

Overview of Risk Assessment and Risk Management Frameworks



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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*
- $R = P(E) \times P(H|E)$, a probability

Risk Assessment

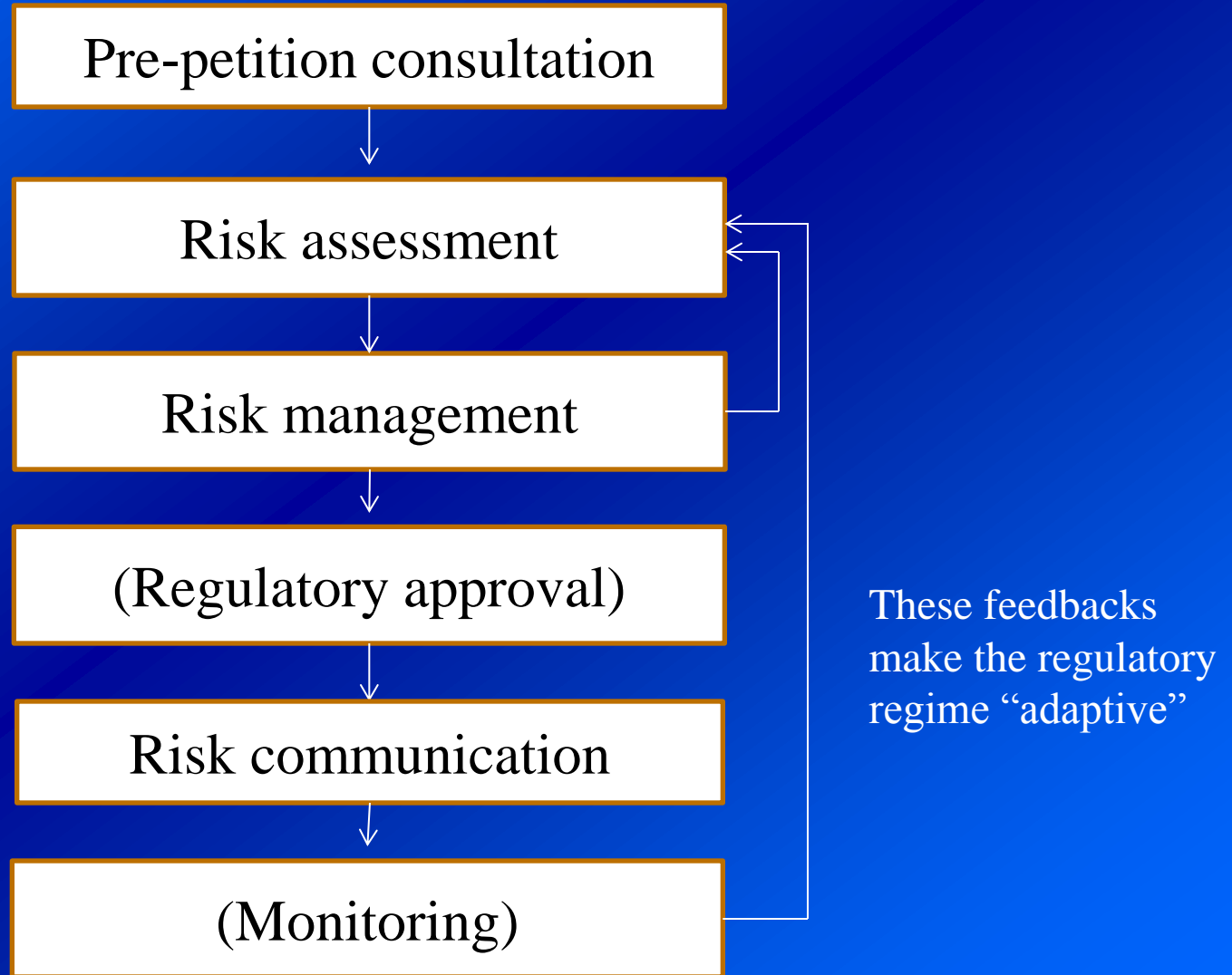
Considered on a case-by-case basis:

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

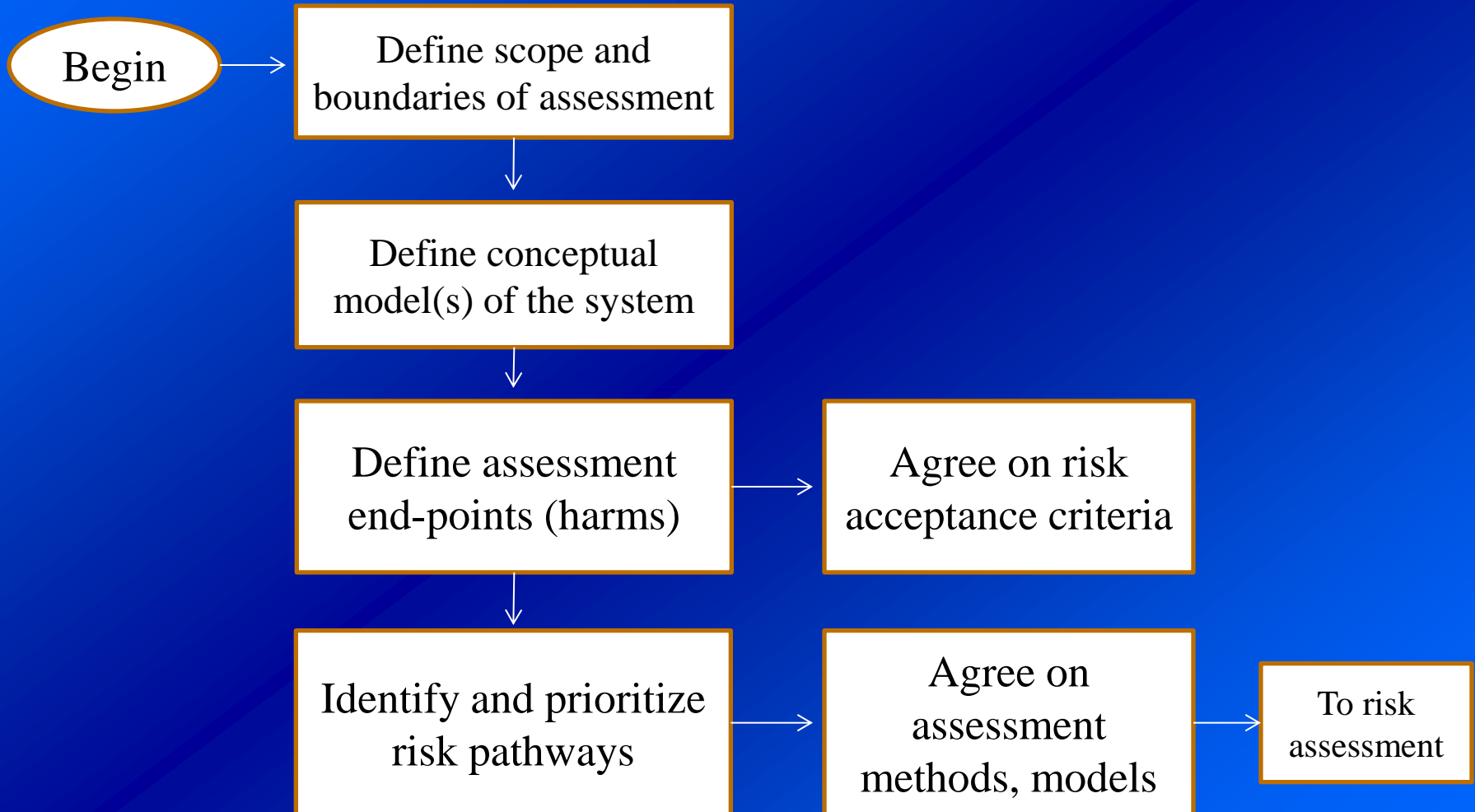
Risk assessment may be:

- *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

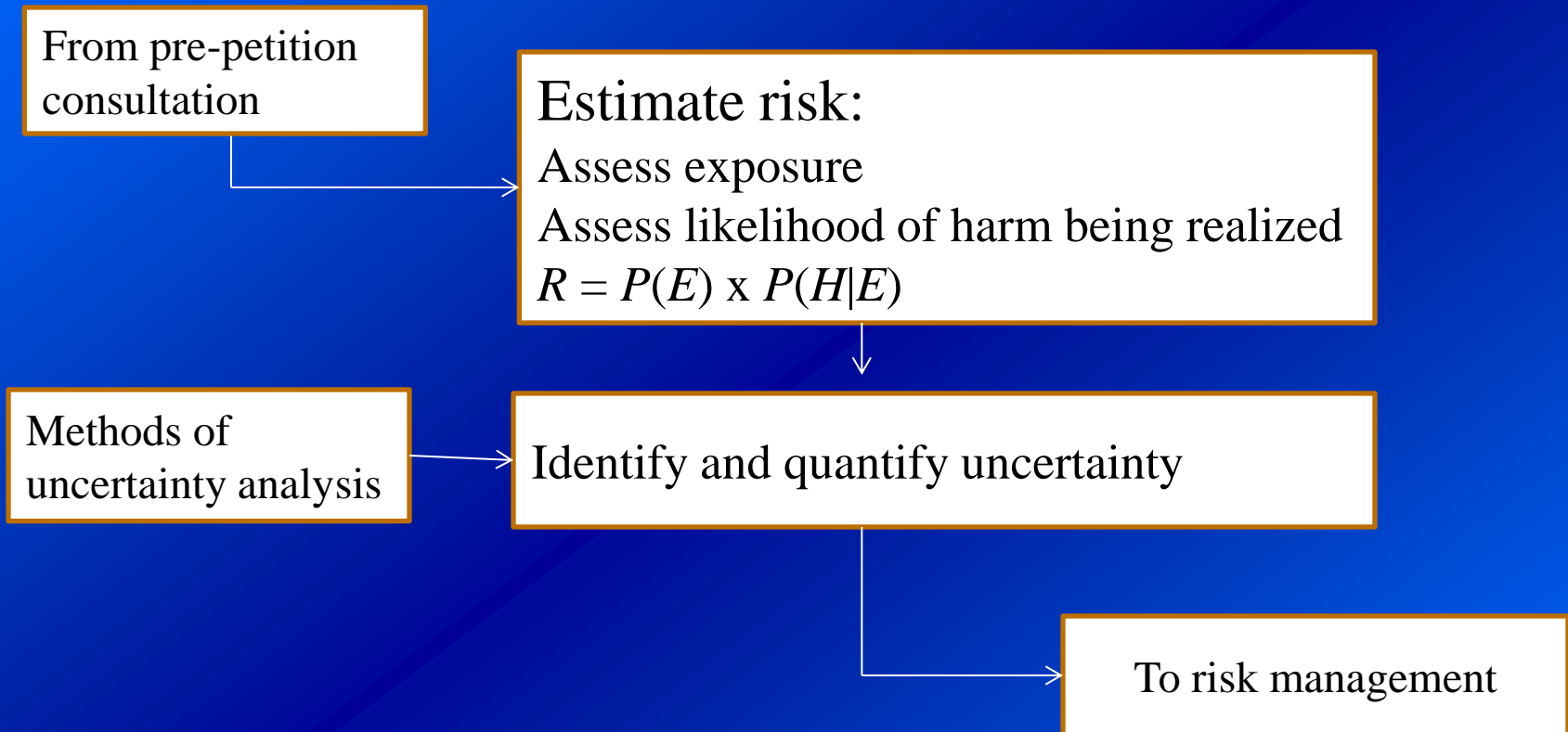
Let's consider the risk analysis process



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

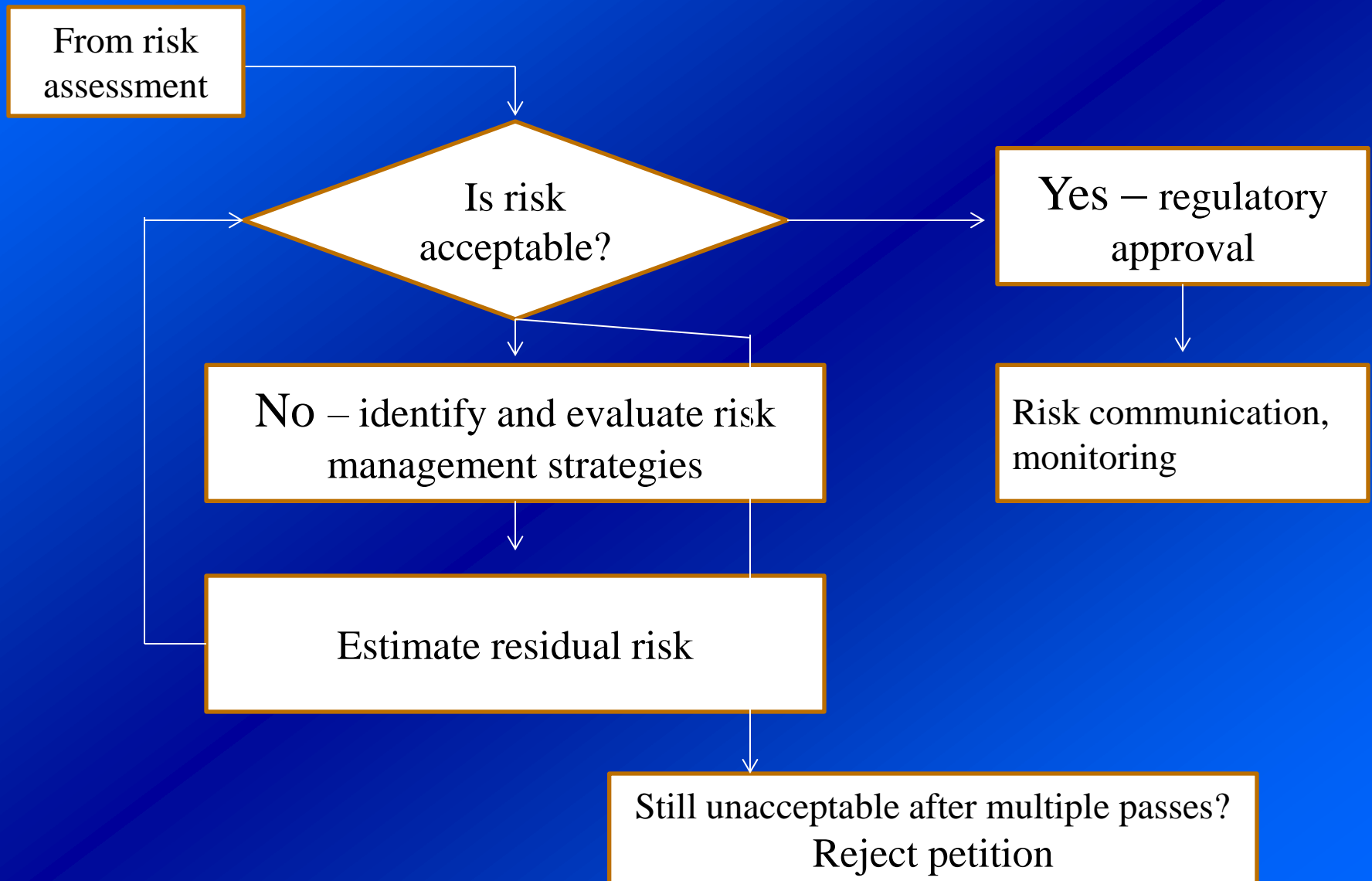
To enhance the credibility of a risk assessment

- 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 $P(E)$

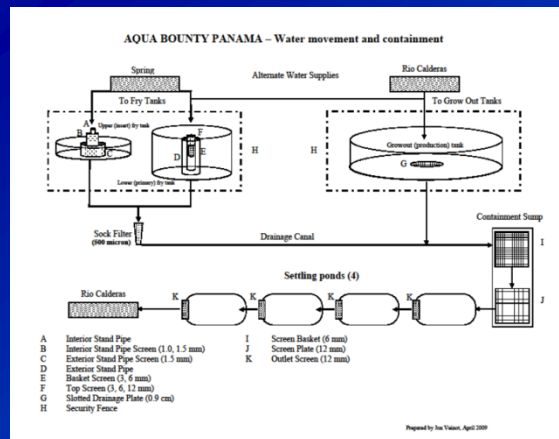
Risk management



Let's briefly consider a case study

AquaAdvantage Atlantic salmon

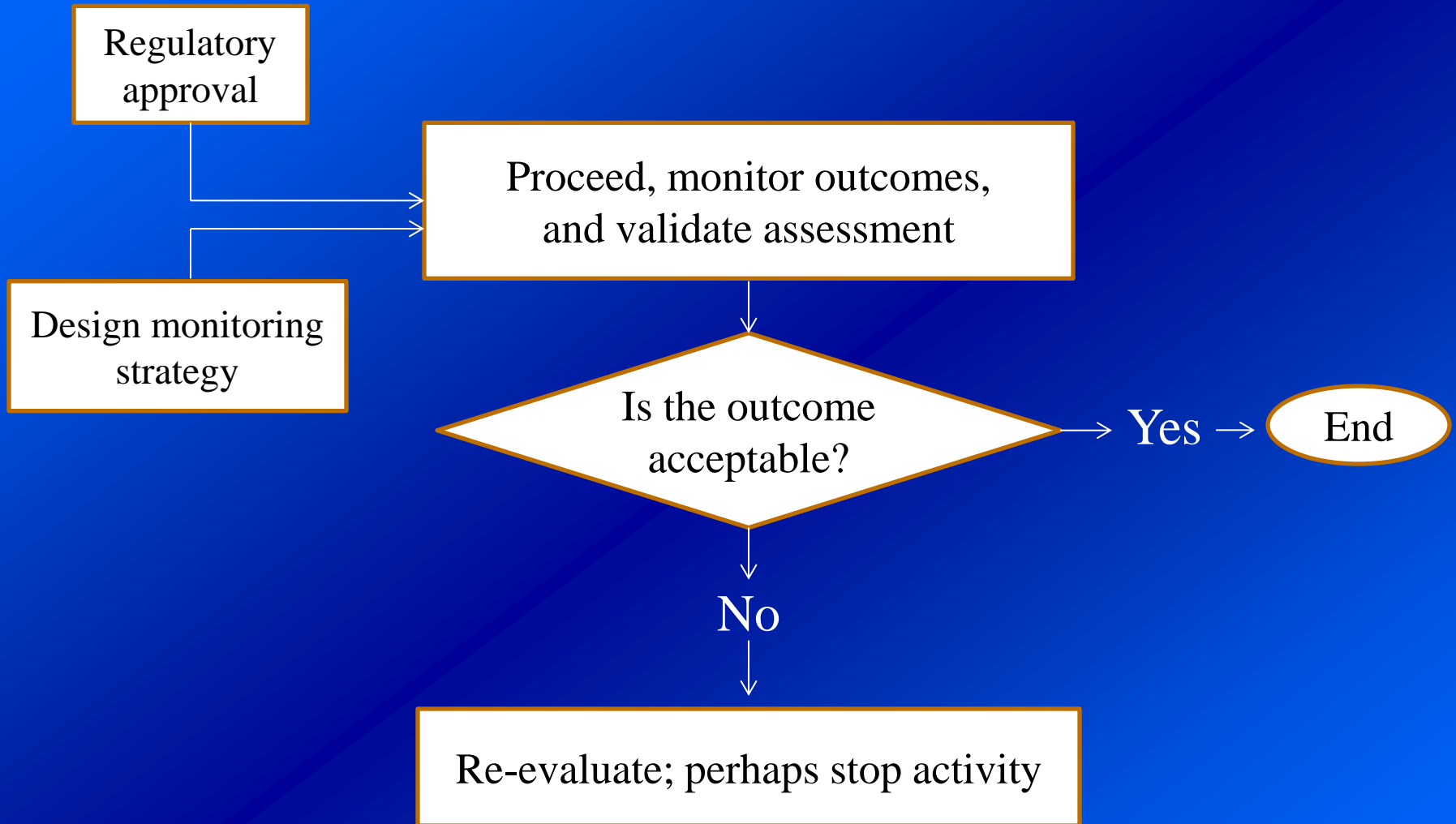
- Any ecological risk is minimized by culturing GM fish under strict confinement.
- Hence, AquaBounty produces its fish using redundant confinement measures:
- In Panama, → *geographical* confinement
- In recirculating aquaculture systems with redundant *physical* confinements
- With *reproductive* confinement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



GM animal risk assessment

Coming talks:

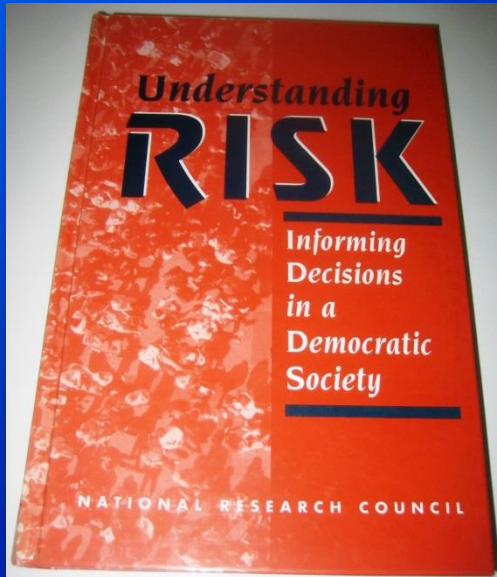
- Food safety assessment
- How to start and conduct a risk assessment?
- Environmental release of animals developed via biotechnology
- Gene drive

This afternoon:

- Process of risk assessment
- Case studies - Screwworm, Nile tilapia, Bt corn

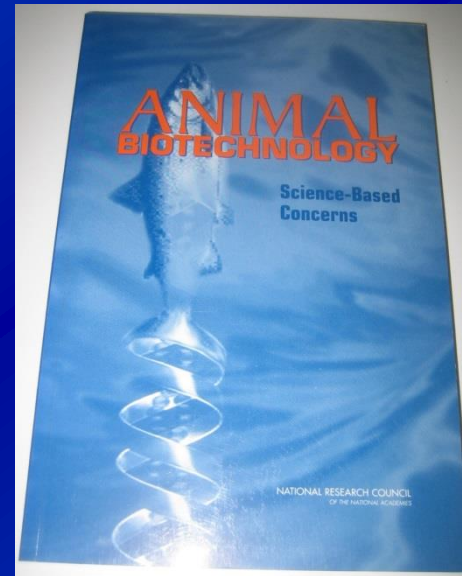


To gain greater depth, read onward...



National Research
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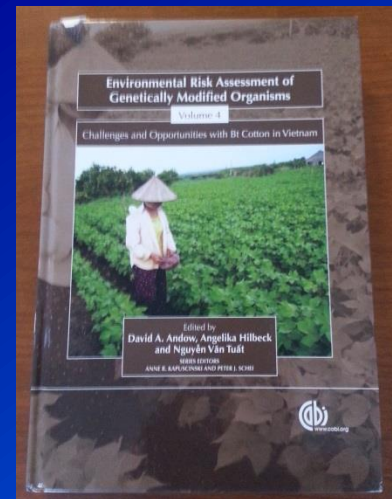
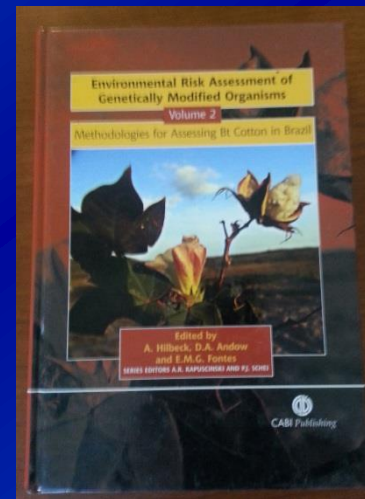
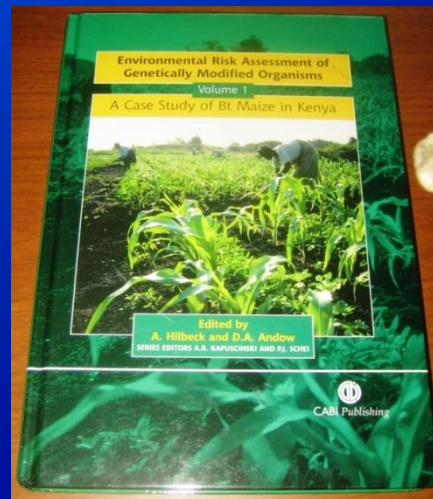
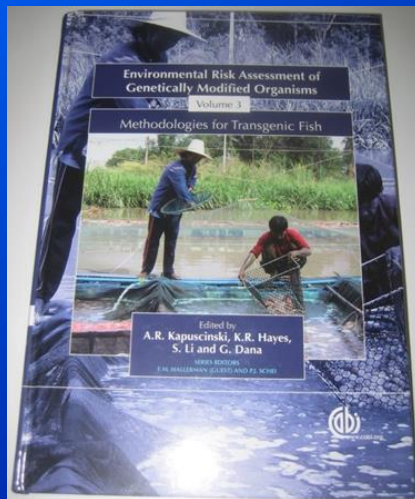
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National Research
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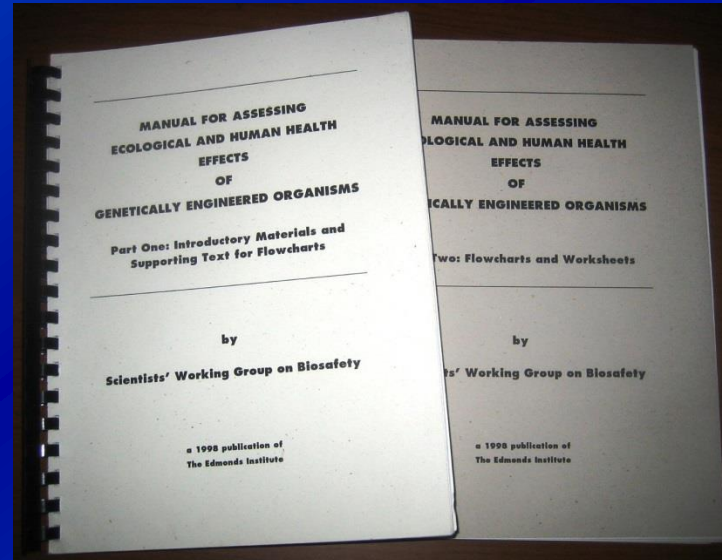
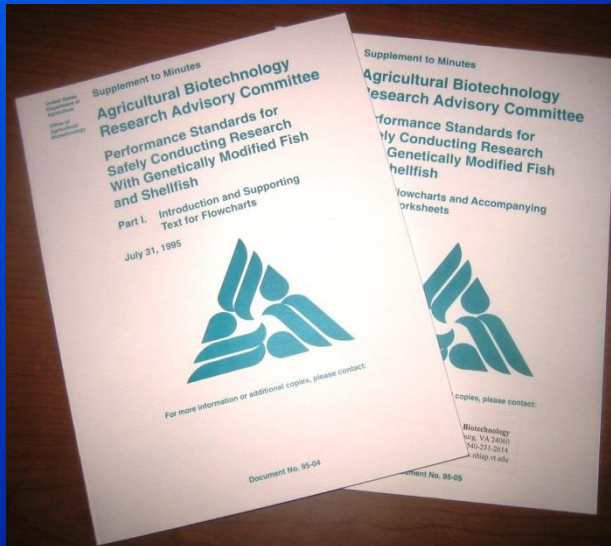
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To gain greater depth, read onward...



Environmental risk assessment – transgenic fish, Bt maize in Kenya, Bt cotton in Brazil and Viet Nam – CABI Press, www.cabi-publishing.org

To gain greater depth, read onward...



Performance standards for safely conducting research with GM fish and shellfish -

<https://sites.google.com/a/vt.edu/animalbiotechresources/standards>

Manual for assessing ecological and human health effects of GE organisms –

<https://www.edmonds-institute.org/manplpr.pdf>



**KEEP
CALM
AND
CARRY OUT A
RISK ASSESSMENT**