The importance of problem formulation and identifying protection goals for ERA

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Contents of the talk

- What is Problem Formulation?
- What are Protection Goals?
  - How can risk assessors identify them?
- The benefits of transparency and explicit problem formulation
- Challenges
  - Refining broad protection goals
  - (e.g. Biodiversity)
- Consequences in the absence of problem formulation
  - Biodiversity and the UK Farm Scale Evaluations

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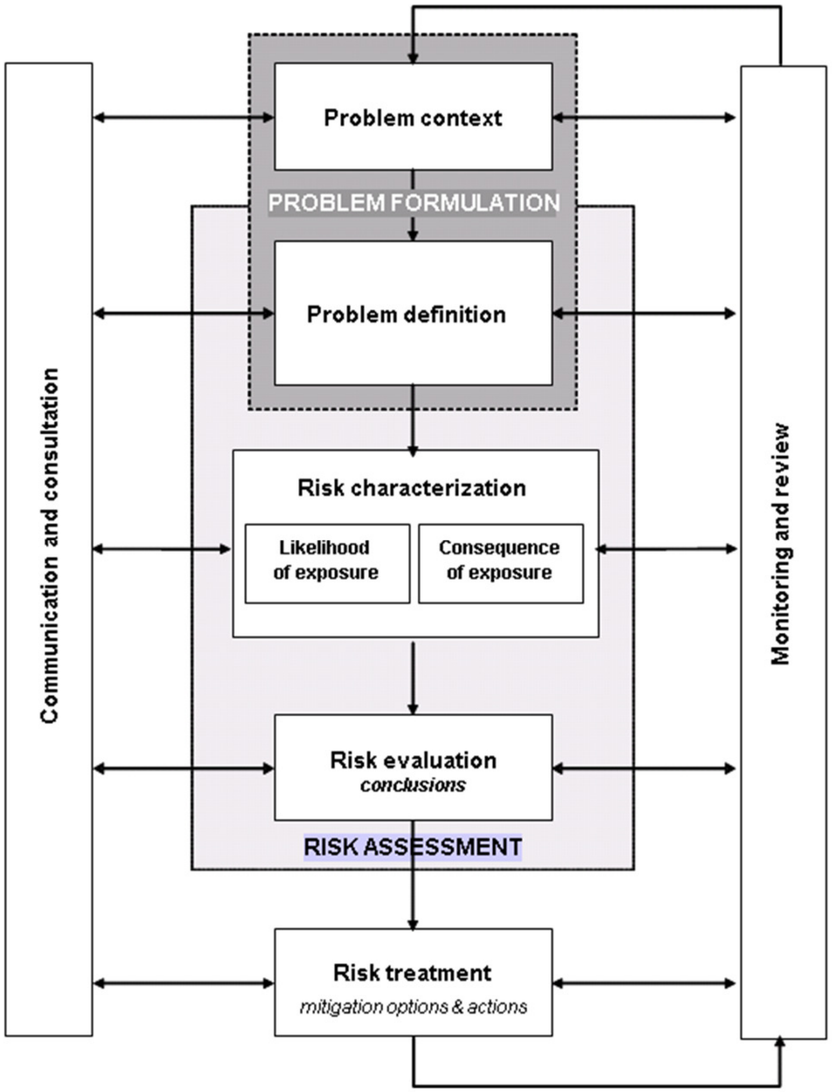
Problem formulation for ERA

Credit:
A. Gray



- Problem context develops the parameters and identifies constraints for the ERA
- Problem definition shapes the ERA into a tractable form for analysis

Wolt, J. D. *et al.* (2010). Problem Formulation in the environmental risk assessment for genetically modified plants. Transgenic Research 19: 425-436

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Problem Formulation

- Problem Context
  - Laws, Regulations
  - Protection goals
- Problem Definition
  - Refining your protection goals
  - Identifying risk scenarios – whereby the introduction of a GE plant might have an adverse impact on your protection goal
  - Identifying testable hypotheses related to risk scenarios

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Practical application of problem formulation

- Four Questions:

1. What do we not want to see harmed? What must be protected?
2. Can we envision a way in which they could be harmed?
3. How can we assess whether they are likely to be harmed?
4. Does it matter?

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Practical application of problem formulation

Four Questions	Steps in Problem Formulation	Primary Inputs
What do we want to see protected?	Problem Context (Identification of Protection Goals)	Policy
Can we envision a way in which they could be harmed?	Problem Definition (Generation of risk hypotheses)	Science
How can we assess whether they are likely to be harmed?	Problem Definition (Generation of an analysis plan)	Science
Does it Matter?	Context and Definition	Policy

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What must be protected? – Identifying protection goals

- Protection goals are identified in the context of public policy
  - Laws
  - Regulations
  - Previous decisions
- These incorporate societal values
  - Cannot be derived from science
- Protection goals can be derived from a broad range of public policy
  - Not just laws and regulations specifically on GMOs

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Refining protection goals for the ERA

- Protection goals should be relevant
  - Have some plausible link to the GE plant
- Should be considered in the context of overall environmental policy
  - e.g. agricultural biodiversity
- Should be able to derive practical assessment endpoints
  - e.g. abundance of beneficial arthropods

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Why is explicit problem formulation important?

- Transparency
  - Allows for input from stakeholders
    - Policy-makers; Management; Public
  - Input is sometimes avoided for fear of criticism
    - Criticism abounds, regardless of transparency
    - Feedback is important to know if your ERA is meeting the need
- Improves the ability to identify useful information
- Improves confidence in the ERA process

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Challenges for problem formulation and the identification of protections goals

- Process challenges
  - Who is responsible for the problem formulation?
    - Policy makers?
    - Regulators?
    - Applicants?
- Challenges in refining broad protection goals
  - Identifying useful assessment endpoints

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Biodiversity as a protection goal

- Cartagena Protocol on Biosafety:
  - "conservation and sustainable use of biodiversity"
- What does this mean?
  - How does an assessor identify assessment endpoints

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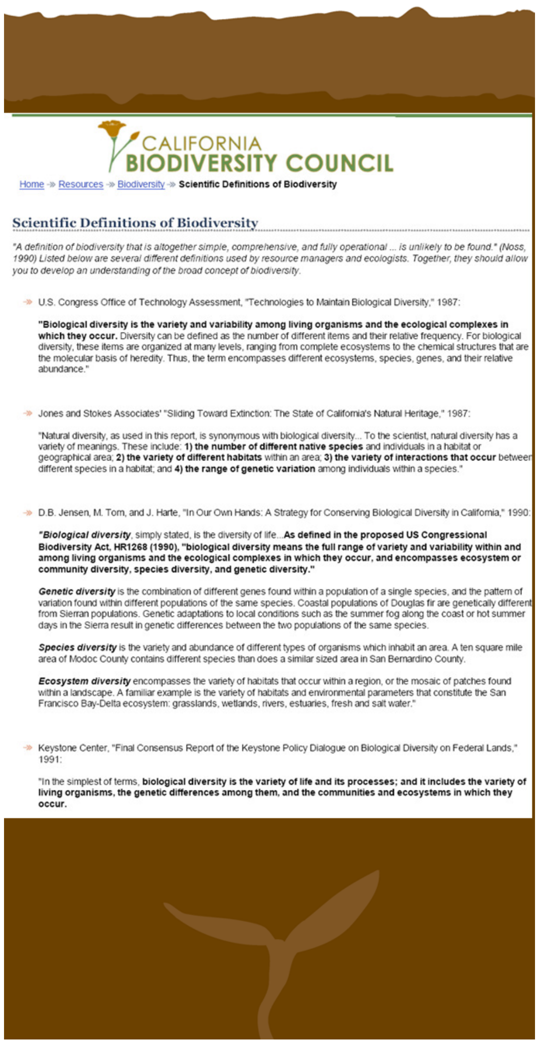
Definitions of Biodiversity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Home » Resources » Biodiversity » **Scientific Definitions of Biodiversity**

Scientific Definitions of Biodiversity

"A definition of biodiversity that is altogether simple, comprehensive, and fully operational ... is unlikely to be found." (Noss, 1990) Listed below are several different definitions used by resource managers and ecologists. Together, they should allow you to develop an understanding of the broad concept of biodiversity.

- U.S. Congress Office of Technology Assessment, "Technologies to Maintain Biological Diversity," 1987:

  "Biological diversity is the variety and variability among living organisms and the ecological complexes in which they occur. Diversity can be defined as the number of different items and their relative frequency. For biological diversity, these items are organized at many levels, ranging from complete ecosystems to the chemical structures that are the molecular basis of heredity. Thus, the term encompasses different ecosystems, species, genes, and their relative abundance."

- Jones and Stokes Associates' "Sliding Toward Extinction: The State of California's Natural Heritage," 1987:

  "Natural diversity, as used in this report, is synonymous with biological diversity... To the scientist, natural diversity has a variety of meanings. These include: **1) the number of different native species** and individuals in a habitat or geographical area; **2) the variety of different habitats** within an area; **3) the variety of interactions that occur** between different species in a habitat; and **4) the range of genetic variation** among individuals within a species."

- D.B. Jensen, M. Torn, and J. Harte, "In Our Own Hands: A Strategy for Conserving Biological Diversity in California," 1990:

  "Biological diversity, simply stated, is the diversity of life...**As defined in the proposed US Congressional Biodiversity Act, HR1268 (1990), "biological diversity means the full range of variety and variability within and among living organisms and the ecological complexes in which they occur, and encompasses ecosystem or community diversity, species diversity, and genetic diversity."**

  Genetic diversity is the combination of different genes found within a population of a single species, and the pattern of variation found within different populations of the same species. Coastal populations of Douglas fir are genetically different from Sierran populations. Genetic adaptations to local conditions such as the summer fog along the coast or hot summer days in the Sierra result in genetic differences between the two populations of the same species.

  Species diversity is the variety and abundance of different types of organisms which inhabit an area. A ten square mile area of Modoc County contains different species than does a similar sized area in San Bernardino County.

  Ecosystem diversity encompasses the variety of habitats that occur within a region, or the mosaic of patches found within a landscape. A familiar example is the variety of habitats and environmental parameters that constitute the San Francisco Bay-Delta ecosystem: grasslands, wetlands, rivers, estuaries, fresh and salt water."

- Keystone Center, "Final Consensus Report of the Keystone Policy Dialogue on Biological Diversity on Federal Lands," 1991:

  "In the simplest of terms, **biological diversity is the variety of life and its processes; and it includes the variety of living organisms, the genetic differences among them, and the communities and ecosystems in which they occur.**

- *"A definition of biodiversity that is altogether simple, comprehensive, and fully operational ... is unlikely to be found." (Noss, 1990)*

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Defining Biodiversity

- Convention on Biological Diversity:
  - "Biological diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

What Part of Biodiversity is Important?

- Ecosystems, populations, and interactions among species and individuals are dynamic and constantly changing
  - Predator Prey Relationships
  - Seasonal Changes
  - Timeframe?

Predator Prey Cycle

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- In the classic Lynx-Hare example, high biodiversity of the Lynx leads to low Biodiversity of the Hare.

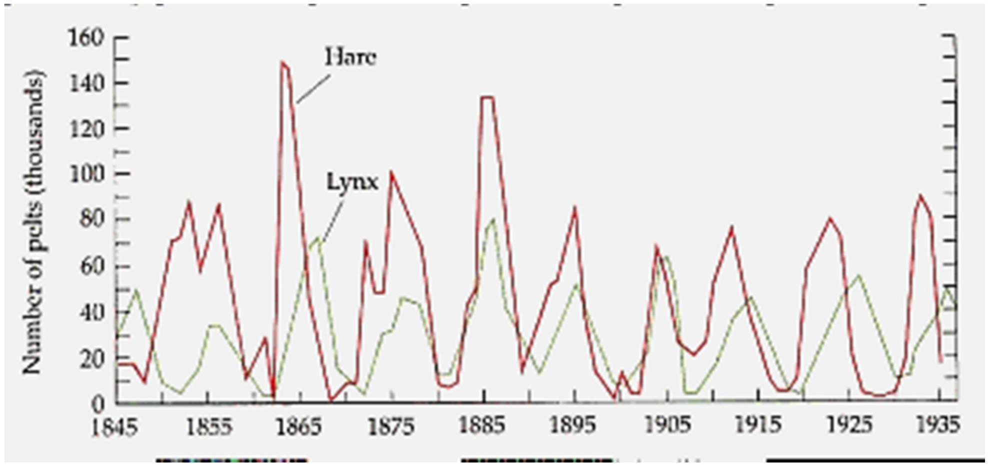

Image from http://ccl.northwestern.edu/papers/bio/long/

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Not all biodiversity is valued equally

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Why do we value Biodiversity at all?

- Utility
  - Forestry
  - Fisheries
  - Renewable resources
  - Source of genes for crop breeding
  - "Ecosystem Services"
    - Water Quality
- Aesthetics
  - Appreciation of nature
  - Biodiversity for its own sake
- Heritage
  - Future generations should be able to experience the same enjoyment of the environment as their ancestors

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Measuring Value

- Utility can generally be measured
  - Productivity
  - Measures of utility may be highly dependent on certain species/populations but independent of others
- Aesthetics are more esoteric
  - But may be no less important for public policy!
  - Measurement is essentially limited to census (i.e. population numbers)
    - Threatened or Endangered Species

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Defining Harm

- Utility
  - Reduction in productivity
- Aesthetic
  - Reduction in population of one or more valued species
- Both
  - Changes need to be of significant magnitude
  - Not easily reversible

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More Data is Not the Answer!

- No amount of data collection can make up for a failure to identify your protection goals!
  - This is a waste of time, money and human resources
    - For both developer and the regulator
  - An abundance of irrelevant information will distract from more important considerations

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A Cautionary Example

- What happens in the absence of explicit problem formulation?
- UK Farm Scale Evaluations (FSE)
  - (figures borrowed with permission from Dr. Alan Gray)
  - Data collection without a proper problem formulation

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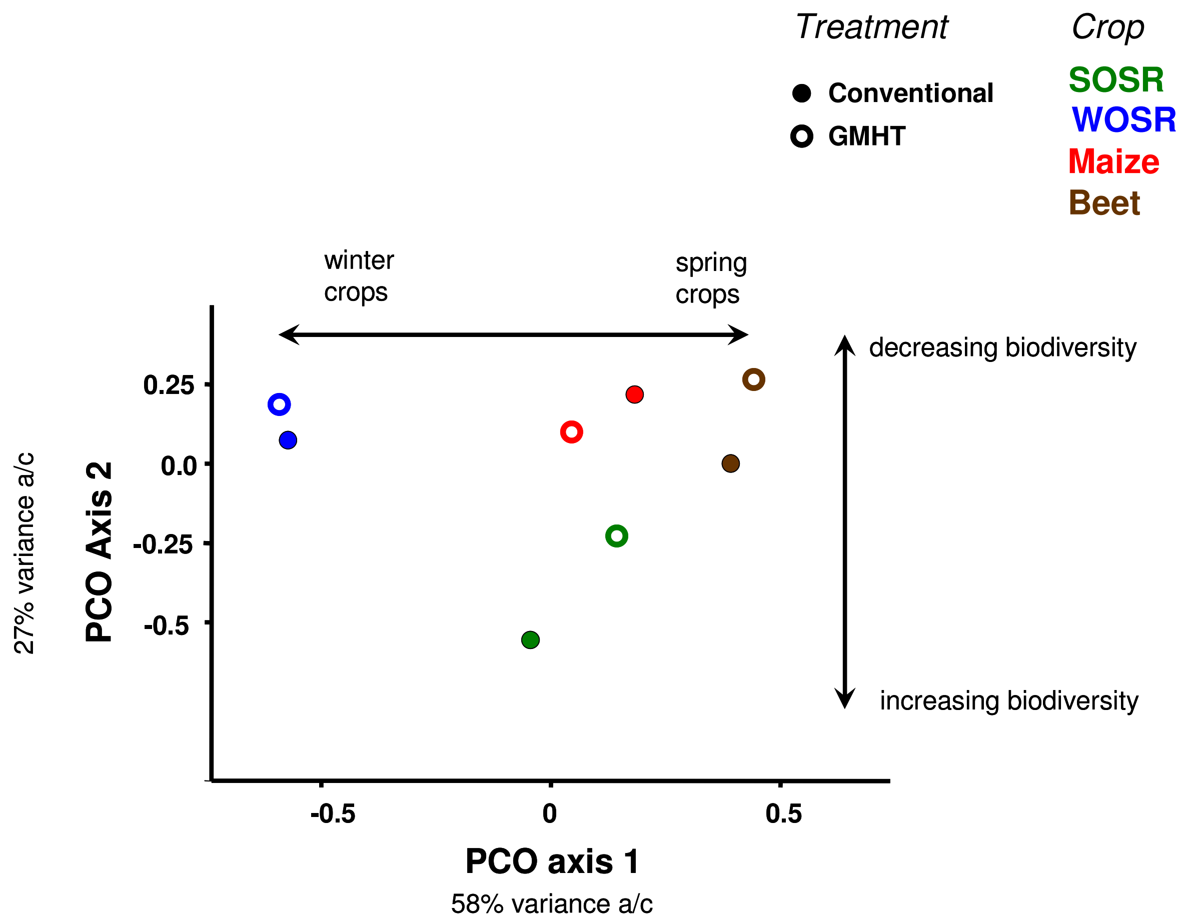
A Cautionary Example

- UK Farm Scale Evaluations (FSE)
  - Intended to address the large scale use of herbicide tolerant GE plants
  - 3 years of field trials
  - 4 crops
    - Spring Oilseed
    - Winter Oilseed
    - Sugar Beet
    - Maize
  - 273 field trials
  - £5 Million

Results: Herbicides Kill Weeds (Except in Maize)



Weeds as Valued Biodiversity

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- The results were reported as showing that herbicide tolerant GE plants caused reductions in farmland biodiversity
  - Despite the reduction in weed populations being a management goal for agriculture

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Criticism of FSE

- Experimental Design
  - Tested impact of differential herbicide use, rather than of transgenic plants
- Relevance of the Data
- *Failure to Put the Results in Context*
- *Failure to Identify Protection Goals Consistent with National Policy*

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Why does the UK value weed populations?

- Almost all arable land in the UK is under production
  - Vast majority of habitat is agricultural
- Farmland Birds are highly valued biodiversity
  - Weed seeds and flowers are essential food
  - Birds
  - Insects that birds eat

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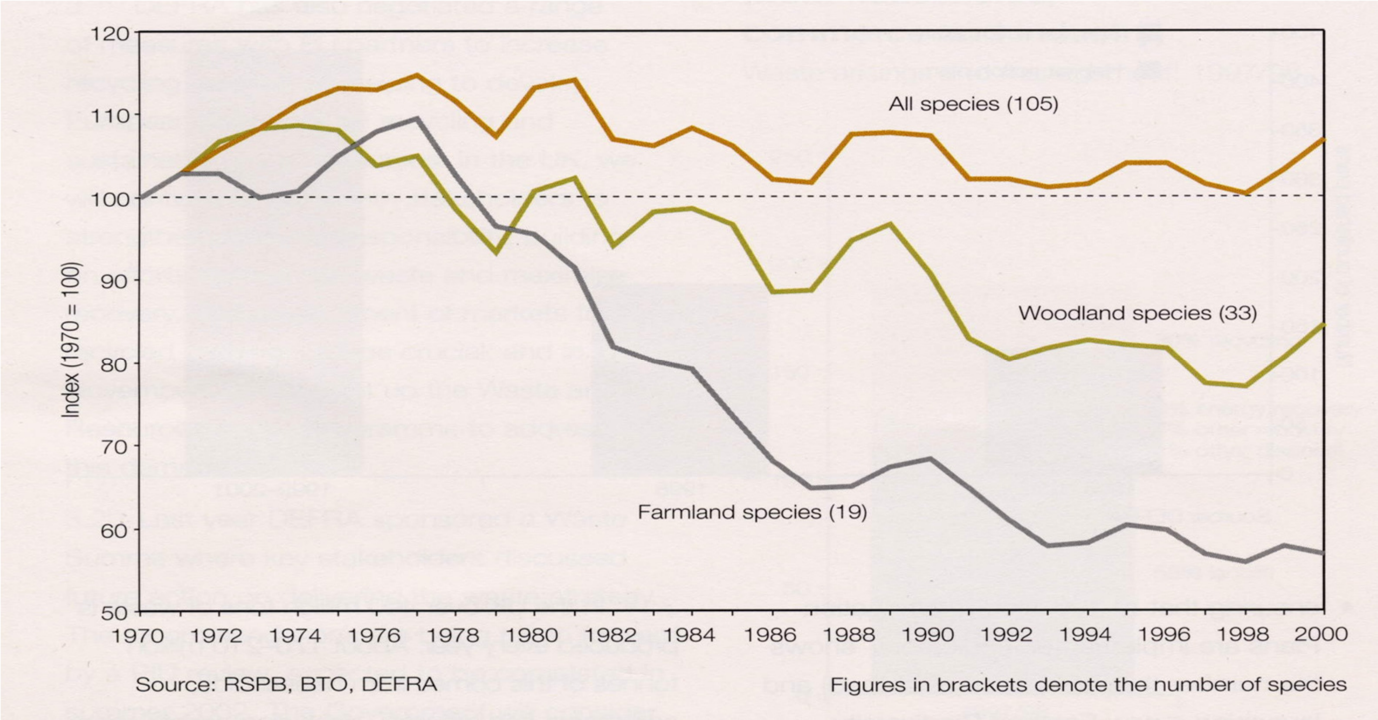
Historical Context



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Inconsistent Protection Goals

- Protection of Farmland Birds could be a legitimate protection goal

BUT

- Agricultural Policy in the UK has been to support intensification
  - Including improved weed control

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Problem for Risk Assessment

- Failure to have a comprehensive and consistent notion of protection goals
  - Data collected from the FSEs did not help solve this problem
  - Protection Goals that are only managed through regulation of GE crops are unlikely to have success in maintaining valued biodiversity

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Conclusions

- Problem formulation answers the four basic questions:
  - What do we not want to see harmed?
  - Can we envision a way in which they could be harmed?
  - How can we assess whether they are likely to be harmed?
  - Does it matter?
- Identifies protection goals
- Establishes the information needed to assess risk
- Done deliberately, explicit problem formulation is a valuable tool for guiding the ERA process

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Thank You!