



4TH INTERNATIONAL WORKSHOP FOR REGULATION OF ANIMAL BIOTECHNOLOGY

Problem Formulation: How to start your risk assessment so you can finish it successfully

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Agriculture &
Food Systems
Institute

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Disclosures



- I have no conflicts of interest to declare
- AFSI's work on Animal Biotechnology is supported by a grant from the U.S. Department of Agriculture
- Other information about AFSI's programs and funding can be found on our website at <https://foodsystems.org>

Contents of the Presentation



- Introduction to myself and to the Agriculture & Food Systems Institute
- Context for Risk Assessment
 - Intuitive processes
 - Regulatory Assessment
- Problem Formulation
 - A tool to formalize your risk assessment process
 - (Why you *definitely* want to use this)
- Example – “So, you’re going to Sao Paulo”

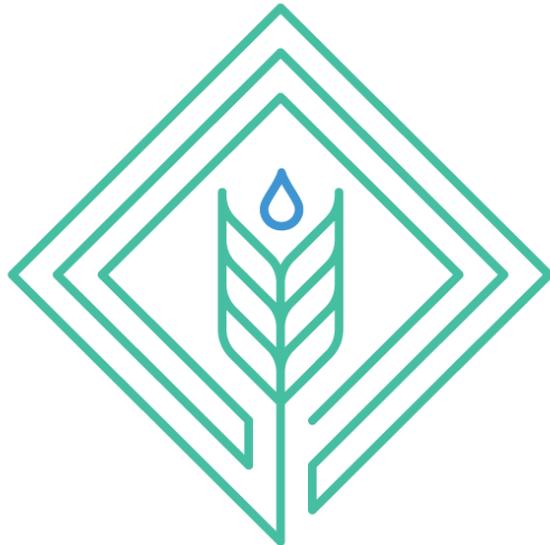




Who am I?

- Ph.D. Cell and Developmental Biology
- Joined the USDA in 2005 as an AAAS Risk Policy Fellow
- Held various positions at USDA until Dec. 2009
 - Joined what is now AFSI
- Spent the last 15 years helping scientists and regulators think about risk assessment





Agriculture & Food Systems Institute

- Not-for-profit scientific organization
- Mission to Foster a Better World Through Science
 - With a focus on innovation and regulation
- Five Current Mission Areas
 - Biosafety Capacity Building*
 - Environmental Risk Assessment
 - Sustainable Nutrition Security
 - Food and Feed Safety Assessment
 - Plant Biologicals for Sustainable Agriculture

Context for Risk Assessment

Risk Assessment is Part of Everyday Life



- Every day, people making dozens if not hundreds of decisions
- Many of these decisions are based on some assessment of risk
 - This is an intuitive concept
 - We do it automatically
 - Rarely recognize what we are doing or make our risk considerations explicit





What is a Risk Assessment?

- Risk Assessment is “the overall process of risk identification and risk characterization”
 - Office of the Gene Technology Regulator
- Risk is “The chance of harm from an activity.”

Why do we perform risk assessments?



Non-Regulatory Risk Assessment

- To inform decision making

Regulatory Risk Assessment

- To inform decision making
- To satisfy the requirement of our regulations
 - Communicate to Decision Makers
 - Communicate to the Public

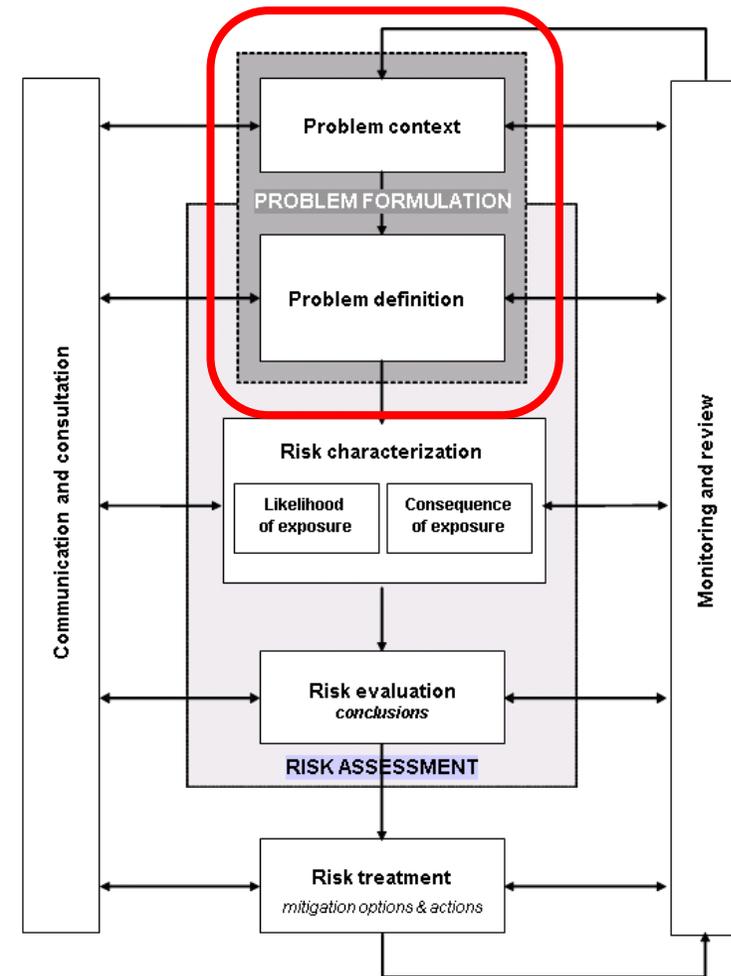
Problem Formulation

Provides a tool for accomplishing regulatory risk assessment

What is Problem Formulation



- The name comes from the idea that science proposes solutions to a set of problems
 - What is the problem we are trying to solve?
- It is essentially a scoping process that formalizes the thinking behind our risk assessment
 - Explicit
 - Transparent



Problem Context



“Everything you know”

- Information on the organism you are evaluating
 - Species
 - Trait
 - Intended Use
- Information on the Receiving Environment
- Your past experiences with similar organisms
- Scientific publications
- General knowledge

“What you have been asked to do”

- This is Regulatory Requirements
- Protection Goals
 - Broad
 - Refined/Operational

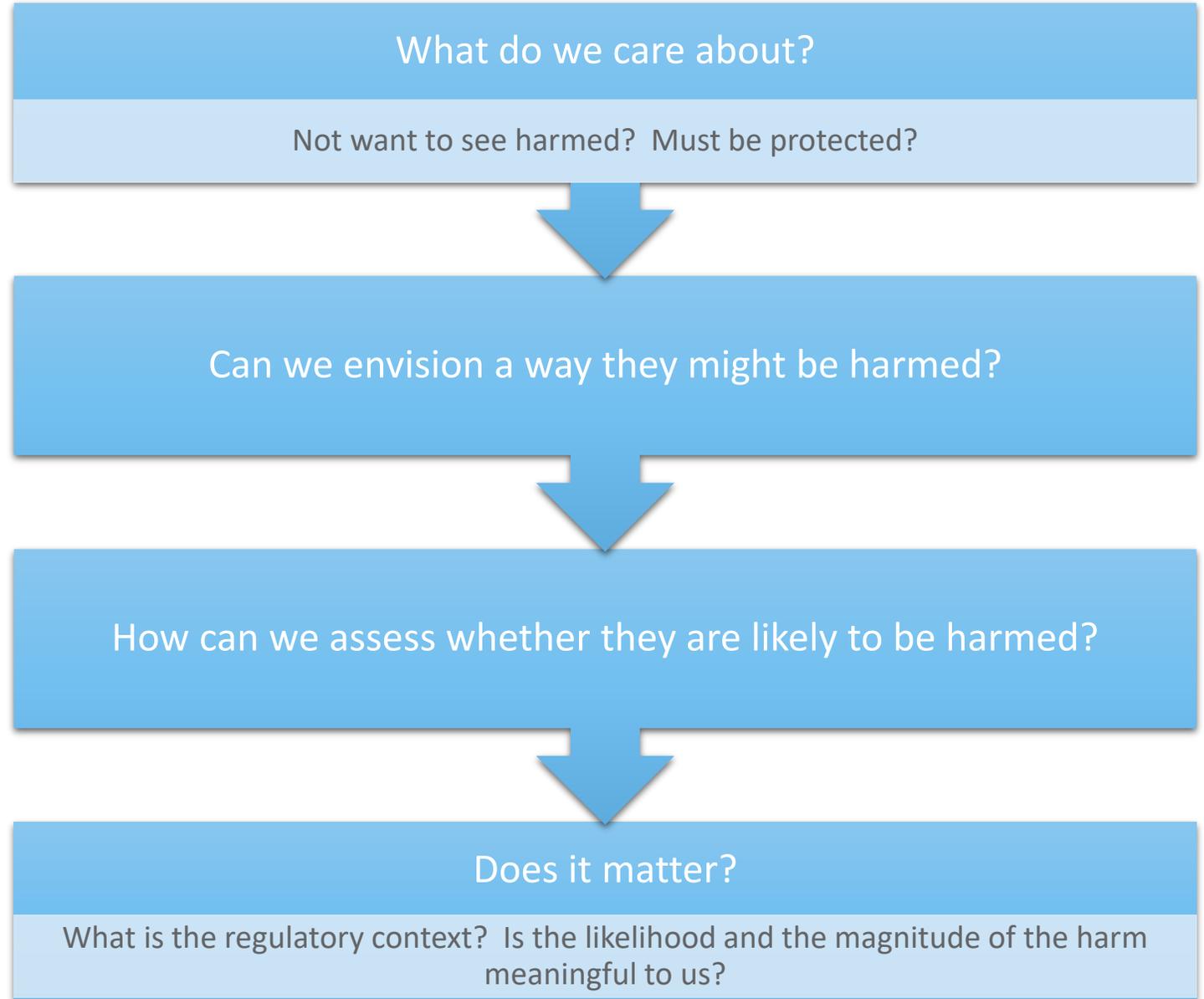


Problem Definition

- Relating your knowledge to your obligations
- Identify how the proposed decision intersects your responsibility
- Applying logic and reason to focus on “plausible” risk hypotheses
 - Discarding “implausible” risk hypotheses
- Identifying what you need to know to determine the likelihood of harm
 - i.e. Risk

The Simple Version

Adapted from Gray, 2012 “Problem Formulation in Environmental Risk Assessment for Genetically Modified Crops: A Practitioner’s Approach”



A Quick Example

We are taking a trip...

The Scenario – completely hypothetical



- Imagine you have been asked to travel to Sao Paulo for a workshop on animal biotechnology
- As part of your travel authorization process, you are required to conduct a risk assessment related to this trip
- Let's walk through a brief problem formulation exercise...

What are we trying to protect?



- Health
- Safety
- Comfort
- Ability to return home



Hypothesize Potential Harms



Hypothesize Potential Harms



- Eaten by Piranha
- Attacked by Polar Bear
- Jaguar attack
- Capybara attack
- Victim of Urban Crime
- Struck by Lightning
- Aviation Disaster
- Abducted by UFOs
- Tropical Disease
- Covid-19

Eliminate those that don't merit consideration



- Eaten by Piranha
- ~~Attacked by Polar Bear~~
- Jaguar attack
- Capybara attack
- Victim of Urban Crime
- Struck by Lightning
- Aviation Disaster
- ~~Abducted by UFOs~~
- Tropical Disease
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Animal Attacks

- Piranha, Jaguars and Capybara are real
 - They live in Brazil
 - People have been hurt by them with some frequency
- But I am going to be in Sao Paulo
 - In a conference room
 - I can conclude that this risks are negligible without collecting or analyzing data



Real Events of Low Probability



- Aviation disasters and lightning strikes are real
 - They occur everywhere but at a low frequency
 - Difficult to predict
 - Managed by a routine set of practices
- It may be worth mentioning in my report that these are possibilities
 - But there is nothing *especially* risky about travelling to Sao Paulo in this regard



Urban Crime



Tropical Diseases and Covid-19



- Tropical diseases are real, and present in Brazil
 - Magnitude of the harm can be substantial – Yellow Fever
- Nobody needs me to tell them about Covid-19
- These risks would merit an assessment involving look at real data
 - Prevalence of diseases
 - Vaccination/Quarantine requirements for entry to Brazil, re-entry to the U.S.
- Available data can be attained from U.S. State Dept.
 - Other traveler resources

Concluding Thoughts



“Problem Formulation” is the name of a formal scoping process for conducting risk assessments

- It incorporates your available knowledge and experience
- As well as your mandated protection goals, laws and regulations

Helps you plan and explain your risk assessment

- Provide a record of the judgements and decisions that are inherent in the assessment process
- You are either doing this deliberately and well, or you are doing it badly. You are never NOT doing this

Those of you who stay for the workshop Friday will walk through some more realistic examples

- Explore some tools for helping us with the process



A close-up photograph of a person's hands kneading dough in a large metal bowl. The person is wearing red bangles and a ring. The dough is light brown and appears to be in the process of being shaped. The background is blurred, showing what might be a kitchen or food preparation area.

Thank You!



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