Tools for Prioritizing Food Safety Concerns

Report From Breakout Group 4

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Bernadene Magnuson, Facilitator

Selection of compounds/agents for inclusion

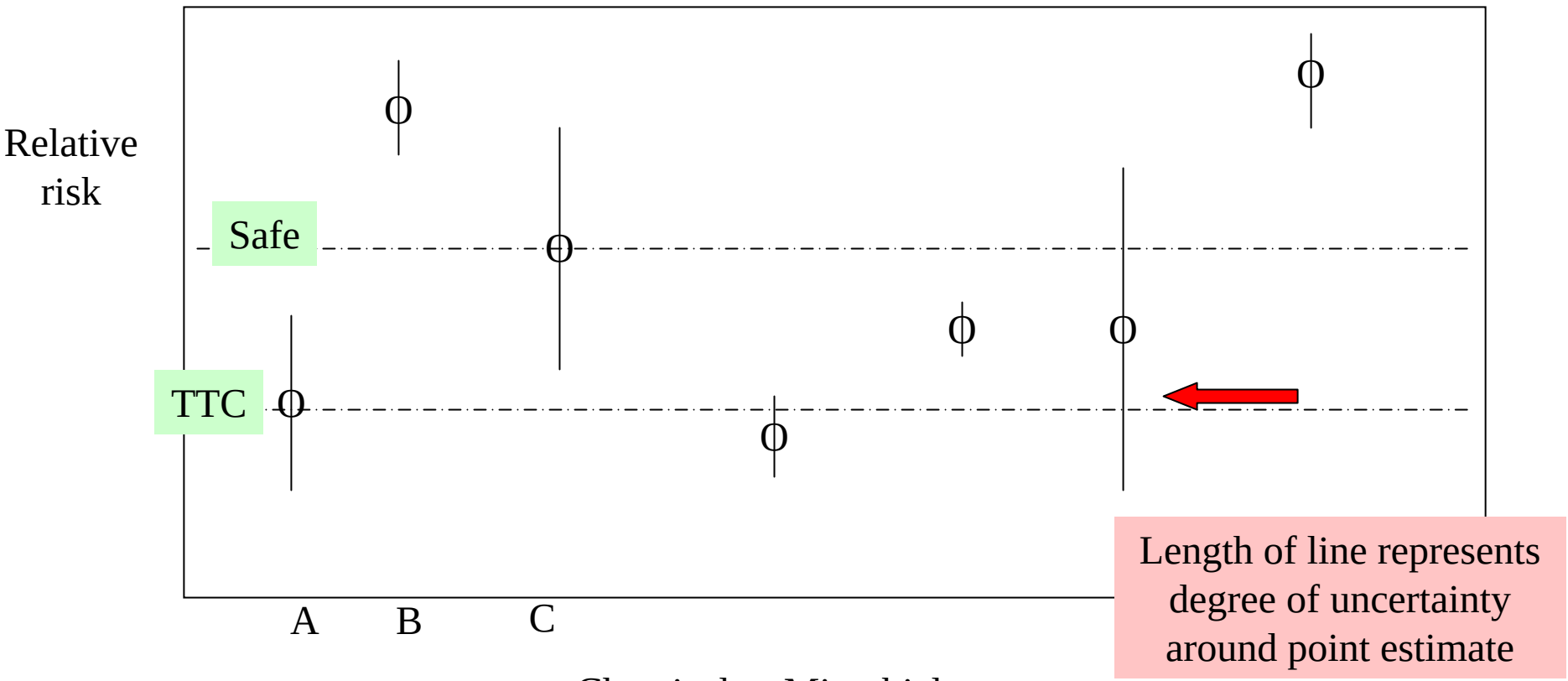
1. Known single agents
2. Known complex mixtures
3. Unknown agents –

   -may be added based on observed adverse effect

   -structural alert

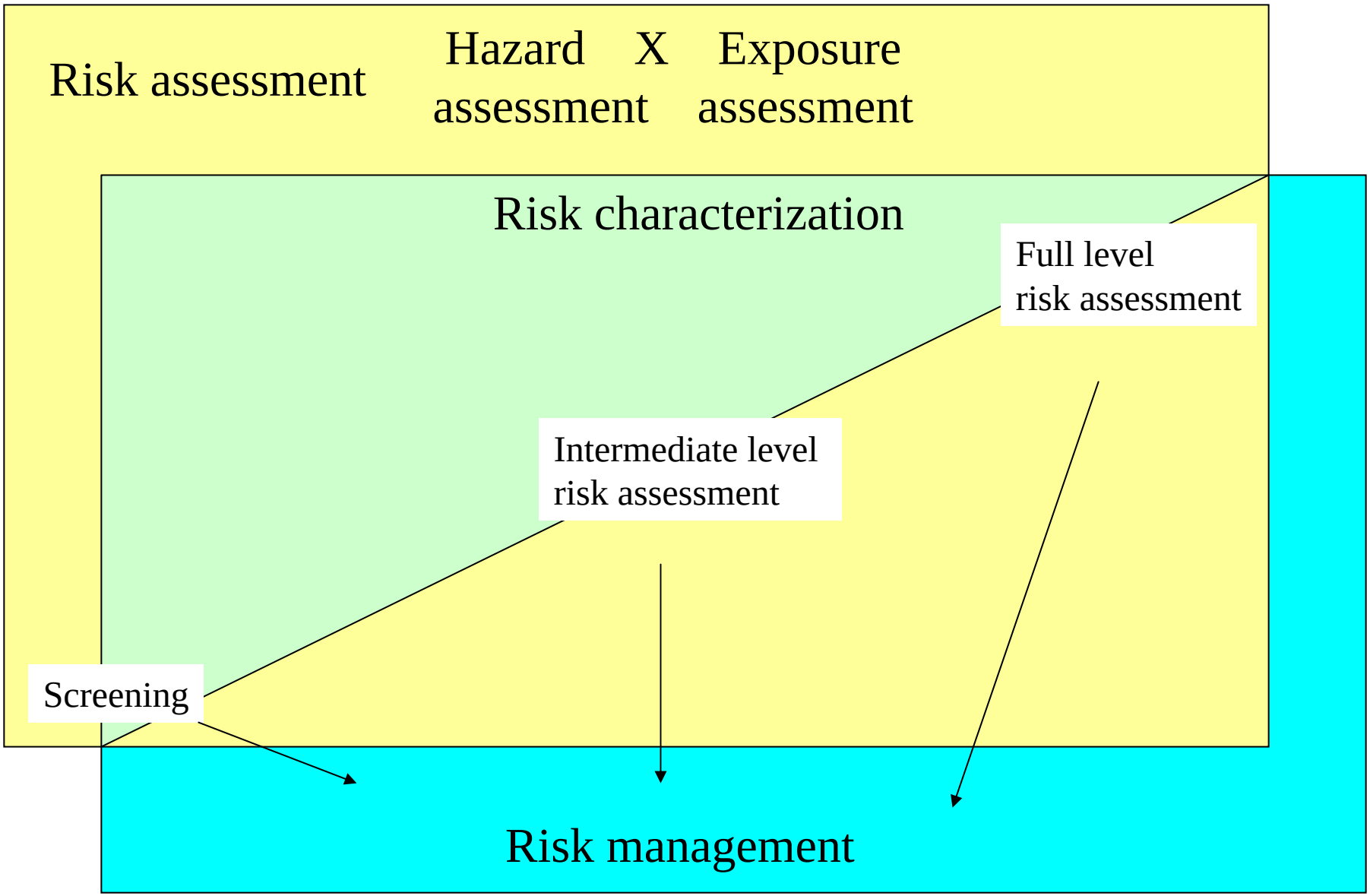
   -emerging contaminant arises

Conceptual Illustration



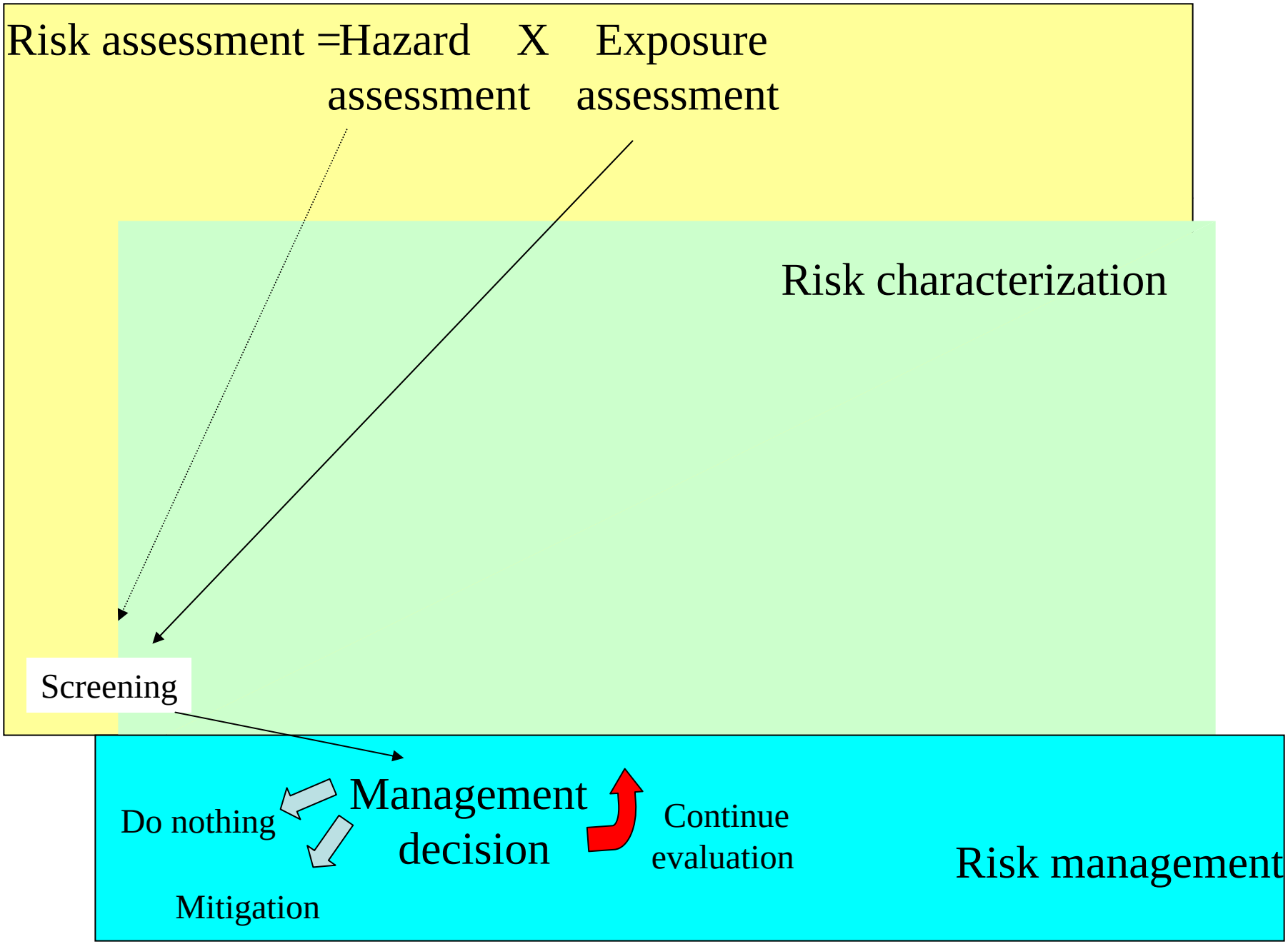
Relative risk = Exposure (ie. Concentration in foods x consumption of food
Hazard assessment (e.g. BMDL, etc)
Note – ADI, TTC not relevant for micro-chem comparison

Overall approach – multilevels



Risk characterization – Screening stage

- Hazard assessment
  - Benchmark dose (BMD), ADI, RfD, TTC, MOE
    - Need common scaler
  - Structure/activity relationship
- Exposure assessment
  - Concentration in foods
- Output - Yes – No decision
  - Not signif public health risk, or need more data or consideration

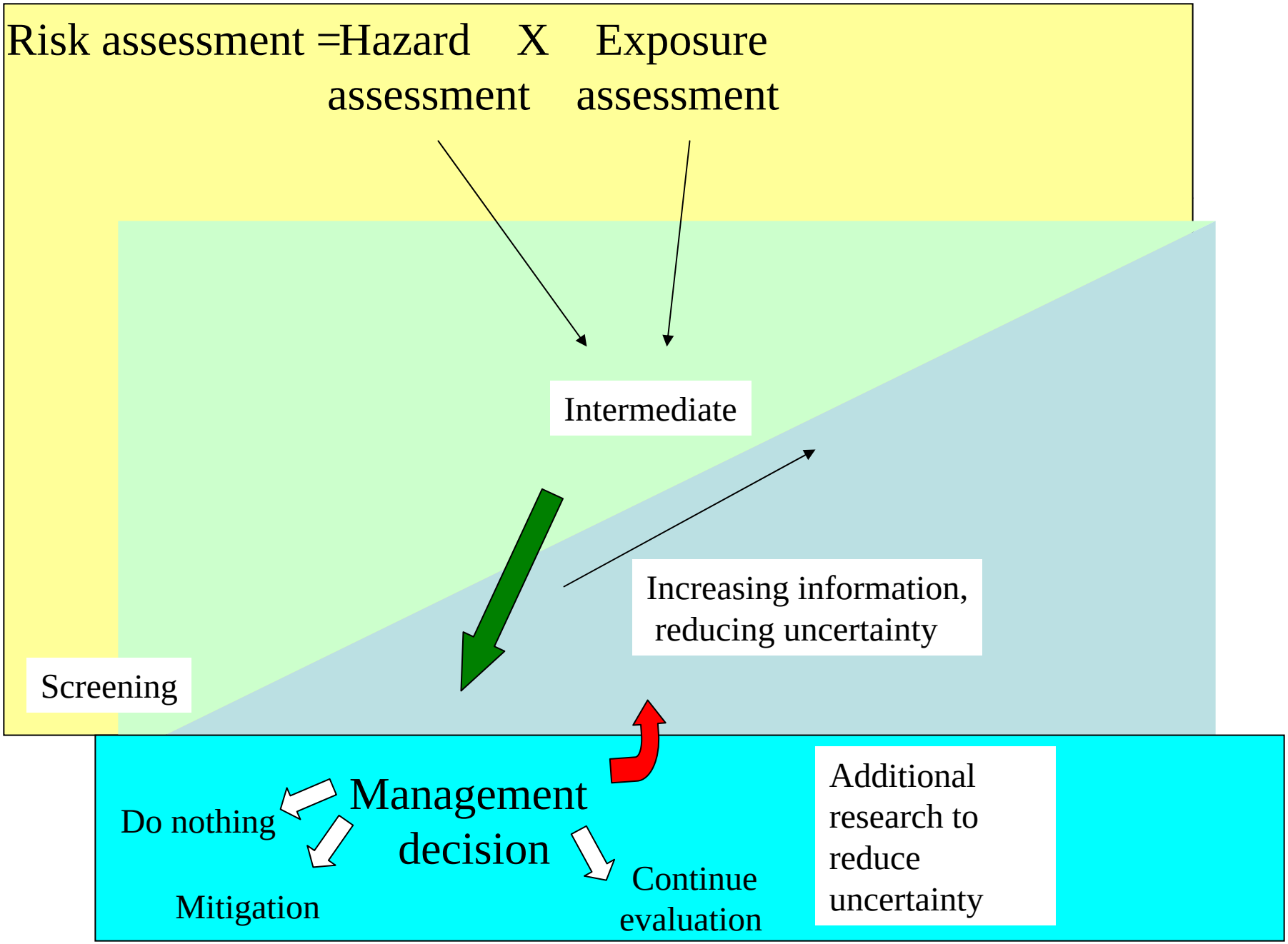

Risk assessment =Hazard assessment X Exposure assessment
Risk characterization
Screening
Management decision
Do nothing
Mitigation
Continue evaluation
Risk management

Considerations for screening step

- Level of certainty ? – quality of data points/number of observations
- How low below established ADI, RfD, TTC, tolerance levels? Margin of Safety
- Helpful to have widespread acceptance of approach and levels
- Need unbiased evaluators involved
- Post-analysis and re-visitation needed

Inputs for remaining risks

- Amount in food
  - Analytical methods validated?
  - Food consumption – diet, special populations
- Animal tox data;
- Human data preferred – epi, use to develop upper bounds if no effect, dose-response if effect
  - Exposure biomarkers
- Assessment of health outcomes

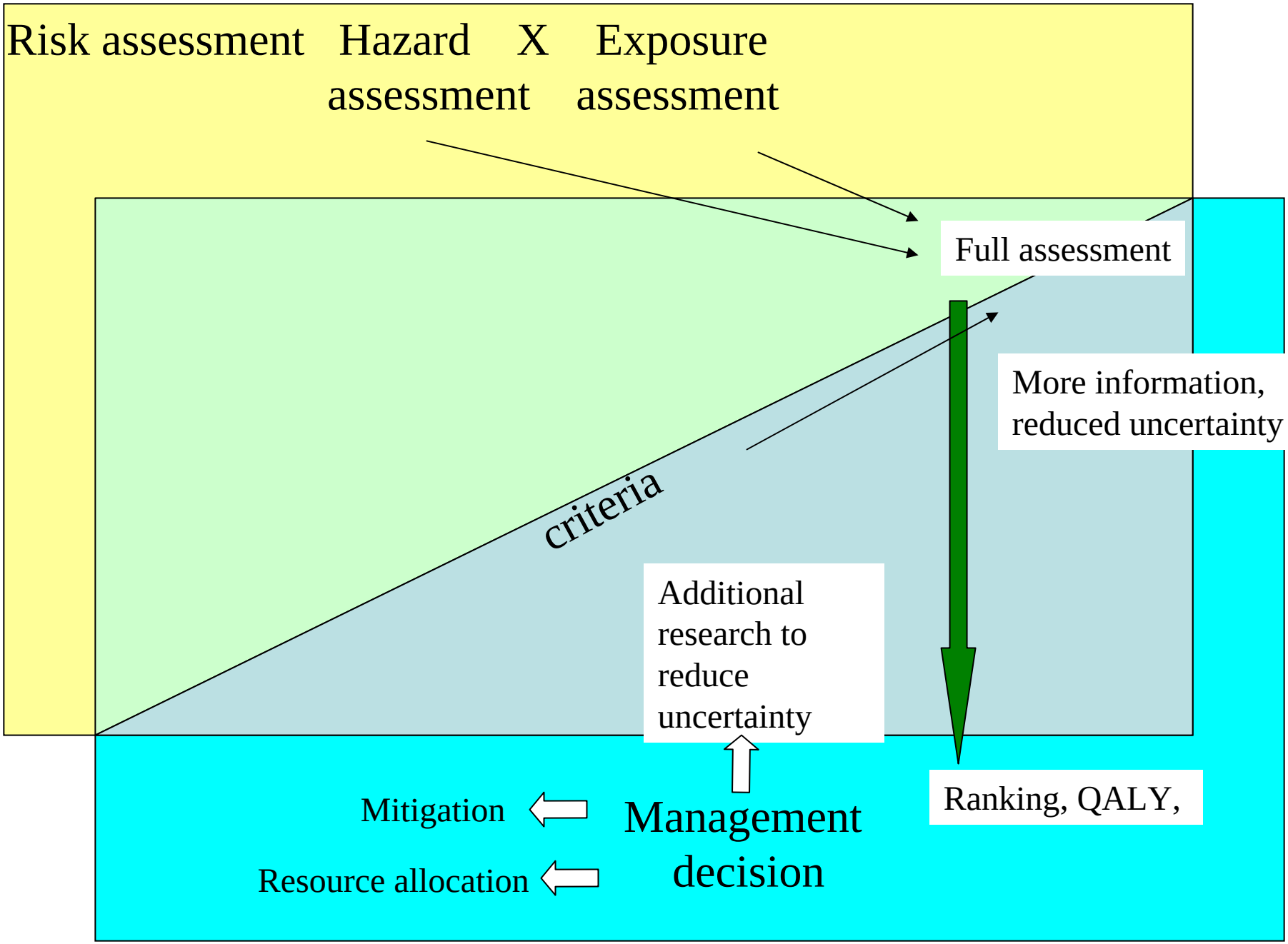

Risk assessment =Hazard assessment X Exposure assessment
Intermediate
Increasing information, reducing uncertainty
Screening
Management decision
Do nothing
Mitigation
Continue evaluation
Additional research to reduce uncertainty

Risk characterization – Intermediate stage

- Hazard assessment
  - Primarily using existing data, SAR
- Exposure assessment
  - Primarily using existing data, may need method development
- Outputs
  - Level of Risk or Risk distribution, with uncertainties
  - Data gaps associated with uncertainty –identify data that will achieve maximal reduction of uncertainty

Considerations for intermediate and full assessment

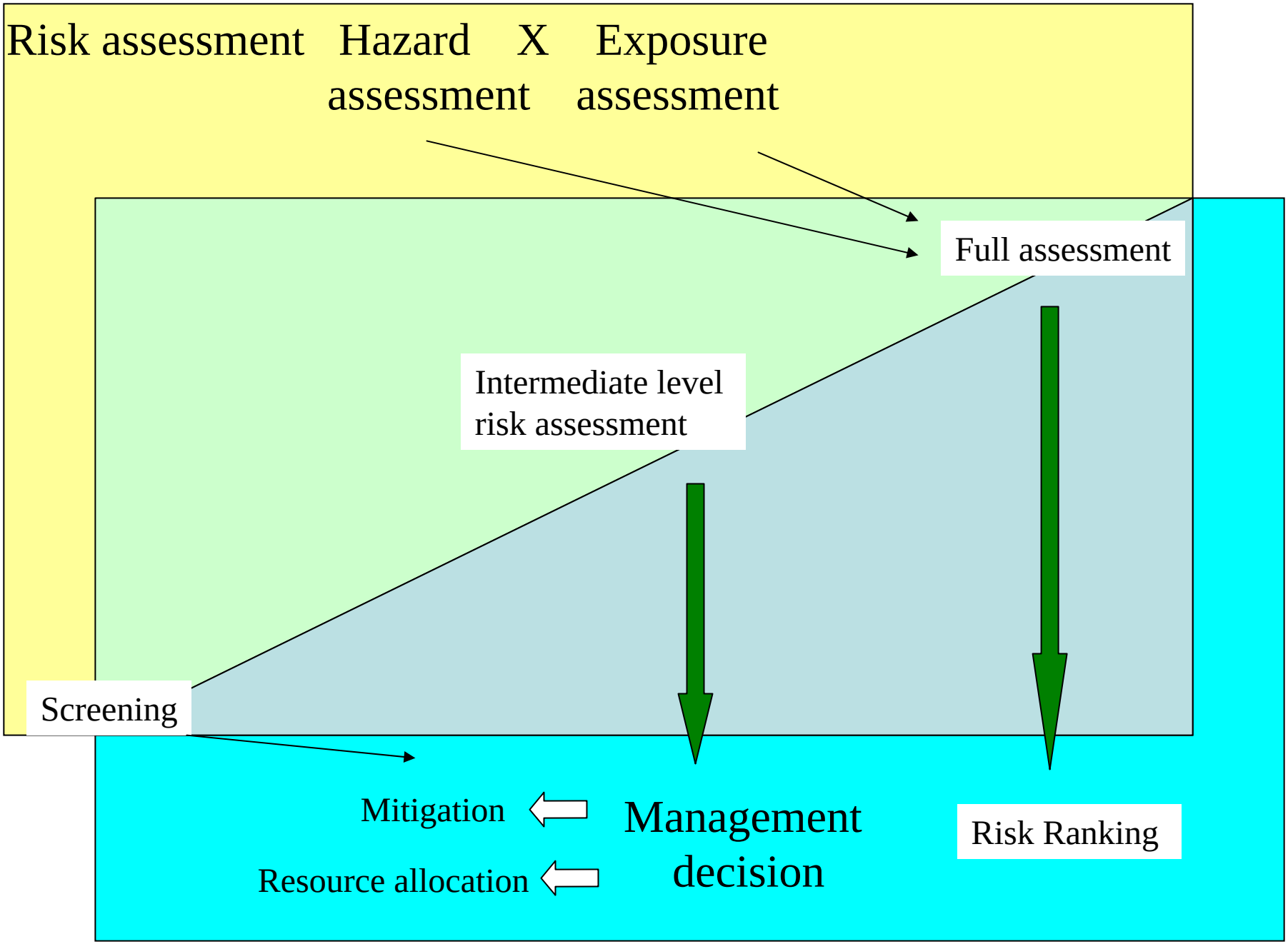
- Data quality issues
- Acute versus Chronic
- Severity of effect
- Frequency in food (one time, reoccurs)
- Target population – infants, pregnant, aged
- Scientific agreement


Risk assessment
Hazard assessment
X
Exposure assessment
Full assessment
More information, reduced uncertainty
criteria
Additional research to reduce uncertainty
Ranking, QALY,
Mitigation
Resource allocation
Management decision

Risk characterization – "Full" stage

- Hazard assessment – more detail
- Exposure assessment – more detail
- Outputs –
  - assess public health impact more accurately (QALY, DALY)
- Additional considerations to note for prioritization of resources

  - Economic impacts, public perception, naturally occurring or contaminant, impact on other risks – nutritional risks of avoidance of specific foods


Risk assessment
Hazard assessment
X
Exposure assessment
Full assessment
Intermediate level risk assessment
Screening
Mitigation
Resource allocation
Management decision
Risk Ranking

Comparability of risks

- May need to do chem and micro separately to get ranking within class, then merge
- Visibility of effect
- Are you assessing predicted risk or observed?
- Need to generate measure (ie.QALY) that can be applied to both chem and micro, then may allow cross comparison using categorical regression
- Need to consider quality of data

Criteria for Framework to be Acceptable

- KISS
- Transparency
- Scientifically sound
- Established data quality
- Results – do they make sense, results are self-consistent (test or real case checks), “gut check”
- Useful as a decision tool
- Adaptable – able to incorporate new data/situations/agent
- International involvement
- Post Review – of individual decisions and of overall approach