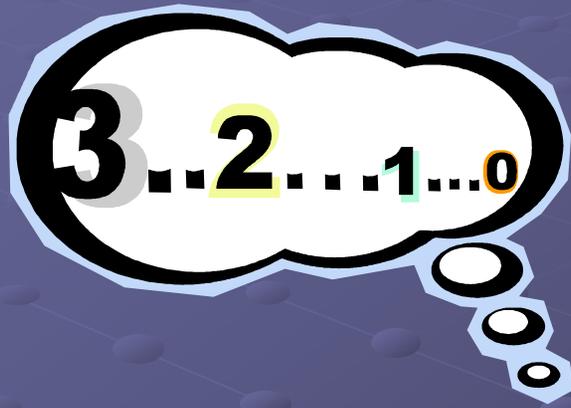


The Animal Feed Safety

System:



Ranking
Relative
Risks

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Overview

- What is the purpose of this talk?
- Why are we doing this?
- What is risk?
- What is risk assessment?
- What is risk ranking?
- How are we going to apply a risk ranking approach to the AFSS?

The Purpose of the AFSS

- To develop and implement a **comprehensive, risk-based, preventive** animal feed safety system that minimizes, reduces or eliminates the **risks to animal and human health** that can arise from animal feed

Why a Risk-Based Approach?

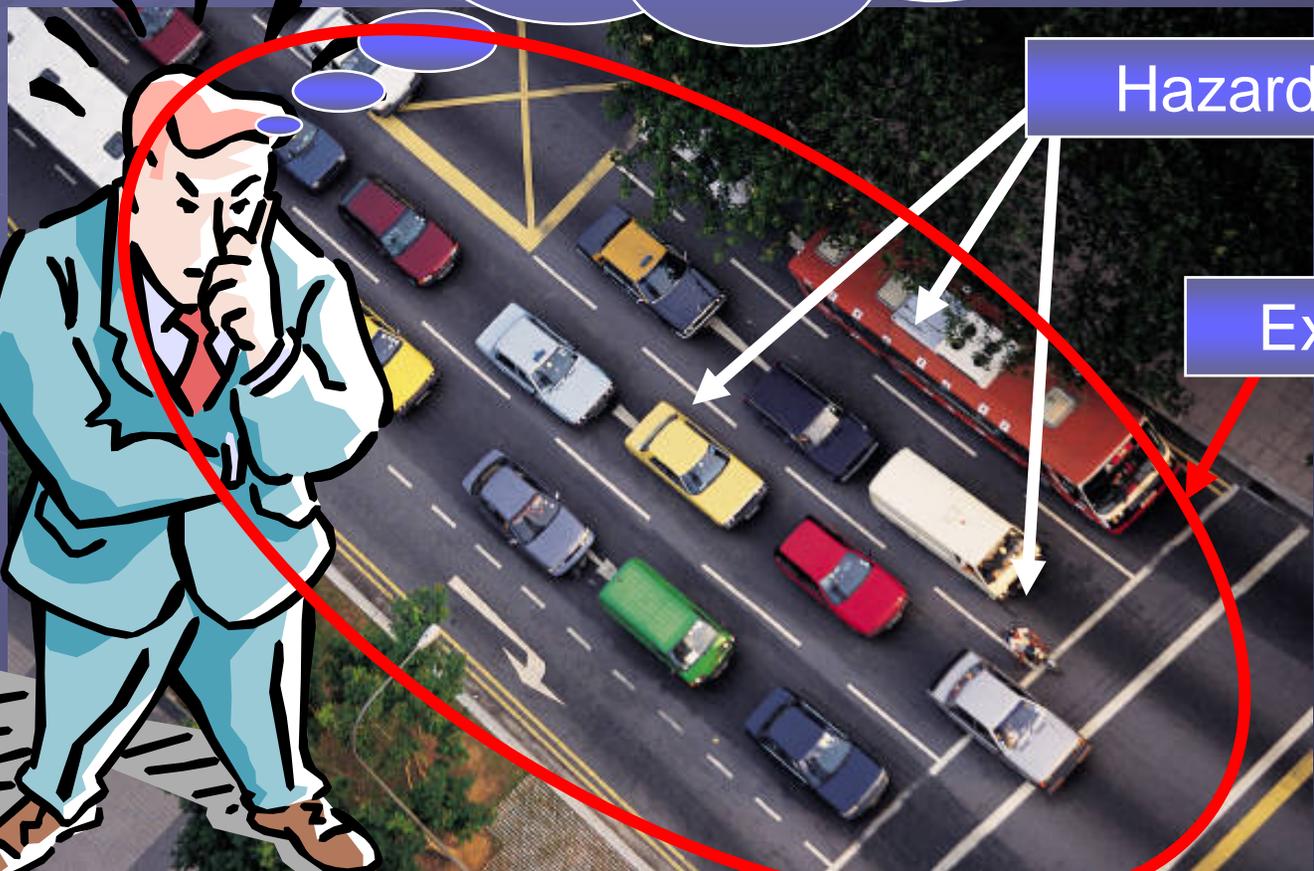
- Risk assessment is a logical process for collecting, organizing and analyzing information to inform a risk decision (*“science-based decision making”*).
- Risk assessment approach is also a forecasting process for the prevention of illnesses/adverse health risks.
- Eases the interactions between decision makers, stakeholders, and the public

Can I cross this street safely?

Hazards

Exposure

Consequences



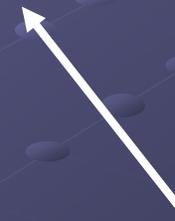
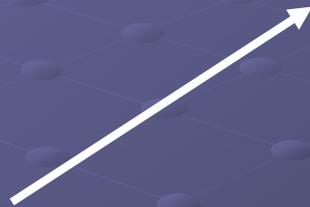
Risk Assessment Poses Four Simple Questions:

- What can go wrong?
 - Hazard Identification
- What are the consequences?
 - Consequence Assessment
- How can it happen?
 - Exposure Assessment
- What is the likelihood it would go wrong?
 - Risk Estimation

What is Risk?

- Risk is a function of hazard and exposure

$$\text{Risk} = \text{Hazard} \times \text{Exposure}$$



Health Consequences

Severity

(skin irritation/off-feed to death)

+

Potency

(amount to cause illness)

Routes

(how are we exposed)

+

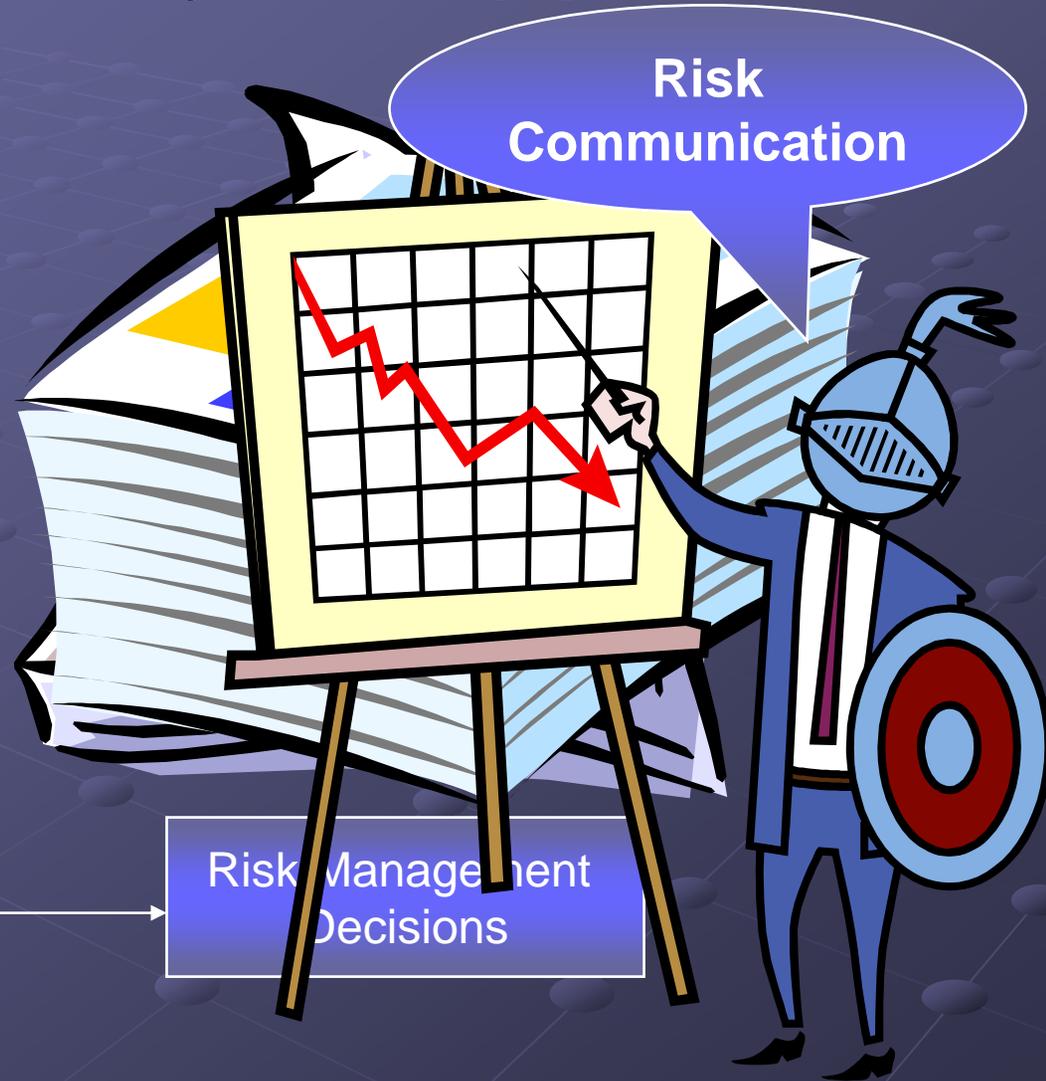
Likelihood

(improbable to common)

Risk Management Asks:

- What can be done?
- What options are available?
- What are risk trade-offs in terms of risks, benefits and costs?
- What are the impacts of current management decisions on future options?

Risk Analysis Approach



Implementing Risk Management

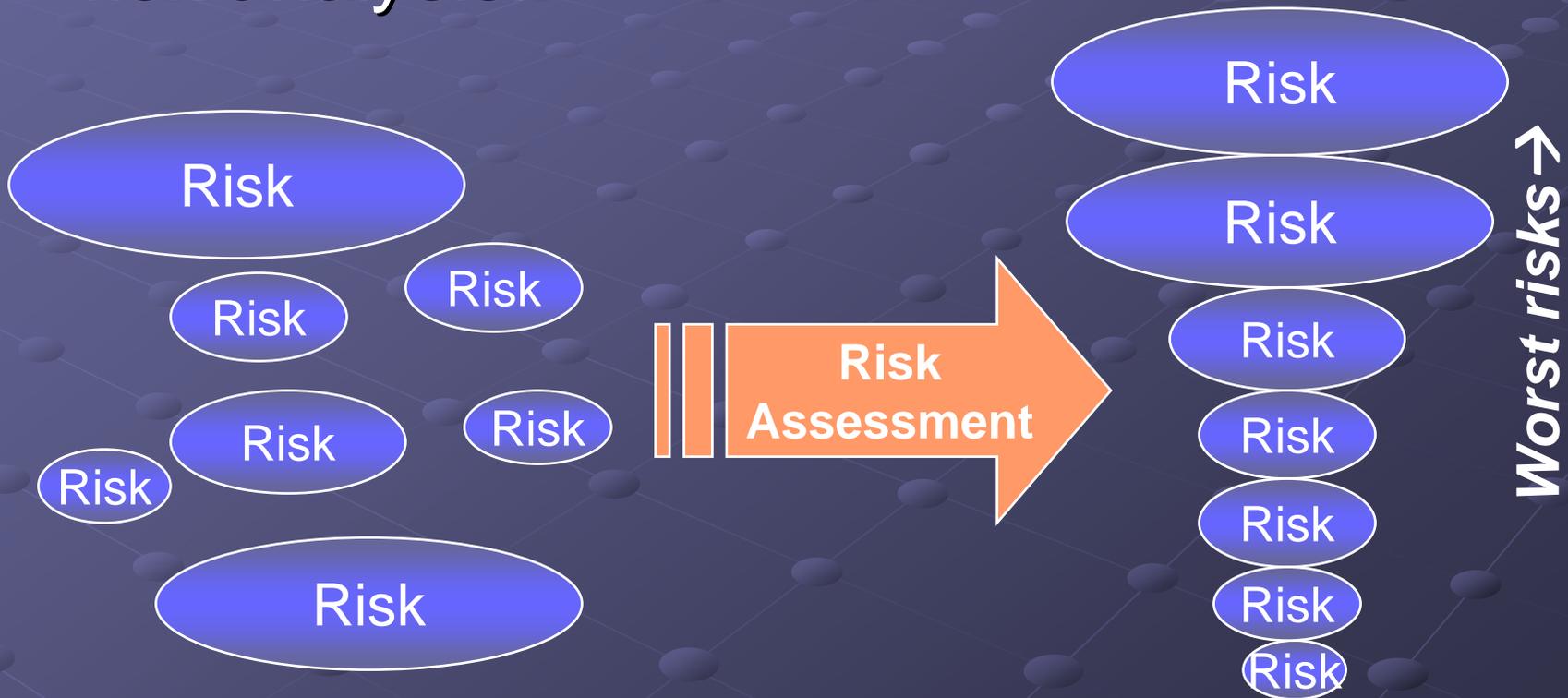
I wonder if I can
cross before
the light...

*The Risk
analysis cycle
repeats!*



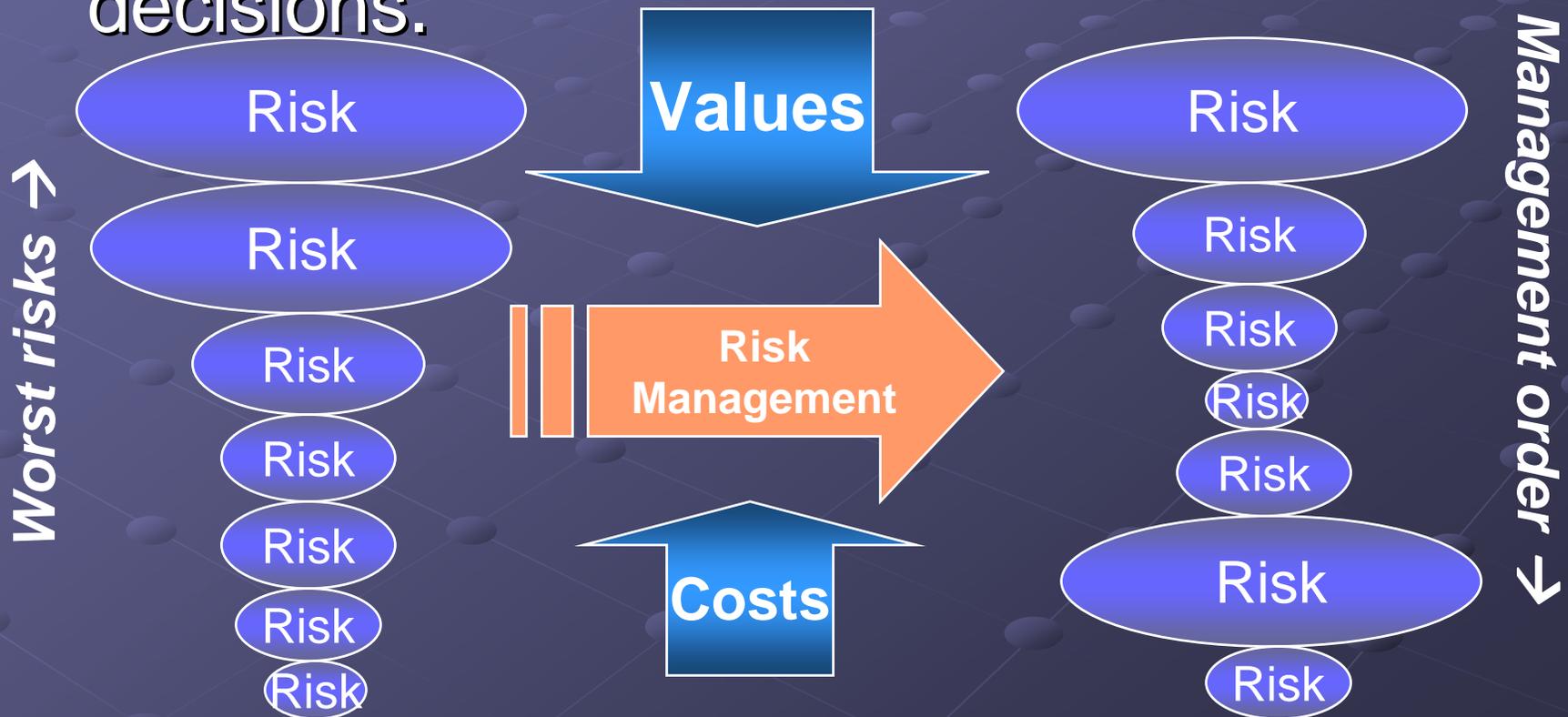
What is Risk Ranking?

- Risk *assessments* provide the “facts” for risk analysis.



Risk Ranking

- The risk *management* decisions about which risks to manage first are value-laden decisions.



Risk Ranking

!CAUTION!

- AFSS risk ranking system does not estimate individual risks!
- The ranked risks are **relative** risks

!CAUTION!

Risk Assessment – Four Steps

- Step 1: What can go wrong?

 - Hazard Identification

- What are the consequences?

 - Consequence Assessment

- How can it happen?

 - Exposure Assessment

- What is the likelihood it would go wrong?

 - Risk Estimation

Risk Ranking Method

Step 1

● Hazard Identification

- Categorize - Chemical, biological and physical hazards
- Group within categories
- Hazards with similar characteristics
- **Guiding Principle – Simplify**

Identifying Feed Hazards

~175 hazardous agents identified

CATEGORIES

● Unintentional

- Physical
- Microbiological
- Chemical

● Intentional

- Physical
- Microbiological
- Chemical

GROUPS

- Bacteria
- Viruses
- Fungi
- Rickettsia
- Mycoplasma
- Others



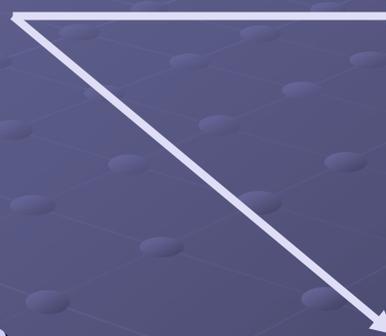
Identifying Feed Hazards (2)

GROUPS

- Bacteria
- Viruses
- Fungi
- Rickettsia
- Mycoplasma
- Others

HAZARDS

- *Salmonella*
- *E. coli 0157:H7*
- *C. botulinum*
- *Others*



Risk Assessment - Four Steps

- What can go wrong?
 - Hazard Identification
- Step 2: What are the consequences?
 - **Consequence Assessment**
- How can it happen?
 - Exposure Assessment
- What is the likelihood it would go wrong?
 - Risk Estimation

Risk Ranking Method

Step 2

● Health Consequences

- Two factors:

- Likelihood of the illness

- If you are exposed to the hazardous agent, how likely is it that you will become ill?
 - May be referred to as the potency of the hazardous agent (e.g., the amount of hazard required to cause the illness/adverse effect)

- Severity of the illness

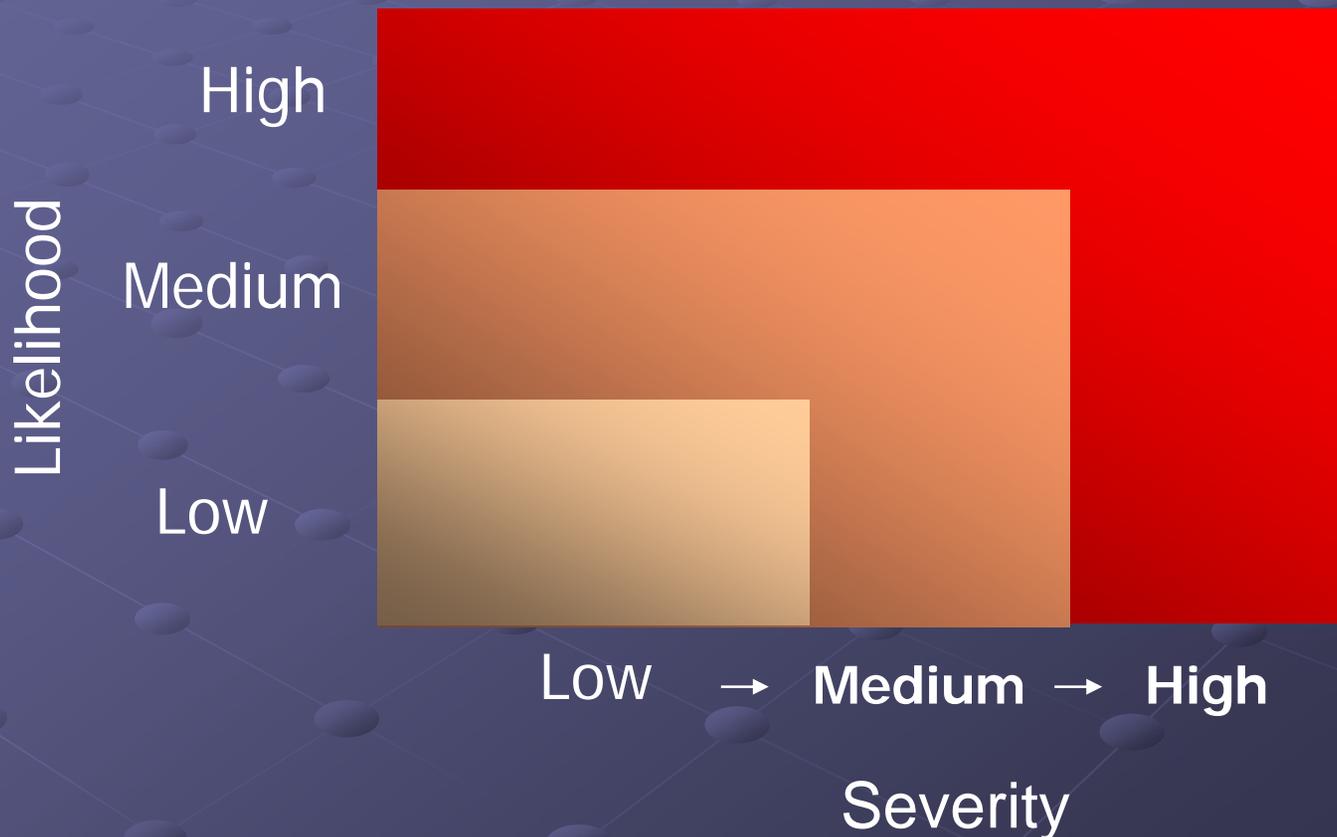
- If you become ill, how severe is the illness? (e.g., death v. vomiting v. skin irritation)

Risk Ranking Method

Step 2

● Health Consequences Score

- Likelihood and Severity combined

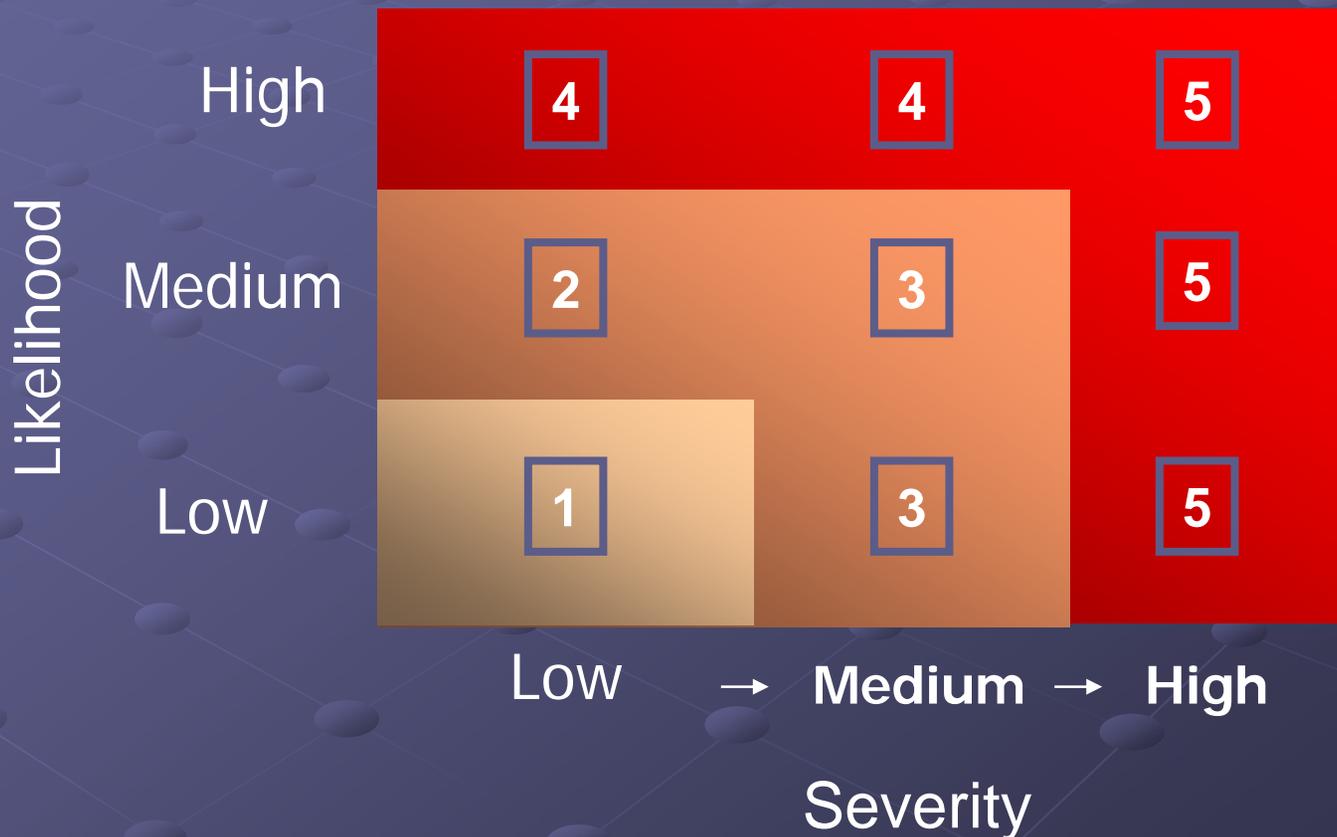


Risk Ranking Method

Step 2

Health Consequences Score

- What It May Look Like Numerically



Risk Ranking Method

Step 2

● Health Consequences Score

- Scores developed for both animals and humans
- Scores for chemical agents may be based on existing health standards (RfDs, ADIs, etc.)
- Scores for physical agents likely to be higher for animals than humans
- Scores for biological agents a more difficult challenge

Risk Assessment - Four Steps

- What can go wrong?
 - Hazard Identification
- What are the consequences?
 - Consequence Assessment
- Step 3: How can it happen?
 - **Exposure Assessment**
- What is the likelihood it would go wrong?
 - Risk Estimation

Risk Ranking Method

Step 3

● Exposure

- Identify source of each hazard entering the feed process.
- Feed ingredients will be linked to each hazard they may contain, resulting in a set of Ingredient:Hazard pairs for each ingredient, such as Corn:Aflatoxin and Clay:Dioxin.
- Initial level of a hazard in a feed ingredient or feed will depend on:
 - Environmental conditions
 - Human activities
 - Source and type of contaminant
 - Source and type of feed ingredient

Risk Ranking Method

Step 3

● Initial Exposure Score

- For each pair, a quantitative or semi-quantitative Exposure Score will be calculated or estimated. (Exposure is the amount of the hazard in the feed ingredient.)
- Score based on:
 - Measured data (when available)
 - Salmonella contamination data
 - Expert opinion

Risk Ranking Method

Step 3

● Manufacturing Process(es) Modifying Factors

- Feed manufacturing process(es) will either increase, decrease or not affect the level of a particular hazard in the ingredient and feed
- Manufacturing processes include transportation, storage, steps in feed manufacturing, and on-farm processes

Risk Ranking Method

Step 3

● Final Exposure Score

- Initial Exposure Score will be modified based on manufacturing processes used in the production of the specific feed ingredient.
- For example, a process may involve sufficient heat to eliminate the possible exposure to a bacterial hazard.

Risk Assessment - Four Steps

- What can go wrong?
 - Hazard Identification
- What are the consequences?
 - Consequence Assessment
- How can it happen?
 - Exposure Assessment
- Step 4: What is the likelihood it would go wrong?
 - **Risk Estimation**

Risk Ranking Method

Step 4

● Relative Risk Score

- For each Ingredient:Hazard pair, the Consequence Score will be multiplied by the Exposure Score to yield a Relative Risk Score.
- For example, the Consequence Scores and Exposure Scores may range from 1 - 5, resulting in a range of Relative Risk Scores from 1 – 25.

How Will Ranked Risks Be Used?

- Decide how risks from contaminants can best be prevented or controlled:
 - Do limits for higher-risk contaminants need to be identified? If yes, which contaminants?
 - Do analytical methods for higher-risk contaminants need to be developed?
 - What process changes can feed manufacturers make to reduce risks from contaminants?
 - What surveillance/sampling programs are needed to ensure compliance with contaminant limits?

Summary of Risk Ranking Method

- Hazard Identification
 - Categories, groups, similar characteristics
- Consequence Assessment
 - Consequence score (severity + likelihood)
- Exposure Assessment
 - Initial Exposure score modified by manufacturing processes
- Risk Ranking
 - Consequence score x Exposure score

Limitations

● Approach

- “Top-down” – Start with observed health effects and work down to potential causes (or start with final feeds and work down to potential causes)
 - Benefits – focuses on endpoint of concern
 - Problems – little data on health effects (or little data on potential hazards in final feeds); difficult to use as preventive tool
- “Bottom-up” - Start with sources of hazards and work up to estimate risks to health
 - Benefits – addresses the complexity of the system; permits isolation of specific problems; it allows a preventive approach
 - Problems - requires risk assessments for each hazard

Limitations

● Risk-Ranking Method

- A semi-quantitative method pushes most assignments into the middle of the range

● Does not distinguish between intermediate risks

- Acute vs. mild chronic (severed finger vs. long-term health effect)
- High exposure/low consequence vs. low exposure/high consequence

Limitations

● DATA!

- Primarily an issue in exposure
 - Limited measured data for many hazards
 - Strong reliance on expert opinion (not that there is anything wrong with that!)