Overview of Risk Assessment and Risk Management Frameworks

Eric Hallerman
Department of Fish and Wildlife Conservation
Virginia Polytechnic Institute and State University
Blacksburg, VA 24061, USA
540-231-3257 ehallerm@vt.edu

GM animals have been developed with many positive applications in mind…

- …yet, many sectors of society are wary

- *How is society to approach smooth and purposeful adoption of well-chosen GM animals?*
- A comprehensive scientific and sociopolitical approach must include effective *risk assessment*, *risk management*, and *risk communication*

Let's define key terms

- *Harm* – An outcome to be avoided, e.g., ecological impacts on non-target species, or loss of a locally-adapted natural population
- *Hazard* – A substance or agent that, upon exposure, might result in a defined harm
- *Risk* – The likelihood of a defined harm being realized
- *Risk analysis* – The complete process of risk assessment, risk management (and risk communication)
- *Risk assessment* – the estimation of likelihood of harm being realized given a well-defined situation and a recognized hazard…
- *Risk management* – the taking of actions to minimize, monitor, and control the probability of harm being realized…
- *Risk communication* – the action of making the risk comprehensible to a target audience

Focusing on the risk assessment aspect…

- Identify potential *harms* - outcomes
- Identify *hazard* that might lead to harms – the GM line itself
- Assess *probability of exposure* – e.g., likelihood of escape and persistence of GM animals in a receiving ecosystem
- Assess *probability of harm given exposure*
- $R = P(E)$ x $P(H|E)$, a probability

Risk Assessment

Considered on a case-by-case basis:

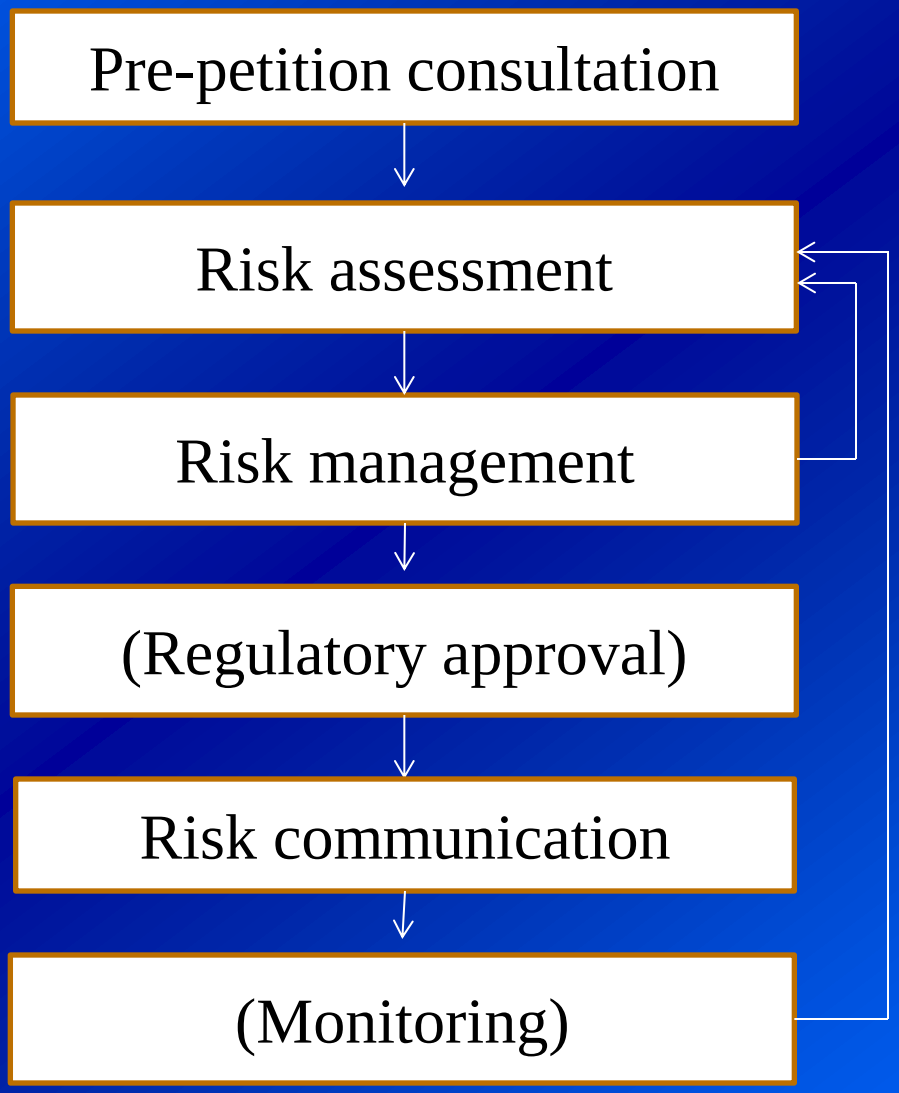
- Host species
- Introduced genetic construct
- Integration event
- Receiving ecosystem, including the human socioeconomic system

Risk assessment may be:

- *Retrospective* – seek to identify causes and characteristics of harmful events that have *already* occurred (e.g., terror attacks)
- *Predictive* – attempt to estimate the likelihood and consequences of harmful event that *might yet* occur (e.g., harm due to GM animals)

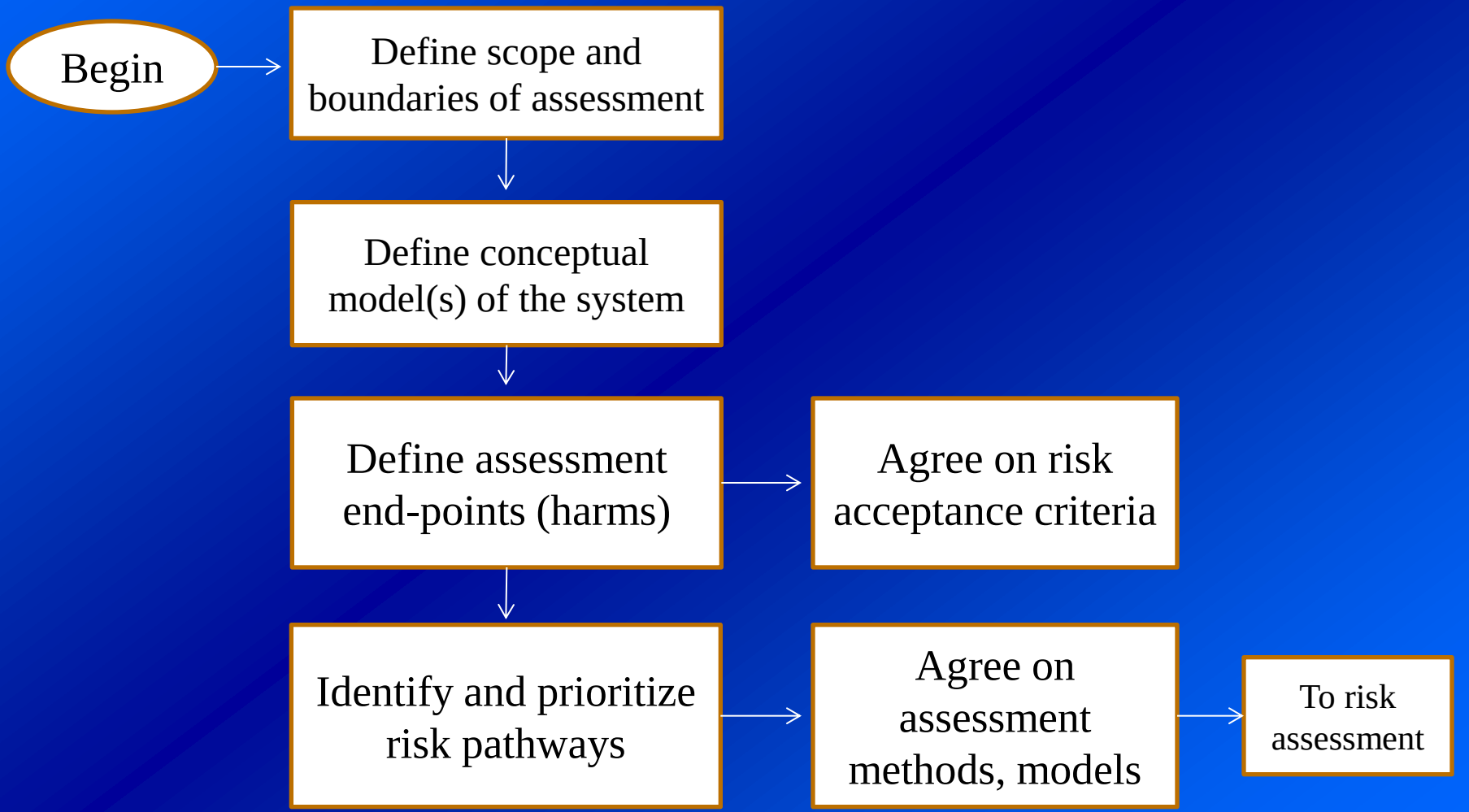
- *Qualitative* – produce nominal outputs (low, medium, or high risk), based on expert or stakeholder opinion
- *Semi-quantitative* – produce interval outputs (<10%, 10-50%, >50% risk)
- *Quantitative* – produce continuous risk estimates

Let's consider the risk analysis process

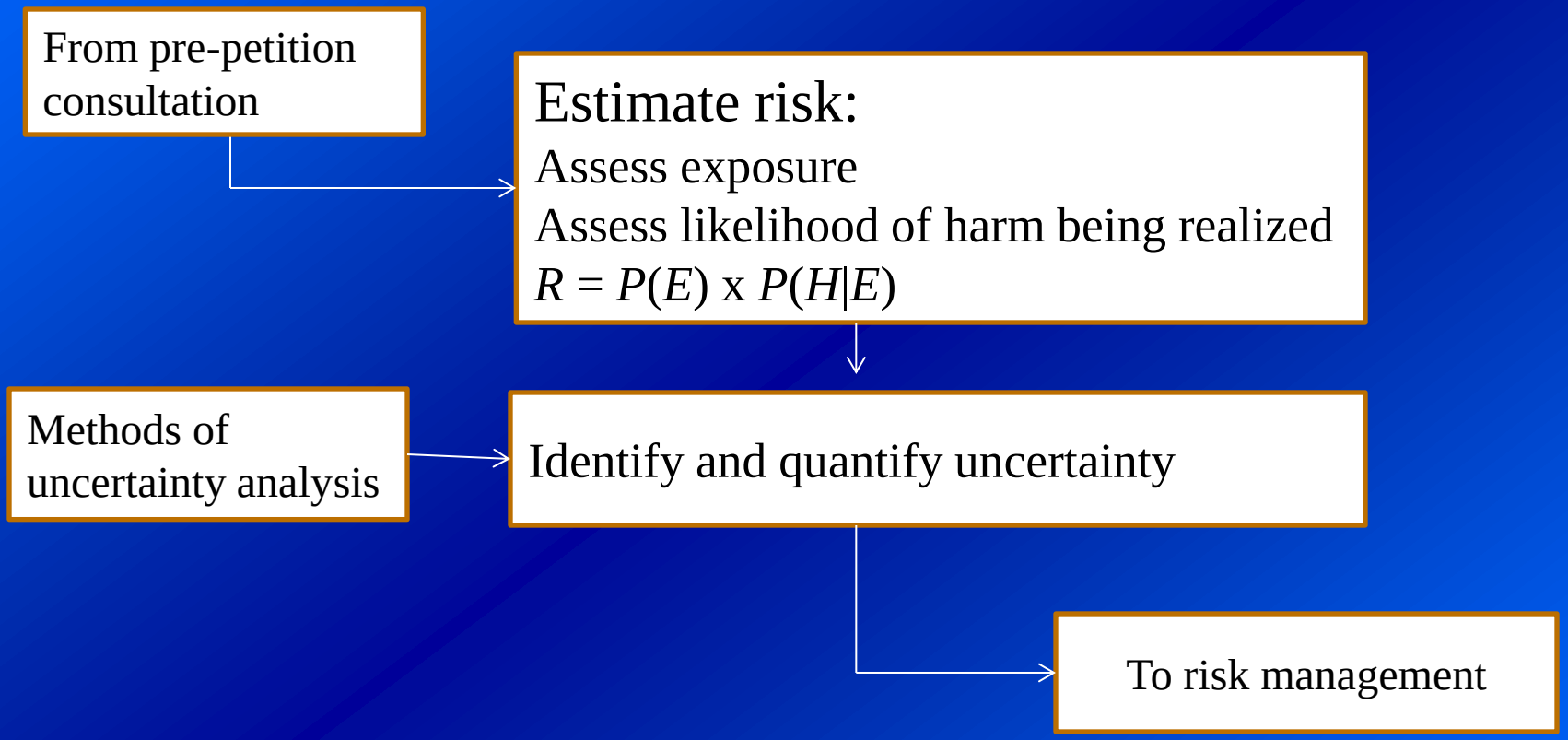


These feedbacks make the regulatory regime "adaptive"

Pre-petition consultation



Risk assessment



The scientific credibility of a risk assessment is determined by:

- How well developed the model is, how well the parameters are selected, how well the parameters are estimated
- How realistic and relevant the model predictions are
- How well the model is corroborated or validated

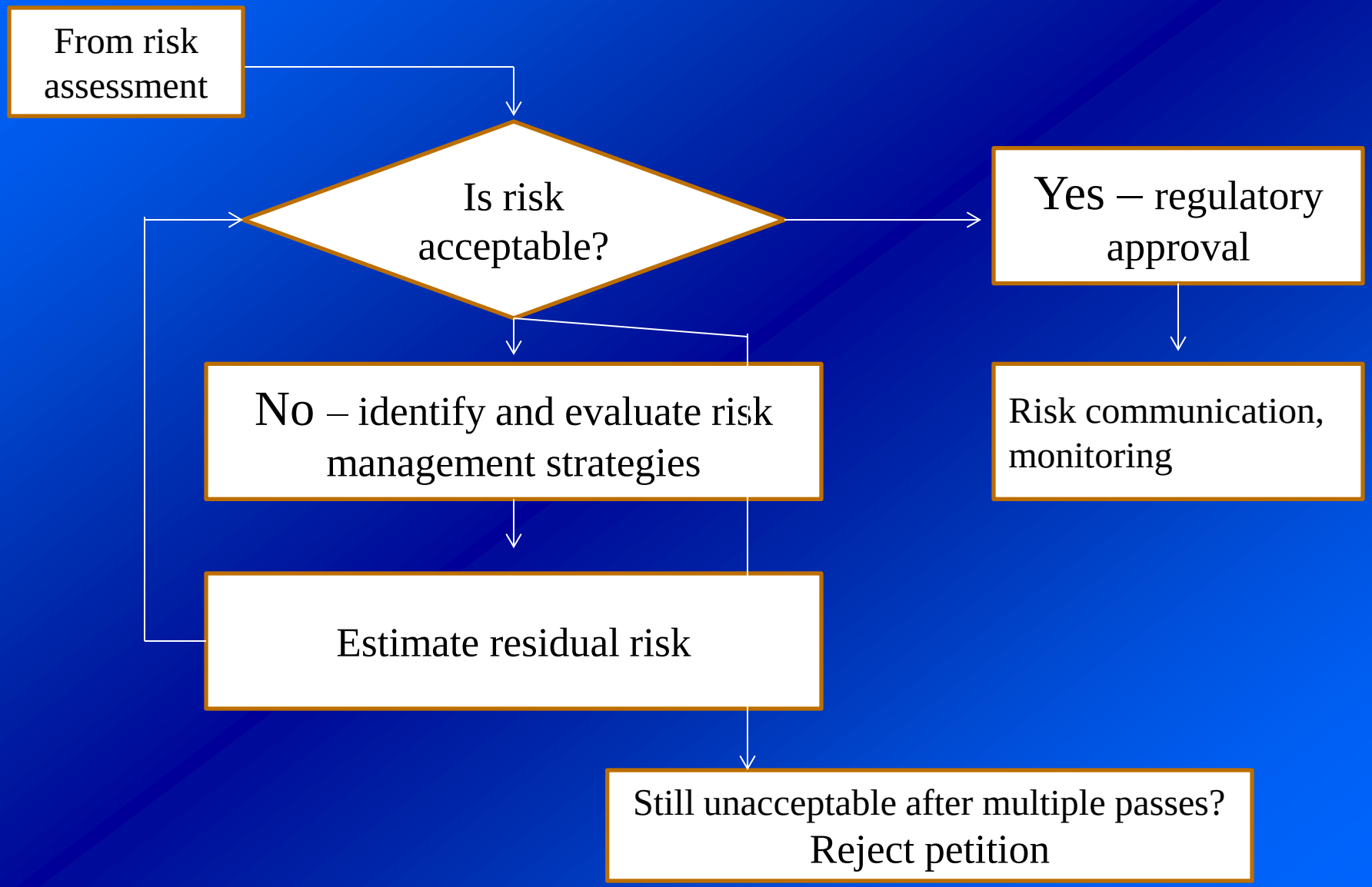
To enhance the credibility of a risk assessment

- Select appropriate end-points (harms)
- Identify all possible risk pathways
- Choose mathematical models carefully
- Consider model uncertainty and parameter variability
- Specify interval rather than point risk scores
- Avoid predictive bias
- Maintain transparency
- Subject model to peer review
- Monitor and test predictions…

Risk assessment → Risk management (→ Risk assessment)

- Recognize that $R = P(E) \times P(H|E)$,
- Hence, R may be minimized by minimizing $P(E)$

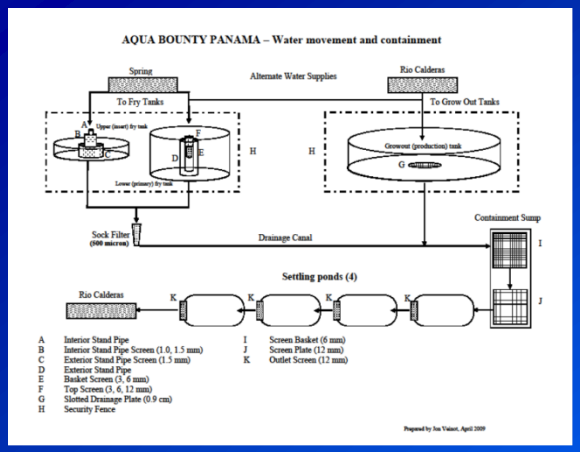
Risk management



Let's briefly consider a case study

AquaAdvantage Atlantic salmon

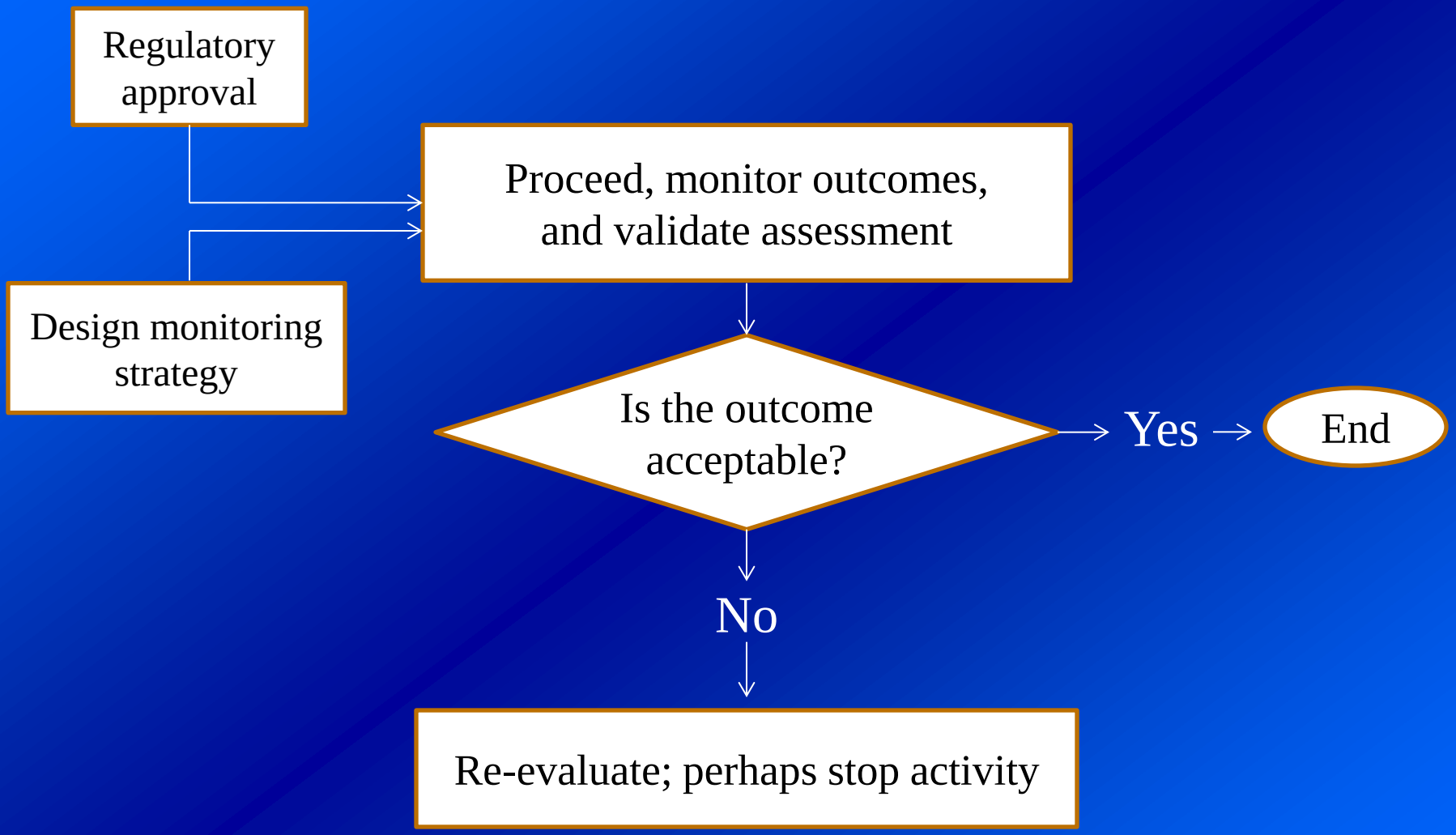
- Any ecological risk is minimized by culturing GM fish under strict confinement.
- Hence, AquaBounty produces its fish using redundant confinement measures:
- In Panama, → *geographical* confinement
- In recirculating aquaculture systems with redundant *physical* confinements
- With *reproductive* confinement – all-female triploid fish



Risk communication

- We consider GM animals within a societal context.
- *Risk communication* – an interdisciplinary field relating risk to the core values of targeted audiences.
- Key issues are:
- How to reach the intended audience
- How to make the risk comprehensible and relatable to other risks
- How to pay appropriate respect to the audience's values related to the risk
- How to predict the audience's response to the communication
- An *ultimate* goal is to improve collective and individual decision making.

Monitoring


Regulatory approval
Design monitoring strategy
Proceed, monitor outcomes, and validate assessment
Is the outcome acceptable?
Yes
End
No
Re-evaluate; perhaps stop activity

GM animal risk assessment

Session 6:

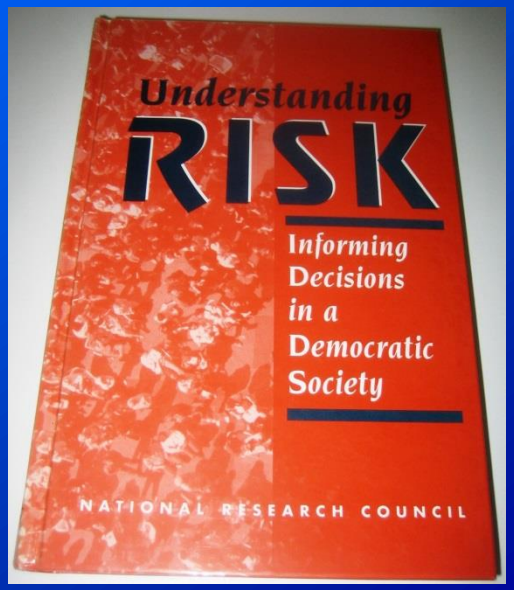
- Food safety assessment
- How to start and conduct a risk assessment?
- Environmental release of GM animals
- Gene drive case study

Session 8A:

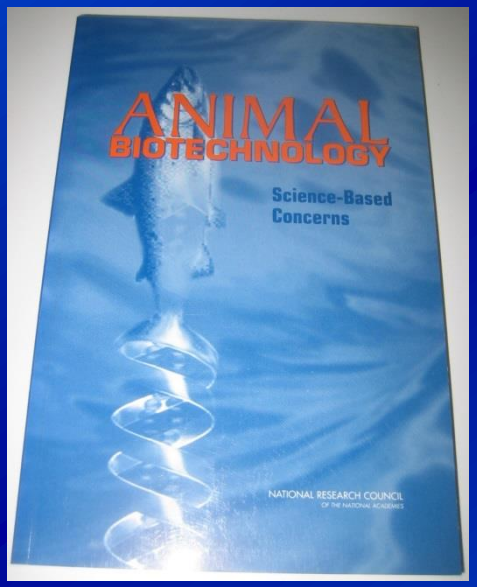
- Trypanosome-resistant cattle

Risk communication – A cross-cutting theme of this workshop

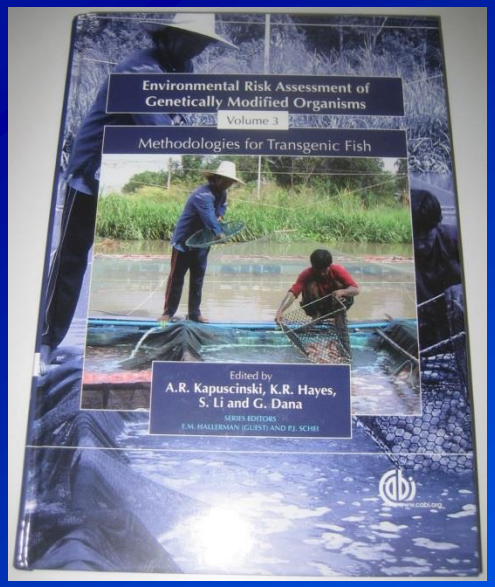
To gain greater depth, read onward…



National Research Council (1996)
www.nap.edu



National Research Council (2002)
www.nap.edu



Kapuscinski et al. (2007)
www.cabi.org


KEEP
CALM
AND
CARRY OUT A
RISK ASSESSMENT