







 PRO-POOR HPAI
RISK REDUCTION


Controlling Avian Flu and Protecting People's
Livelihoods in the Mekong Region, Africa and Indonesia

Introduction to Risk Assessment

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Overview

- Concepts:
 - Risk
 - Hazard
 - Risk Analysis and Risk Assessment
- Approaches to Risk Assessment:
 - OIE vs Codex Alimentarius Framework
 - Qualitative vs Quantitative
- Risk Assessment Methodology
 - Requirements
 - Main steps

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Concepts

- Risk:
 - a situation involving exposure to danger
 - the possibility that something unpleasant will happen

Compact Oxford English Dictionary of Current English


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Concepts (cont.)

- Hazard:
 - A biological, chemical or physical agent in, or condition of, food with the potential to **cause** an **adverse** health effect (Codex Alimentarius Commission)
 - A condition or physical situation with a potential for an undesirable consequence (Society for Risk Analysis)


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Concepts (cont.)

- Risk vs Hazard:
 - Hazard: something with the potential to cause harm.
 - Risk: the **likelihood** of occurrence **and** the **magnitude of consequences** of a specified hazard being realized.

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Concepts (cont.)

- Risk Analysis:
 - analytical process to provide information regarding undesirable events;
 - process of estimating probabilities and expected consequences for identified risks.
 - detailed examination including risk assessment, risk evaluation and risk management alternatives, performed to understand the nature of unwanted outcome;

Society for Risk Analysis
http://www.sra.org/resources_glossary

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Concepts (cont.)

- Risk Analysis:
A process undertaken to deal with matters which pose a potential danger, managed according to certain **standard procedure** and that involves:
 - Hazard Identification
 - Risk Assessment
 - Risk Management
 - Risk Communication

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Concepts (cont.)

- Hazard Identification:
Identification of the hazard(s) (something potentially harmful) in the given context
 - List of pathogens / adverse agents associated with the product(s) of interest
 - List of disease(s) in the species / exporting areas

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Concepts (cont.)

- Risk Assessment:

The process of evaluating the risk resulting from a hazard (probability of occurrence and magnitude of consequences).

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Concepts (cont.)

- Risk Management:
 - Based on the results of the risk assessment and the judgement of the 'risk managers', decisions are taken and policy is formulated.
 - Risk management is the process of weighting policy alternatives in consultation with all interested parties considering risk assessment and other factors (institutional context, economic analysis, etc.).

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Concepts (cont.)

- Risk Communication:

Information exchange between risk assessors, risk managers and those affected by both the risk and the decisions taken before the final policy decisions are taken.

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Concepts (cont.)

- Risk Assessment is only one part of the Risk Analysis process:

```

    graph TD
      HI[Hazard Identification] --> RA[Risk Assessment  
Qualitative / Quantitative]
      RA --> RM[Risk Management]
      HI <--> RC[Risk Communication]
      RA <--> RC
      RM <--> RC
      subgraph Risk_Analysis [Risk Analysis]
        HI
        RA
        RM
      end
  
```

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Approaches to Risk Assessment

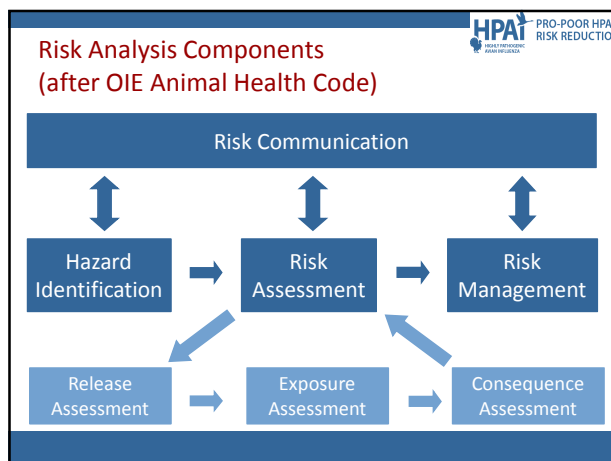
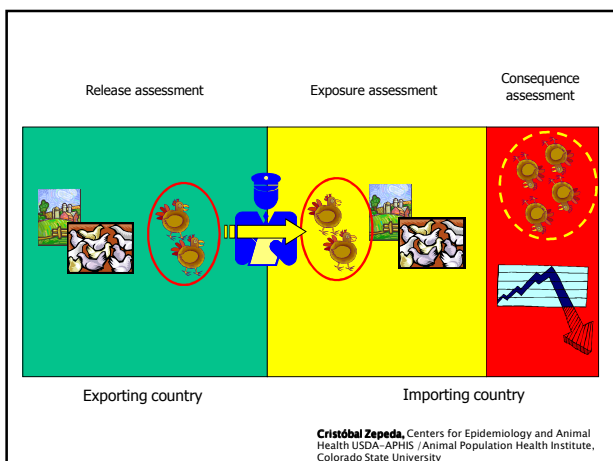
- Main systems used in animal health, food safety, veterinary public health:
 - OIE International Animal Health Code
 - Codex Alimentarius Commission
- Different systems, developed to answer different types of risk questions:
 - OIE: Versatile, used to address risk questions of different types
 - Codex: Designed to answer questions in relation to maximum levels of substances or pathogens; main focus: microbiological food safety assessment

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Approaches to Risk Assessment

- **OIE International Animal Health Code**
The risk assessment includes the following steps:
 - **Release assessment:** description of biological pathways for release of hazard and estimation of its probability.
 - **Exposure assessment:** description of biological pathways necessary for exposure of humans / animals to the hazards released and estimation of its probability.
 - **Consequence assessment:** description of relationships between exposures to hazards and consequences of those exposures (biological, economic, etc.).
 - **Risk estimation:** Integration of results from previous 3 steps to produce overall measures of risk associated with the hazards

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Approaches to Risk Assessment

- Qualitative vs Quantitative Approach

The risk estimate can be presented either:

- Qualitatively: the evaluated risk is described in words. The estimate of risk is ranked or separated into descriptive categories.
- Quantitatively: the evaluated risk is estimate numerically; numerical expressions of risk are provided.

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Qualitative Risk Assessment

When:

- As a 1st step, before quantitative approach.
- Results -> rule out some pathways, identify non-negligible risk requiring quantification, or gaps in knowledge, etc.
- When numerical data is not available
- When risks perceived do not justify time and effort required with the quantitative approach...

What:

- Import policies,
- Surveillance activities,
- Etc.

⇒ Common approach to support routine decision-making

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Requirements for Risk Assessment

- Clear definition of terms:
 - Risk question
 - Hazard identification
 - Qualitative risk assessment: risk categories and combination matrix
- Transparency:

A risk assessment must be clearly set out, transparent and fully referenced in the resulting report

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Requirements for Risk Assessment

Risk Category	Definition
Negligible	Event is so rare that does not merit to be considered
Very low	Event is very rare but cannot be excluded
Low	Event is rare but does occur
Medium	Event occurs regularly
High	Event occurs very often
Very high	Even occurs almost at certainly

		Risk estimate 2					
		Neg	V Low	Low	Med	High	V High
Risk Estimate 1	V High	N	VL	L	M	H	VH
	High	N	VL	L	M	H	H
	Med	N	VL	VL	L	M	M
	Low	N	N	VL	VL	L	L
	V Low	N	N	VL	VL	VL	VL
	Neg	N	N	N	N	N	N

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Main steps of Risk Assessment

- Framing the risk question
- Identifying the hazard(s)
- Outlining the risk pathways
- Identifying data needs
- Collecting data
- Assessing the risk

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Main steps of Risk Assessment

- Framing the risk question:

The risk to be assessed should be clearly defined
- Points to consider:
 - What is the specific hazard of concern?
 - What specific risk do we want to assess?
 - What particular time frame are we interested in?

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- If not specific enough, a risk question can be interpreted in different ways:
- Ex: What is the risk for the introduction of HPAI H5N1 (through migratory birds / poultry trade / wild bird trade ?) into (wild bird / domestic / human population?) in (Indonesia / Greater Jakarta?)

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Main steps of Risk Assessment

- Identifying the hazard(s):

Hazard may be explicit in risk question

 - Ex: What is the risk of importing Pathogen X in this group of animals?

Otherwise full hazard identification must be undertaken

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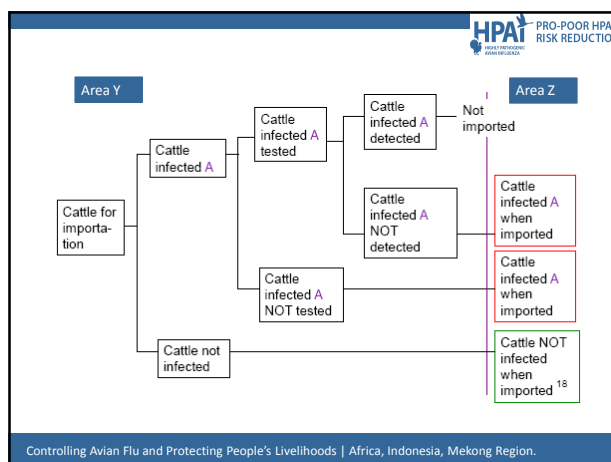
Main steps of Risk Assessment

- Outlining the risk pathways:

A Risk pathway is the framework on which to base the risk assessment, describing all stages in the biological process that lead to the outcome of interest.

 - list all steps required for the risk to occur, differentiating release, exposure and consequence
 - report your underlying assumptions

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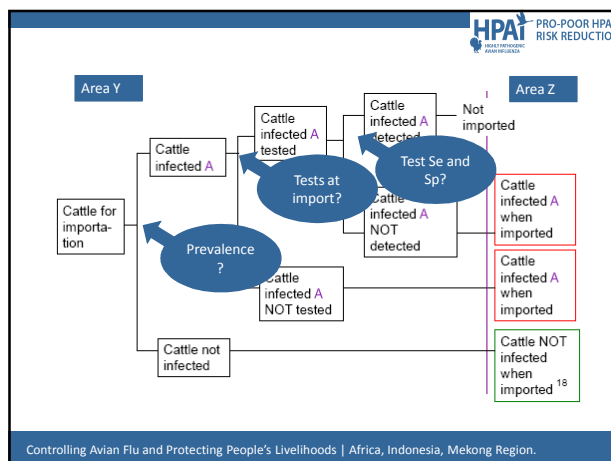


Main steps of Risk Assessment

- Identification of data needs:

The data required to assess the likelihood of occurrence of each step of the pathway must be identified.

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Main steps of Risk Assessment

- Data collection:
 - Different sources of information: literature, experimental, expert opinion...
 - Consider validity:
 - Most up-to-date
 - Estimates of prevalence from surveillance systems, Expert opinion
 - => Best available data should be used
 - Fully referenced (transparency)
 - For Qualitative approach, no new data collected; rather identification gaps in knowledge

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Main steps the Risk Assessment

- Assess the risk:

Once the relevant information for the different steps is collected the overall risk is assessed :

 - For qualitative risk assessments a logical overall conclusion will be reached based on the probability of occurrence of each of the individual steps. The final risk estimate would be expressed in words
 - For quantitative risk assessments: An overall probability of the unwanted outcome will be given in mathematical terms

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Main steps of Risk Assessment

- Qualitative risk assessment:
 - Describe data
 - In concise and objective manner
 - Avoid opinion or interpretation
 - Interpret data
 - Analyse information for each step
 - Estimate risk category
 - Organise information

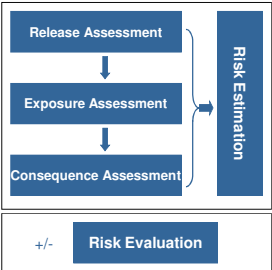
Risk pathway step	Data Need	Source of Information	Risk Category
Risk of cattle from Area Y being infected	Prevalence data in area Y	Surveillance data (Year 2006)	Moderate
Risk of cattle not being tested at importation	Frequency of control at importation	Expert Opinion	High to Very High
Risk of an infected cattle not being detected	Test characteristics (Se and Sp)	Literature: Xxxx et al., 2007	Very Low

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- Qualitative Risk Assessment (cont.):
 - Estimate risk for Release, Exposure and Consequence Assessment
 - Combine parameter estimates using pre-defined matrix
 - Combine risks from Release, Exposure and Consequence Assessment
 - ⇒ Deduct Overall Probability of Occurrence of the risk considered and of unwanted consequences
 - Formulate conclusion

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Main steps of Risk Assessment

- Qualitative RA:
 - Review information available and estimate risk for each step
 - Combine risk estimates using pre-defined combination matrix
 - Deduct the overall probability of occurrence of the risk of interest and of unwanted consequences
 - +/- decide whether this risk is acceptable or not
- OIE Framework (Import Risk Analysis)
 

NB: "low" or "negligible" risk does not imply "acceptable risk" (e.g. when severe consequences for human population)

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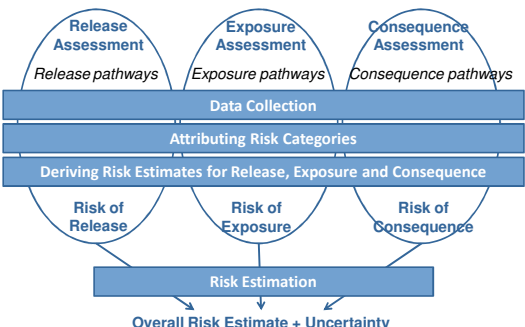
Main steps of Risk Assessment

- Dealing with Uncertainty

Uncertainty category	Interpretation
Low	solid and complete data available; strong evidence provided in multiple references; authors report similar conclusions
Medium	some but no complete data available; evidence provided in small number of references; authors report conclusions that vary
High	scarc or no data available; evidence not provided in references but rather in unpublished reports or based observations, or personal communication; authors report conclusions that vary considerably between them

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Qualitative Risk Assessment



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Additional remarks

- Communication between experts and stakeholders is crucial:
 - Agreement on specific risk question(s)
 - Team effort
- Risk pathways are essential (meaningful diagrams)
- Consider conditionality of risk pathway components
- In order to limit the subjectivity of the assessment, it needs to be transparent and fully referenced

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Additional remarks

In our context:

- Qualitative risk assessment ⇒ Estimation of the overall likelihood of occurrence of the adverse event considered and its biological consequences
- Identification of the pathways and steps of the pathways having high risk of occurrence / high impact on overall risk estimate
- From an epidemiological standpoint, where (on what steps/processes) to focus control efforts

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Examples of risk pathways

- What is the risk for human health from the handling/consumption of wild games?

FIG 1: Generic human exposure pathway for hazards from wild game animals

Coburn, H.L., Snary E. L., *et al.* (2005) Qualitative risk assessment of the hazards and risks from wild games. *Vet record* 157(11): 321-322

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Examples of risk pathways

Hartnett E., Adkins A. *et al.* (2007). *A quantitative assessment of the risks from illegally imported meat contaminated with Foot and Mouth Disease Virus to Great Britain. Risk Analysis* 27(1)

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Example: how to combine risk estimates

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Example: how to combine risk estimates

Risk pathway step	Data Need	Source of Information	Risk Category
Risk of cattle from Area Y being infected	Prevalence data in area Y Number of cattle	Surveillance data (Year 2006) Statistics on imports (2005 – 2008)	Medium
Risk of cattle not being tested at importation	Frequency of control at importation	Expert Opinion	High to Very High
Risk of an infected cattle not being detected	Test characteristics (Se and Sp)	Literature: Xxxxx <i>et al.</i> , 2007	Very Low

		Risk estimate 2					
		N	VL	L	M	H	VH
Risk estimate 1	V High	N	VL	L	M	H	VH
	High	N	VL	L	M	H	H
	Med	N	VL	VL	L	M	M
	Low	N	N	VL	VL	L	L
	V Low	N	N	VL	VL	VL	VL
	Neg	N	N	N	N	N	N

Overall Release Estimate:
Combination of Parameter 1 and 2, and then Parameter 1/2 and 3:
Parameter 1/2 = M x H to VH => L
Release Estimate = L x VL => N

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