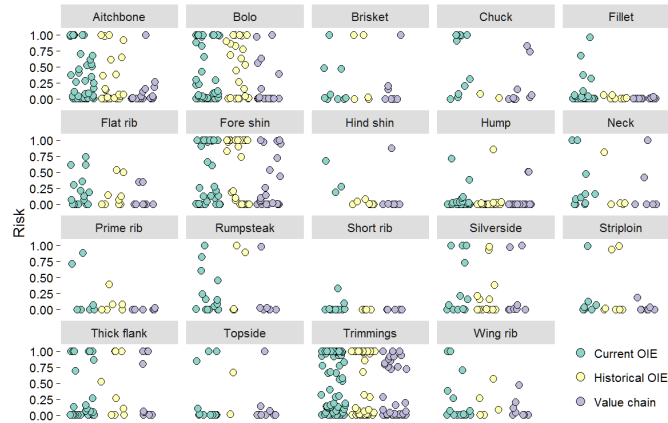


## Modeling uncertainty

Input	Function	Density	Mean	Minimum	Maximum
Number of cattle within quarantine per cycle	Normal(147,26.6)		96.8	$-\infty$	$+\infty$
Biosecurity at quarantine station (camps, double fence)	Beta(5.3,2)		0.73	0	1
Basic reproductive number for subclinical cattle	Exponential(1)		1	0	$+\infty$
Effect of ante and post-mortem inspection	Beta(5.6,30)		0.16	0	1
Trimming (probability of LN)	Beta(2.3, 23)		0.09	0	1
Concentration of FMDV (PFU/g) in LN	Normal(5, 1.8)		5.0	$-\infty$	$+\infty$
Dose/infection constant; 'r'	Normal(4.1,1.8)		4.1	$-\infty$	$+\infty$



# Results



- Simulated over 1 million years of exports
- Cumulative risk was determined for each year



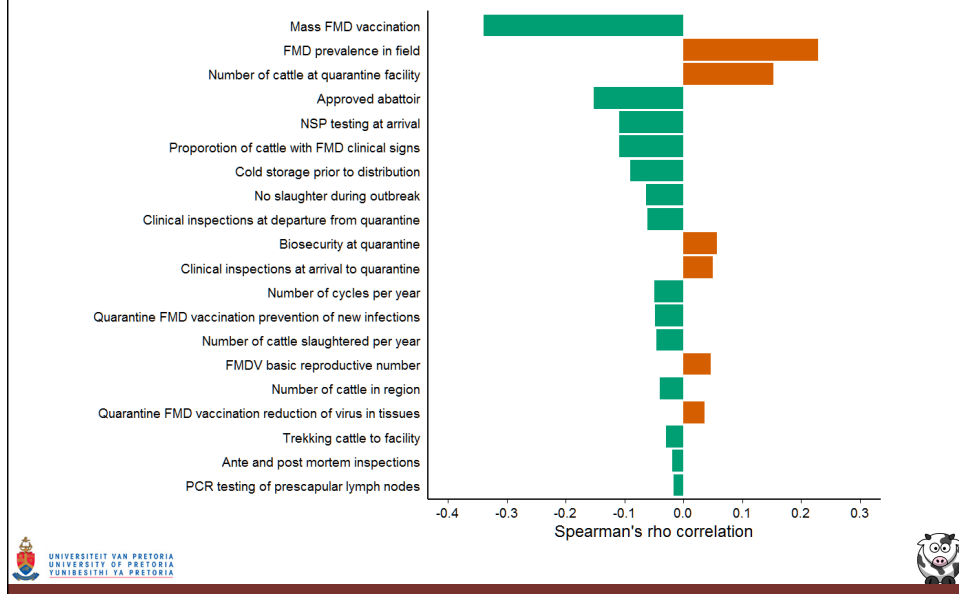
# Results

	Value chain		OIE quarantine		OIE 10 km FMD free		
Beef product	No. >0	< 10 <sup>-6</sup>	No. >0	< 10 <sup>-6</sup>	No. >0	< 10 <sup>-6</sup>	P value
Chuck	9	No	11	No	2	Yes	0.048
Fillet	13	Yes	30	No	10	Yes	0.002
Flat rib	9	Yes	17	No	9	No	0.237
Prime rib	7	Yes	7	No	6	Yes	0.846
Short rib	5	Yes	11	Yes	4	Yes	0.196
Striploin	7	Yes	7	No	7	No	0.951
Topside	9	No	14	No	2	Yes	0.009
Wing rib	9	Yes	17	No	5	Yes	0.027

- Simulated risk compared across the three management systems
- Mean risk less than one in a million considered acceptable level of protection (ALOP)



# Sensitivity analysis



## Discussion

- The export of several products was associated with an acceptable level of risk
- The reduction in risk varied based on the beef product and management system
- Effects of risk management procedures were not always intuitive
  - Mass vaccination had a large impact on risk reduction
  - Clinical inspections at arrival to quarantine station was associated with **increased risk**
  - Ante- and post-mortem inspections at abattoir had virtually no effect on risk
  - NSP testing reduced risk while PCR testing had a minimal effect



# Limitations

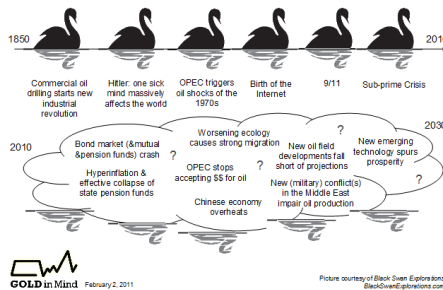
- The model only accounts for the probability of occurrence of a single type of catastrophic outcome
- Many input parameters were based on expert opinion
- It is not possible to validate model results
- A low average risk does not ensure that the event will not occur



**Black Swans:** high-impact, hard-to-predict, rare events.

Can we spot their shadows before it's too late?

And, more importantly: Are we protecting our vulnerable spots?



# Conclusions

- Objective and transparent methods of risk assessment are required to inform trade decisions
- Equivalent risk reduction can be achieved through divergent management procedures
- A quantitative risk assessment can provide important epidemiological information for the development of effective risk mitigation systems
- Intuition and expert opinion might not reflect reality



# Acknowledgments

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