





# **Risk Analysis process**

Introduction to risk assessment: basic concepts, terminology and applications

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#### **Risk analysis process**







Basic concepts The Risk Analysis process

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#### Three components of the same process



## **Risk Assessment**

- The term does not refer to those methods used for a long time in Veterinary medicine
- It indicates, instead, a scientific activity with its own tools and rules
- It is a forecasting analysis established and developed in the engineering field
- Looking at what could happen in the future



for Veterinary Training, Epidemiology, Food Safety and Animal Welfare **Hazard vs Risk** 

- Hazard is a biological, chemical, or physical agents potentially capable of causing adverse health effects.
- It is an attribute of that commodity, food, animal species, etc..
- Risk is a measurement of the probability of occurrence of a specific adverse event and the magnitude of that event





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for Veterinary Training, Epidemiology, Food Safety and Animal Welfare **General aspects of risk** 

Two are the components of risk:

- the probability of the occurrence of an adverse event
- the magnitude of that event
- Risk also includes the measures that can be applied to reduce it:
  - risk is never zero
  - it can be reduced through the application of health control measures (risk mitigation actions)





### **Quantitative definition of risk**

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From a quantitative point of view, risk can be defined by a series of triplets:

What can happen = scenario (s<sub>i</sub>)

**\$**If it happens, what are the consequences = damage (x<sub>ij</sub>)

**?**Likelihood of occurrence = probability (p<sub>ij</sub>)

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R = \{(s_i, x_{ij}, p_{ij})\} i=1, 2, 3, ..., n_1; j=1,2,3,..., n_2
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#### **Risk function & Risk curve**





#### **Risk management**

- Risk management include the evaluation and implementation of control options to reduce (mitigate) the risk
- Risk management is **not** a separate phase, subsequent to the risk assessment phase
- The traditional separation of risk assessment and risk management is mainly due to political reasons and to the concern of splitting managerial and technical responsibilities
  - The functional separation of risk assessment and risk management mainly aims at ensuring the independence of the assessment process



#### **Risk communication**

**RISK COMMUNICATION** is an interactive process of exchange of information and opinion among individuals, groups, and institutions; often involves multiple messages about the nature of risk or expressing concerns, opinions, or reactions to risk messages or to legal and institutional arrangements for risk management.



# INTERNATIONAL ORGANIZATIONS



- OIE
  - Animal health



Codex Alimentarius (FAO)

**CODEX** alimentarius

- Food Safety

FAO/ WHO Food Standards



- IPPC (FAO)
  - Plant Health



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### **OIE – risk analysis process**

- Hazard identification
- Risk assessment

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- Entry assessment
- Exposure assessment
- Consequence assessment
- Risk estimation
- Risk management
- Risk communication
- Related topics





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#### **OIE – risk analysis process**

#### Related topics

- Evaluation of Veterinary Services
- Oie
- Zoning and regionalisation (compartmentalisation) of countries
- Animal health surveillance and monitoring programs





#### CAC – Risk Assessment

- Hazard identification
- Exposure assessment
- Hazard characterization
- Risk characterization



PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT CAC/GL-30 (1999)



#### **Hazard identification**

The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods





#### **Exposure assessment**

 The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant



#### **Hazard characterization**

The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard. For the purpose of microbiological risk assessment the concerns relate to microorganisms and/or their toxins



Fig. 1. Dose response relations for infection, illness given infection, and illness by *Salmonella enterica* Serotype Meleagridis, using data from.<sup>(14)</sup> (a) Exponential model for infection. (b) increasing hazard with dose, (c) product of curves in (a) and (b). Confidence intervals calculated as percentiles (P5-P95) from same models fitted to bootstrap replications of the data.



#### **Risk characterization**

 The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment



Fig. 9. Expected incidence of listeriosis per serving in various at-risk sub-populations.









# Risk Assessment

process

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## **Qualitative vs quantitative** risk assessment

Methods and approaches





## **Risk assessment**

## Both qualitative and quantitative risk assessment methods are valid approaches





Approaches for risk assessment

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# RRA and qualitative approach

- Considering the immediate need for an assessment in case of an urgent threat is observed, a formal quantitative risk assessment approach is not feasible in many cases.
- In addition, a quantitative approach requires the availability of quantitative data for the input variables, which are difficult to obtain in many instances.
- A qualitative approach in risk estimation, therefore, could be preferable in the majority of cases, especially when the rapidity of the assessment has to be preserved.
- However, different approaches can be merged together.



#### **Qualitative risk assessment**

A qualitative assessment is essentially a reasoned and logical discussion of the relevant factors of a hazard in which the likelihood of its release and exposure and the magnitude of its consequences are expressed using non-numerical terms such as high, medium, low or negligible.

Risk level	Explanation
Negligible	Extremely rare, not distinguishable from zero
Very Low	Very rare but cannot be excluded
Low	Rare but it does occur
Medium	Occurs regularly
High	Occurs often
Very High	Event will occur almost certainly





#### **Qualitative risk assessment**

A possible way to represent the risk including both likelihood and consequences is the use of a "risk matrix".

			Consequences				
			1	2	3	4	5
			Insignificant	Minor	Moderate	Major	Catastrophic
	Α	Almost certain	MODERATE	HIGH	VERY HIGH	VERY HIGH	VERY HIGH
od	В	Likely	MODERATE	HIGH	нібн	VERY HIGH	VERY HIGH
eliho	С	Possible	LOW	MODERATE	HIGH	VERY HIGH	VERY HIGH
Like	D	Unlikely	LOW	LOW	MODERATE	нібн	VERY HIGH
	E	Rare	LOW	LOW	MODERATE	HIGH	HIGH
						(	17.0



### Semi-quantitative risk assessment

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To further characterise the risk levels presented in risk matrices, quantitative expression may be used to describe the likelihood and consequences

#### Likelihood levels

Extremely likely Very likely Likely As likely as not Unlikely Very unlikely Extremely unlikely

#### Examples of quantitative definition of likelihood levels

99%-100% chance 90%-99% chance 66%-90% chance 33%-66% chance 10%-30% chance 1%-10% chance 0%-1% chance Not distinguishable from 1 > $10^{-1} < 1$   $10^{-1} - 10^{-2}$   $10^{-2} - 10^{-3}$   $10^{-3} - 10^{-4}$   $10^{-4} - 10^{-5}$ Not distinguishable from 0

#### **Consequences levels**

Catastrophic Major Moderate Minor Insignificant Examples of quantitative definition of consequence levels

> 50% of population affected
30%-50% of population affected
10%-30% of population affected
1%-10% of population affected
< 1% of population affected</li>

>200 human cases 100-200 human cases 50-100 human cases 10-50 human cases < 10 human cases



# Semi-quantitative risk assessment

- The quantitative ranges used to describe the consequences should reflect whether the emphasis of the assessment is on lower or higher values of the scale (i.e. higher granularity of the classes on the extreme that is of main interest) and to adequately express the expected level of uncertainty (i.e. the size of the ranges should be larger when the uncertainty is greater).
- Therefore the ranges do not need to have the same size nor to be symmetric



# RRA and qualitative approach

The type of risk outputs can vary considering the different purposes of the RRA:

- when the main objectives of the assessment are to estimate the probability of pathogen introduction into free countries or zones (entry assessment) or the probability of infection of specific animal/human populations (exposure assessment), the analysis can be described by levels of probability only
- when the effects of the infection or spread have to be considered (consequence assessment), the two components of the risk, probability and consequence, must be taken into account, assessed and jointly evaluated.



### **Probability estimation** (entry and exposure assessment)

# In case of entry and exposure assessment the following probability levels can be used

Level Probability level		Lay Definition	Numerical range (extremes included in the lower level)	
1	Extremely unlikely	May only occur in exceptional circumstances	below 1% chance	
2	Very Unlikely	May occur at some point but not often	1%-10% chance	
3	Unlikely	Could occur at some time but not that likely	10%- 30% chance	
4	As likely as not	Might occur at some time	30-66% chance	7
5	Likely	Will probably occur in many circumstances	66-90% chance	/
6	Very likely	Will very likely occur very often	90-99%	
7	Almost certain	Can be expected to always occur	Over 99%	



#### **Consequence** assessment

- When the magnitude of the possible consequences of the occurrence of a certain health event must be considered, it should be assessed separately from the probability estimation.
- A health event, in fact, may have a high probability to occur but causes minor consequences or viceversa.
- Semi-quantitative tables can be used.



#### **Consequence assessment**

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#### Example of semi-quantitative estimation of consequences/impacts

Levels	Categories	Description	Examples of quantitative definition of
1	Insignificant	few animals infected suffering from mild disease	< 1% of susceptible animal population affected with no case-fatality rate or few production losses
2	Minor	few animals infected suffering from severe disease resulting in both significant production losses and high mortality OR hundreds of animals infected suffering from mild disease	< 1% of susceptible animal population affected with high fatality rate or significant production losses
3	Moderate	hundreds of animals infected suffering from severe disease resulting in both significant production losses and high mortality OR a substantial number of animals infected suffering from mild disease	1%-5% of susceptible animal population affected with high fatality rate or significant production losses
4	Major	a substantial number of animals infected suffering from severe disease resulting in both significant production losses and high mortality OR a large proportion of the animals infected suffering from mild disease	5%-10% of susceptible animal population affected with high fatality rate and significant production losses OR
			>10% of susceptible animal population affected with no case-fatality rate or few production losses
5	Catastrophic	a large proportion of the animals infected suffering from severe disease resulting in both significant production losses and high mortality	>10% of susceptible animal population affected with high fatality rate and significant production losses



**Risk estimation** 

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- A risk matrix can be used to condensate the results in a single risk estimate
- The risk matrix must be very carefully adopted
- In fact, the final level of risk should consider the type of health event of concern. For events with particular social or public awareness, even in the case of minor or moderate consequences and low probability of occurrence, the final risk can be unacceptable for risk managers and requiring urgent control or prevention actions

	А	Almost certain	MODERATE	HIGH	VERY HIGH	VERY HIGH	VERY HIGH
ро	В	Likely	MODERATE	HIGH	HIGH	VERY HIGH	VERY HIGH
eliho	С	Possible	LOW	MODERATE	HIGH	VERY HIGH	VERY HIGH
Ě	D	Unlikely	LOW	LOW	MODERATE	HIGH	VERY HIGH
	E	Rare	LOW	LOW	MODERATE	HIGH	HIGH

Minor

Moderate

Maio

Catastrophie

Incignificant



#### **Risk estimation**

- In addition, the choice on how the final risk values are derived from probability and consequence levels implies an implicit judgement on the shape of the distribution of the final risk estimates.
- For example, in the table below the risk levels are symmetric, giving the same weight and importance to the various levels of risk. In other words, the choice of a certain type of risk matrix may imply some judgments about what it is an acceptable risk, which is ultimately a risk managers' task.





### **Risk estimation**

Nevertheless describing the risk combining both probability and consequences is essential and it could be very useful when risk estimates related to different disease or health events have to be compared

