Science and Policy in Risk Analysis: A Necessary But Incompatible Mix?

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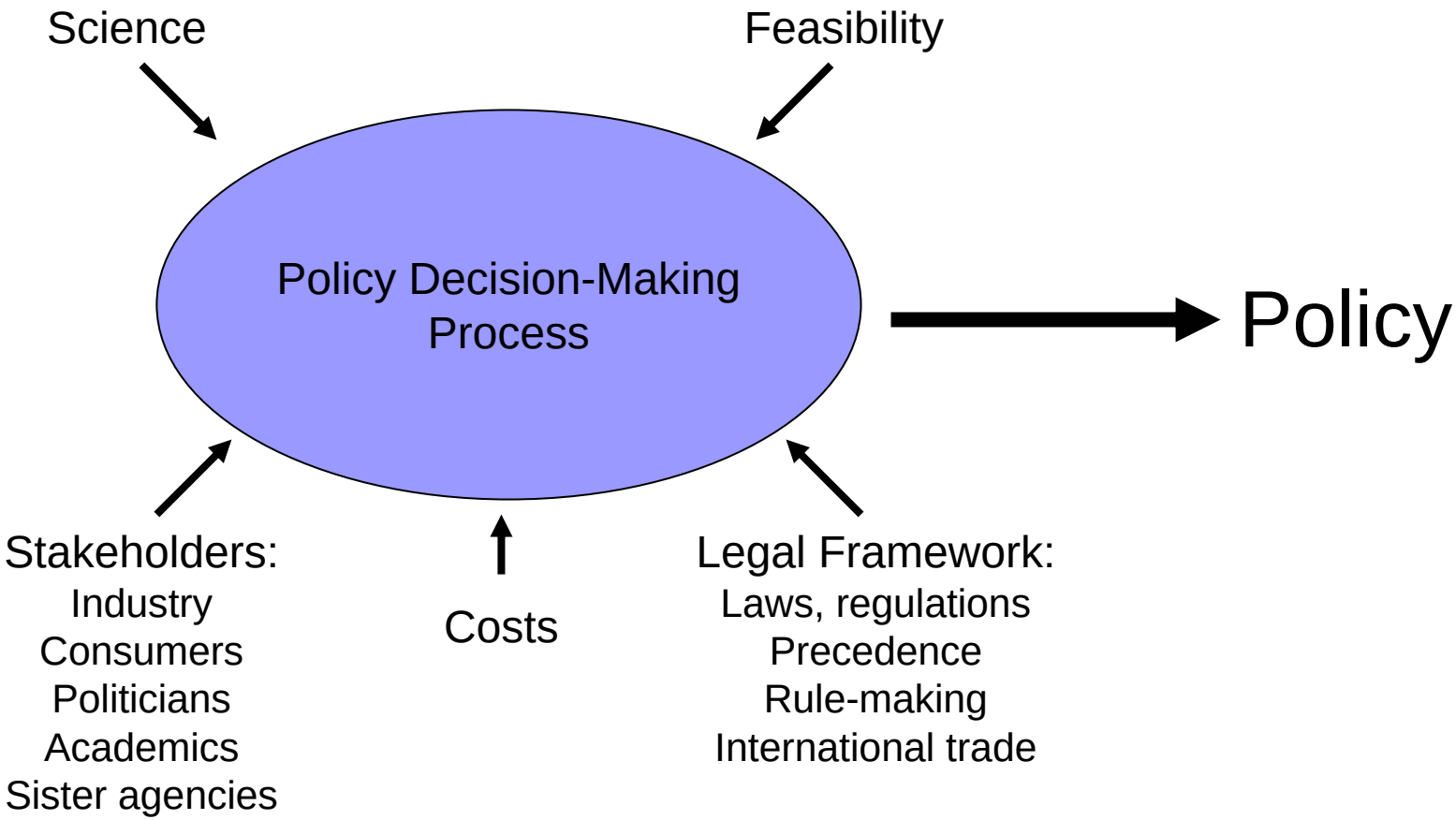
Policy Decision-making Process



Risk Analysis

- A defined process for bringing sound science to policy safety decisions
- Designed to protect public health
- IOM, European, and WHO reports
- Initially used for chemical hazards in food supply and environment
- Extended to microbiological hazards
- Currently being applied to other substances, e.g. nutrients
- International trade disputes

Components of a Risk Analysis

Terminology

- Risk Manager:
  - Government – policy maker
  - Examples: FDA, EPA, FSIS/USDA
- Risk Assessor:
  - Scientist
  - Examples: Toxicologists, Chemists, Clinicians, Nutritionists, Statisticians

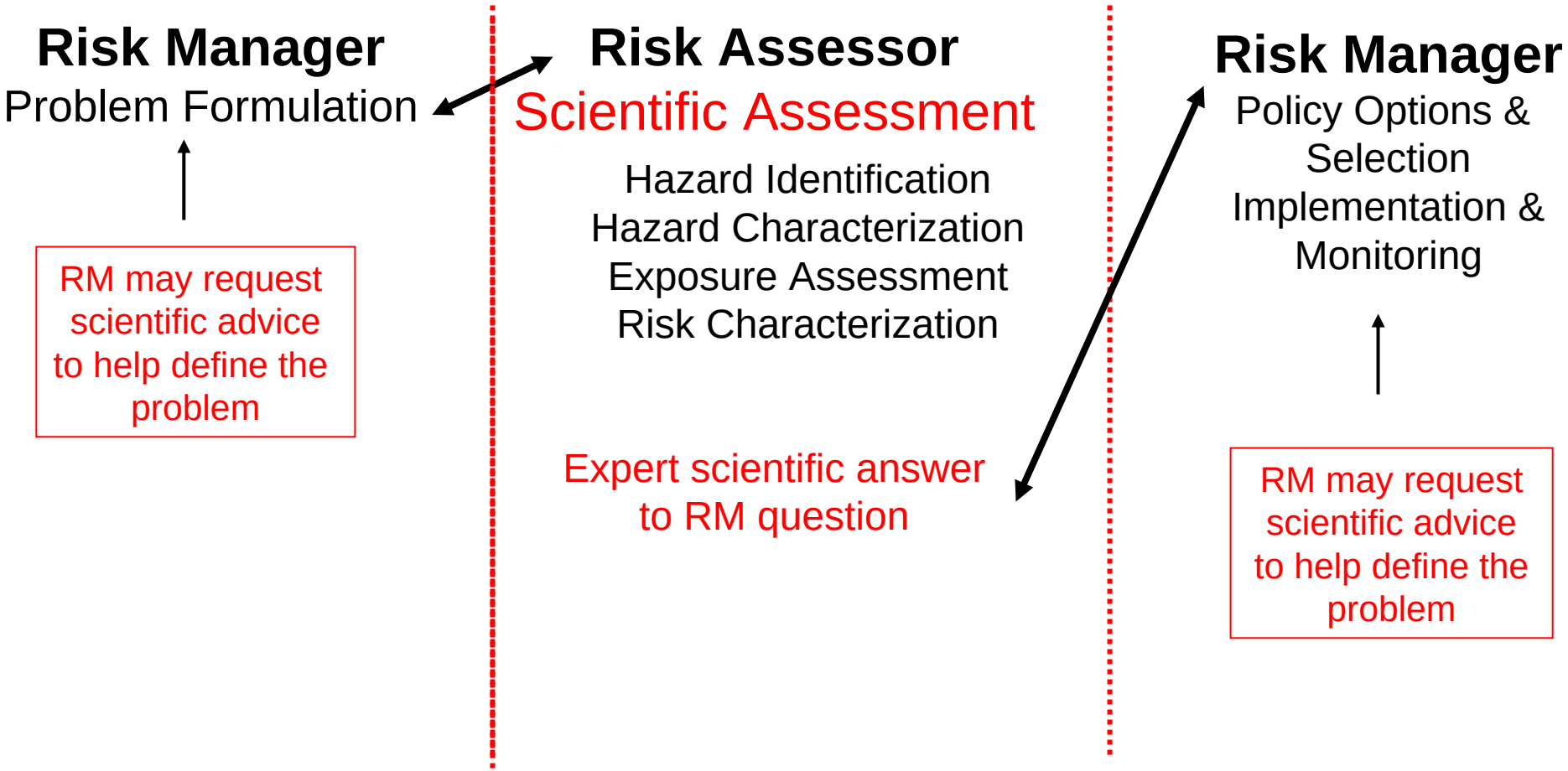
Characteristics of Risk Analysis

- Ethical considerations → data limits
- No decision often not a viable option
- Policy decisions subject to legal challenge and competing stakeholder demands
- Therefore, risk analysis framework requires:
  - transparency
  - an accepted approach for:
    - dealing with data uncertainties, including
    - incorporating scientific judgment

Successes of Risk Analysis

- Successes:
  - E. coli 0157: apple cider; ground beef
  - Listeria: cheese, fish
  - Vibrio parahaemolyticus in raw oysters
  - Acrylamide in potato chips
  - E. sakazakii in infant formulas
  - BSE (“mad cow”)
- Lessons learned
  - Nutrition – an immature risk analysis stage

Structured Process



Problem Formulation

- Goal:
  - Risk Manager: Requests scientific advice
  - Risk Assessor: Avoids policy implications
  - Interaction between risk manager and risk assessor:
    - ensure clarity and appropriateness of problem formulation
    - Maintain “bright line” between the two steps

Problem Formulation: Vitamin A

- Risk Assessment Conclusion:
  - "Careful consideration given to appropriateness of fortification of human foods and animal feeds"
- Dilemma:
  - Violated separation of science and policy
- Why?
  - Inappropriate problem formulation
  - Failure of Risk Assessor to clarify

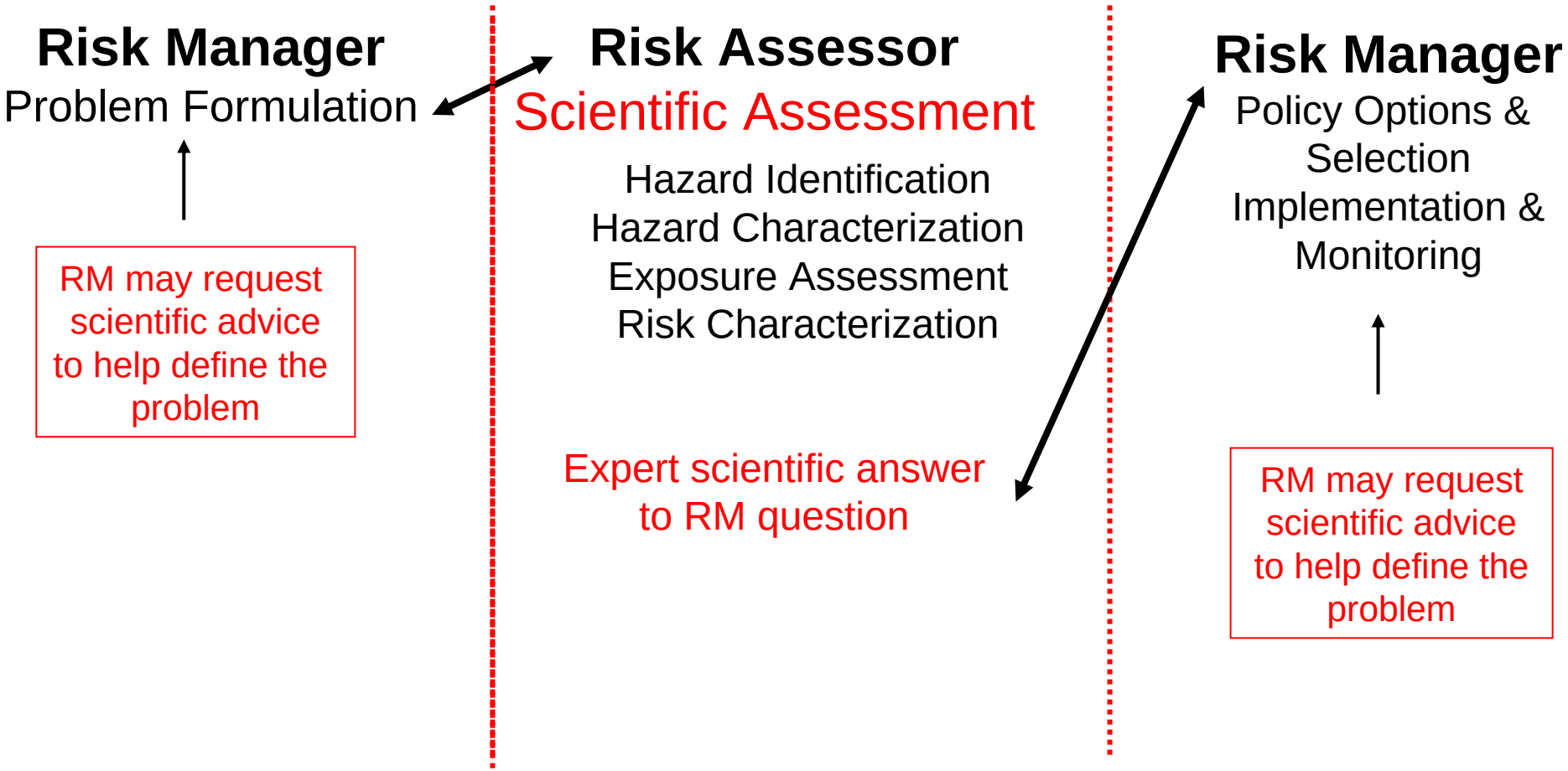
Problem Formulation: Risk Assessment Strategy for D.S.

- Dietary Supplement Safety Review
  - Risk assessment recommendation:
    - “Conclusive” proof of evidence
    - But if not available, appropriate for regulatory agency to take action in its absence
  - Discussion on the inappropriateness of the current legal framework for evaluating safety

D.S. Supplement Safety Strategy

- Why?
  - Risk manager problem formulation not easily addressed
  - Risk assessors changed problem formulation without interacting with risk manager
  - Peer reviewers: Strategy “not feasible”
  - Solution: Add caveats to the Risk Assessment

Structured Process



Scientific Quality: Vitamin A

- U.S. Risk Assessment:
  - Risk of exceeding the UL is small
- European Risk Assessment:
  - Current intakes pose a risk
- Dilemma:
  - Differences in intakes unlikely
  - Same scientific evidence available for R.A.
- Why?
  - Types and breadth of expertise included
  - Failure to correct intake estimates for within-person variability
  - Lack strategy to model intakes from different surveys

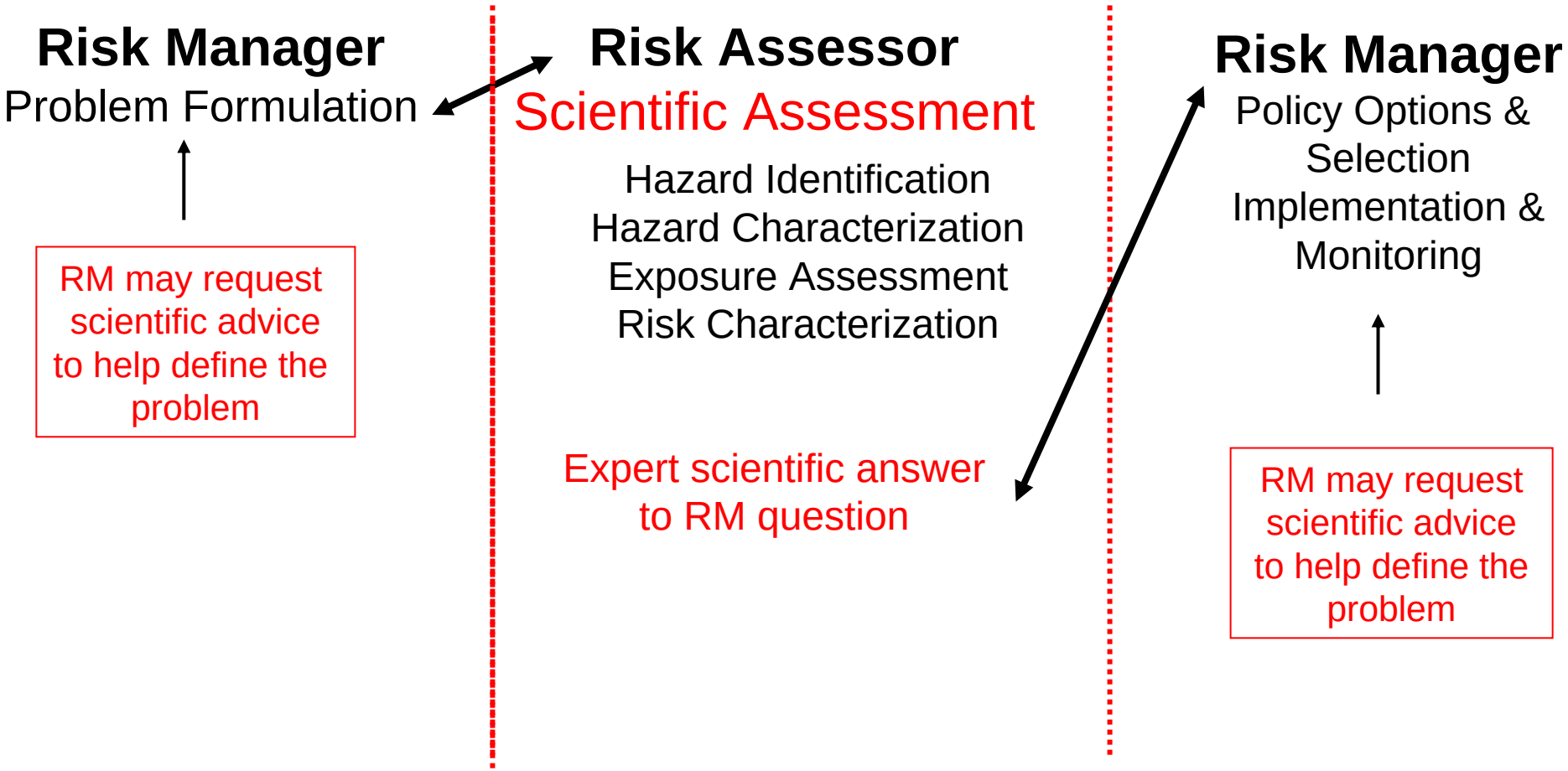
Example: Documentation of Scientific Review

- European and US Reviews:
  - Same database available to both groups
  - Relied upon different studies
  - Conclusions inconsistent
  - No information to determine basis for inconsistencies
- Solution:
  - Document search strategies, evaluation criteria
  - Document criteria for weighing evidence

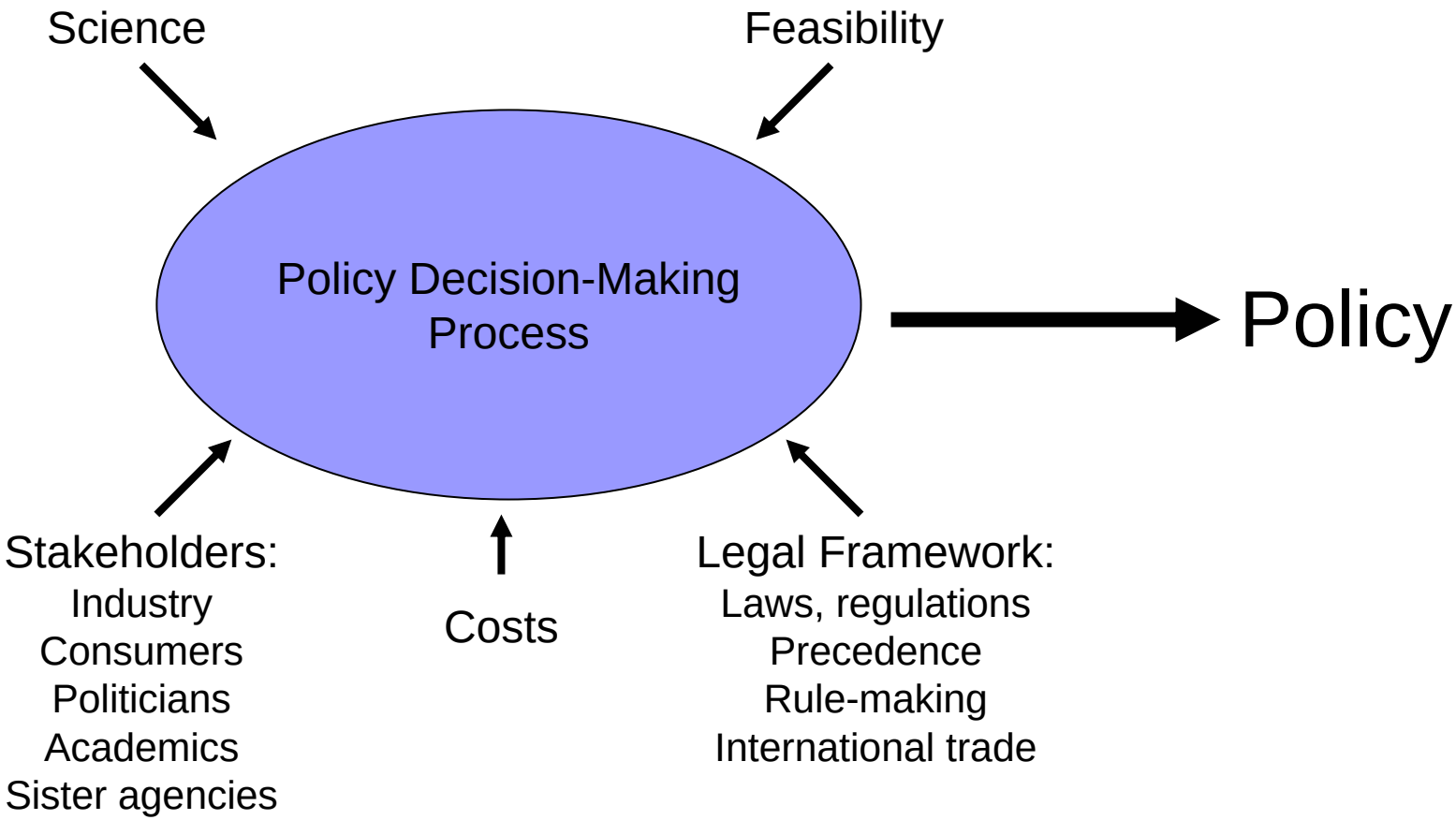
Risk Assessment: Lessons Learned

- Quality of scientific assessment dependent on inclusion of qualified experts that cover the range of types of expertise needed
- Structured process for soliciting stakeholder input might have prevented problems
- Peer review
- Scientific quality of risk assessment influences ability of Risk Manager to use results of the risk assessment

Structured Process



Policy Decision-making Process



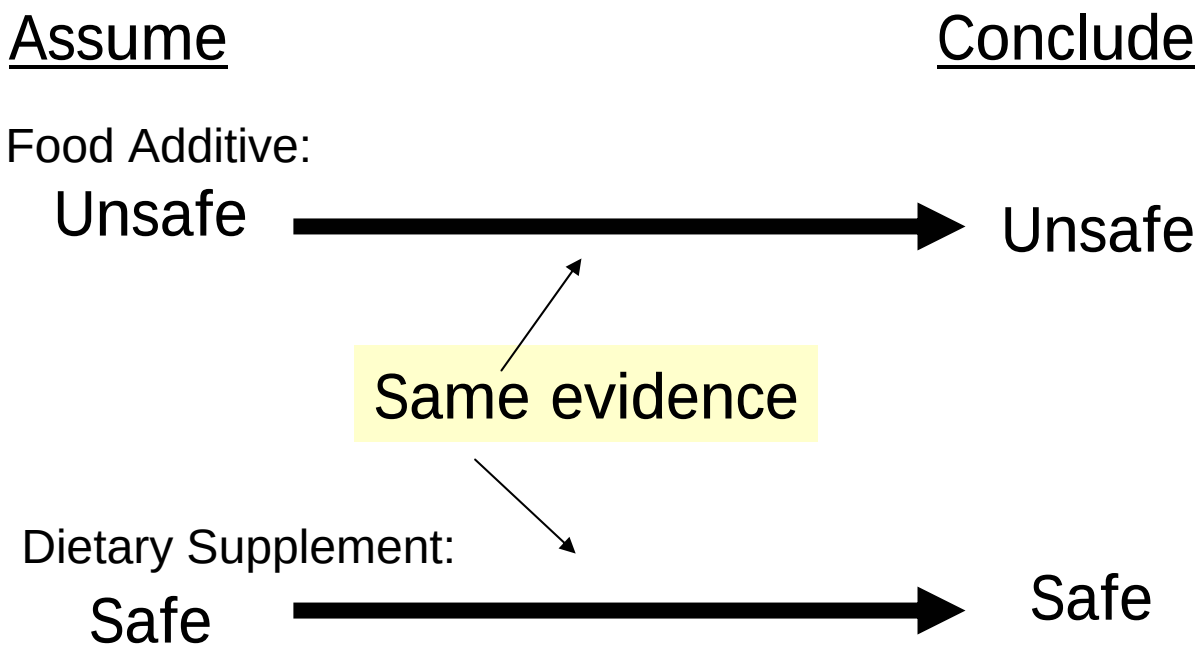
Context Matters: Stevia Example Same data -- different decisions

- “Unsafe” for use as a sweetener in conventional foods
- “No objection to its use as a dietary supplement ingredient
- Science input to both decisions:
  - Same scientific evaluation
  - Same experts

Stevia Risk Assessment

- Chemistry suggests estrogenic activity
- Animal study results, although seriously flawed, are consistent with chemistry
- History of use data undocumented
- No basis to say its safe or not safe, but some basis to hypothesize a concern

What is the Starting Point?



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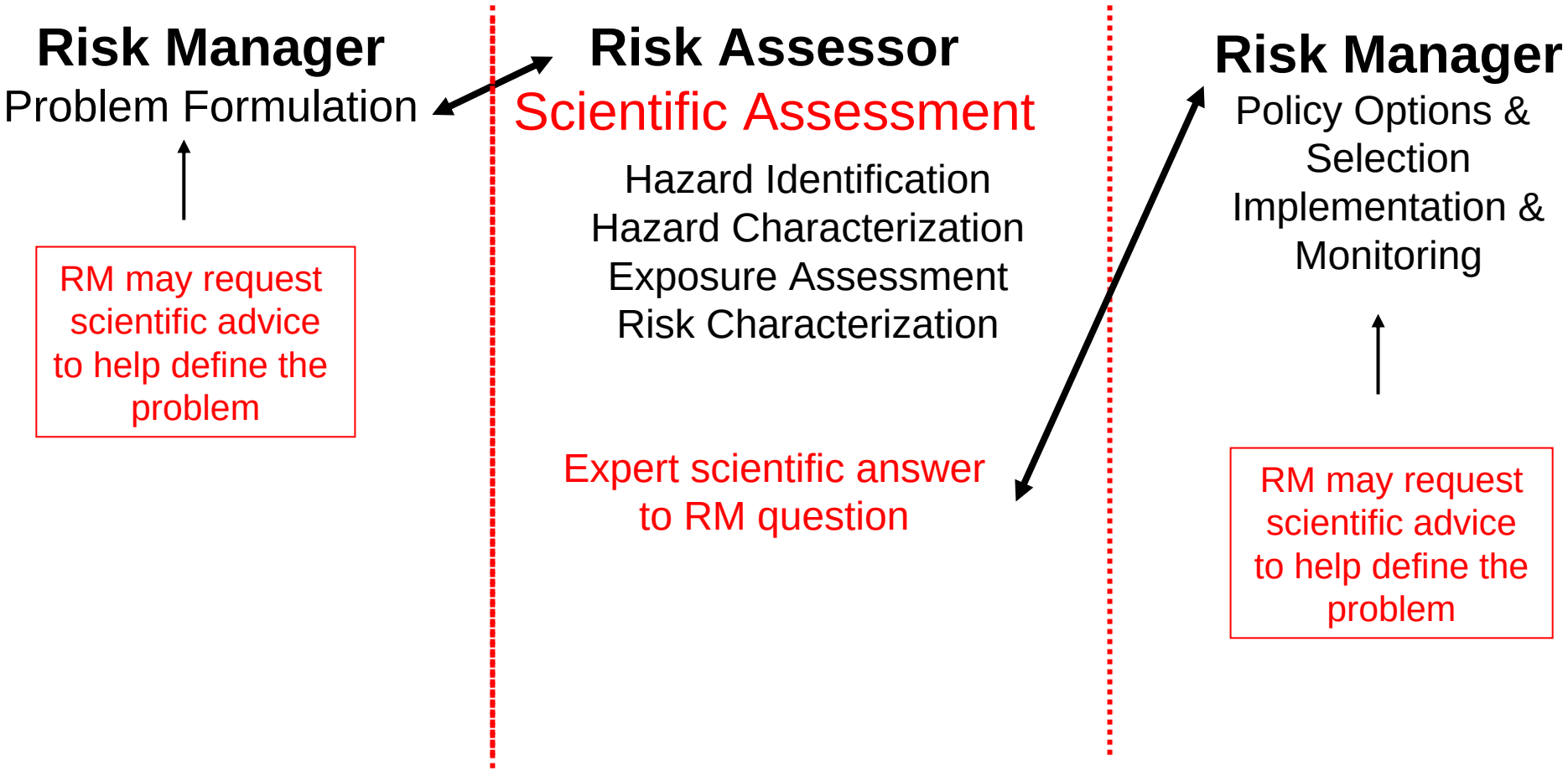


Risk Analysis

- Structured Process
- Deals with necessary “uncertainties” in available evidence
- Inputs sound science into the policy decision-making process
- Protect the integrity of expert scientific determinations
- Enhance the “usability” of the scientific output

Risk Management

- Decision-making process
  - Weigh policy alternatives
  - Consult with all interested parties
- Consider:
  - political, social, economic, and technical factors
  - relevant risk assessment information relating to a hazard
- Develop, analyze, and compare regulatory and non-regulatory options
- Select and implement appropriate regulatory response to that hazard

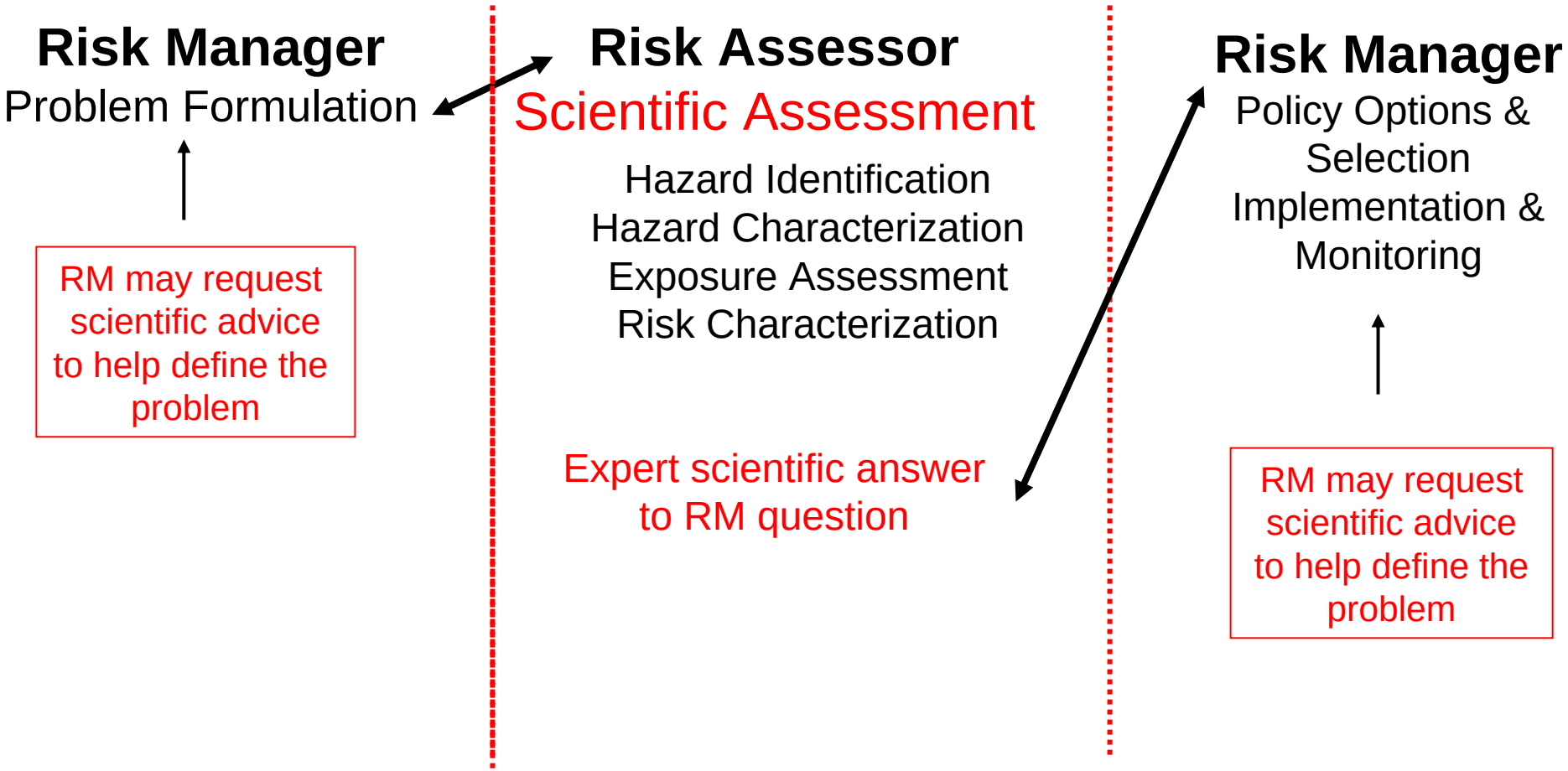
Risk Assessment

- Science-based process
- Identify and describe risk
- Identify attendant uncertainties
- Take into account:
  - Inherent characteristics of the agent
  - Characteristics of target system
- Document, document, document…

Risk Communication

- Interactive exchange of information and opinions throughout the risk analysis process
- Concerning: risk, risk-related factors, and risk perceptions
- Among: risk assessors, risk managers, consumers, industry, the academic community and other interested parties
- Including: explanation of risk assessment findings and the basis of risk management decisions

Structured Process



Statisticians in Risk Assessment

- Hazard identification
  - Statistical criteria for evaluating studies
  - Modeling across studies →
    - Weight of the evidence
    - Causality?
- Hazard characterization
  - Modeling → Dose/response curves

Statisticians in Risk Assessment

- Exposure Assessment
  - Approaches for dealing with biases
  - Modeling → integrate results from different data bases
- Risk characterization
  - Interpretation

Statisticians → Risk Management

- Economic analysis of policy options
- Consumer studies
- Evaluate policy proposals

Summary

- Scientific input into risk analysis is critical
- Scientific input is most impactful when:
  - Scientific quality is achieved
  - Documentation is sufficient
  - Output is relevant and appropriateto policy issues
  - Protection of scientific integrity is balanced against clarification of problem formulation