Public Engagement in Biotechnology Governance

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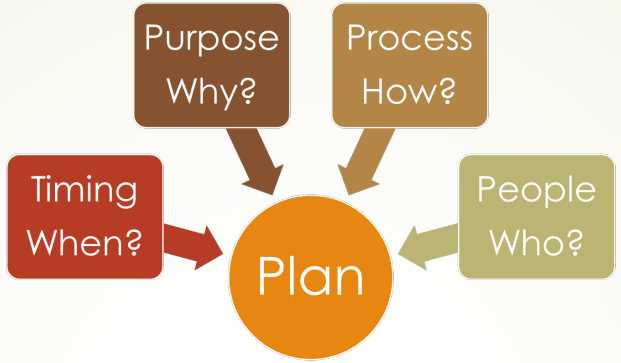
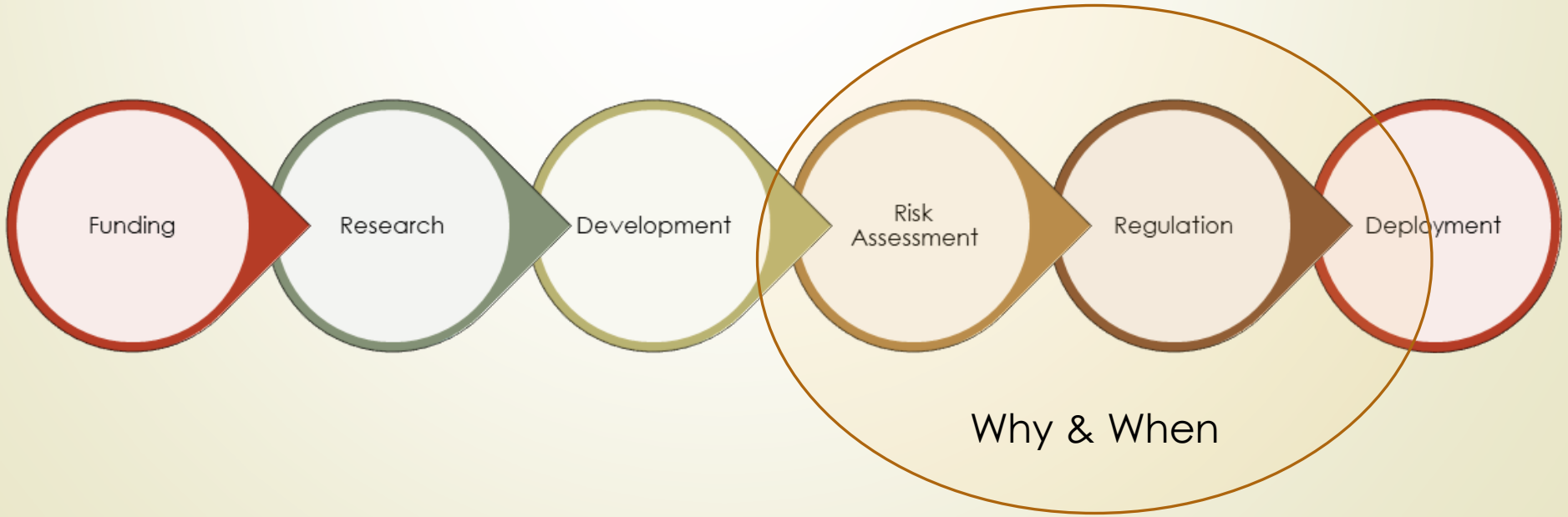
Public Engagement in Formal Decision Making about GDOs



Where the Rubber hits the Road for Release Decisions



Challenges with **Public Engagement** for formal DM in U.S. biotech governance

- **Lack of Policy Mechanism or Political Will**
  - Regulators don't have resources or a mandate (except throu… …g, or EIS)
  - Lack of federal advisory committees for key GM insect d… …l 3 CFRB agencies
  - e.g. EPA's OX5304 decisions; local and communit… …ups are disenfranchised as FL Keys MCD invites only Oxitec scientists to present fo… …aking, no EIS, and no FACA committee
  - (FDA OX 513A was voted on by Key Ho… …eterendum after RA/Reg DM)

- **"Deficit model" thinking**
  - Public Education, "C… …blic doesn't understand the Science

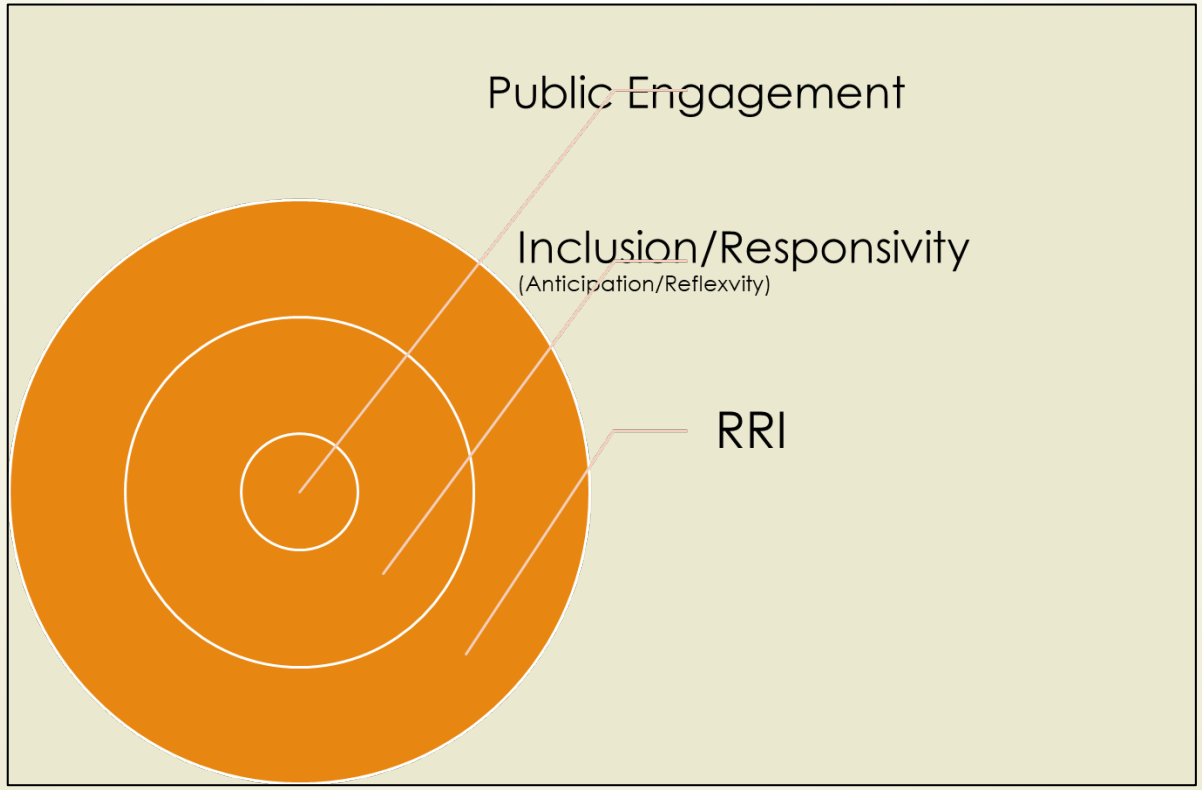
- **Fear of Pu… …face of more information**
  - … …phobia" (Marris 2015)
  - … some studies (GM & nano) that more people learn about technology, greater risks … …ed

Cultural and Policy Core Beliefs among Different Stakeholder Groups

What do Biotech Stakeholders think about Responsible Research and Innovation (RRI) (ala Stilgoe et al. 2013) and its elements of Public Engagement in Decision Making?

Cultivating Cultures of Ethics (NSF Award No. 1540244)

Exploring Meanings of Responsible Innovation in Communities of Biotechnology Innovation



Significant Disagreement among Biotech Stakeholder Groups about Need for Public Engagement

(Roberts, Herkert & Kuzma, *Elementa*, 2020)

Policy beliefs differ among stakeholder groups especially with regard to Responsible Innovation principles of public "inclusion" and public "responsivity"

	Industry				*Trade Org*				*Academe*				*Govt*				*Consumer*			
	core		*implementation*		*core*		*implementation*		*core*		*implementation*		*core*		*implementation*		*core*		*implementation*	
	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post
Inclus	4.5	4.0	4.7	4.7	4.7	4.9	4.8	5.0	5.0	5.3	5.6	4.9	5.4	5.8	5.5	5.9	5.3	6.1	6.4	6.4
Anticip	6.0	5.5	3.3	3.1	6.3	5.8	4.5	4.2	6.1	5.9	5.0	4.4	6.6	6.0	5.0	5.5	6.6	6.9	6.1	6.3
Respons	4.2	4.1	4.1	3.9	4.8	4.7	4.4	4.5	5.0	4.5	4.2	4.0	4.7	5.2	4.7	5.3	5.0	6.0	5.3	6.1
Reflex	6.1	5.5	4.3	4.3	5.7	5.8	5.4	5.0	6.0	6.0	5.3	5.0	6.1	6.5	5.7	5.8	6.3	6.6	6.3	6.6

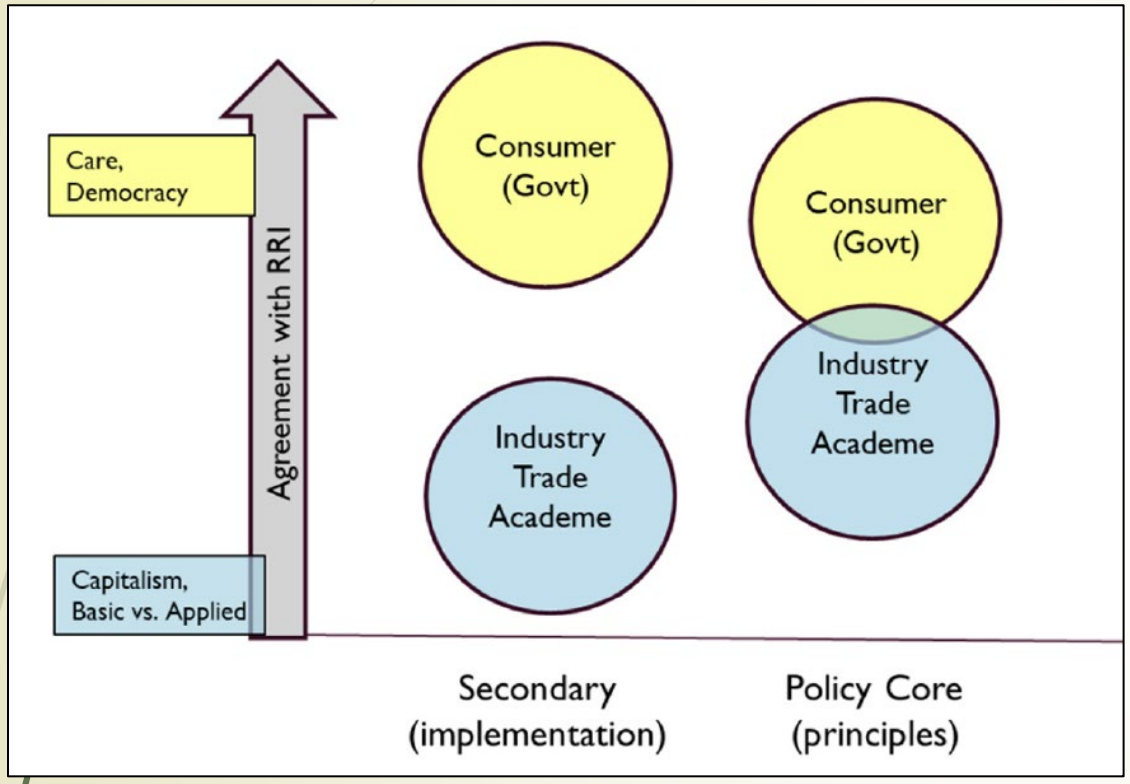
Table 4: RI implementation (ACF secondary beliefs) after focus groups—Significance of differences among stakeholder groups. Tukey multiple comparisons of RI policy implementation–Posttest means, 95% Family-wise confidence interval; p-values (adjusted mean difference). DOI: https://doi.org/10.1525/elementa.446.t4

Group – Group	Policy Implementation			
	Inclusion	Anticipation	Responsiveness	Reflexivity
Consumer – Academe	0.02* (1.48)	0.007** (1.85)	0.000*** (2.14)	0.03* (1.57)
Government – Academe	0.22 (0.99)	0.29 (1.03)	0.66 (1.27)	0.54 (0.00)
Industry – Academe	0.99 (–0.18)	0.03* (–1.31)	1.00 (–0.13)	0.44 (0.00)
Trade – Academe	1.00 (–0.12)	0.98 (–0.26)	0.84 (0.47)	1.00 (0.00)
Government – Consumer	0.89 (–0.49)	0.64 (–0.82)	0.49 (–0.87)	0.69 (0.00)
Industry – Consumer	0.005** (–1.66)	0.000*** (–3.15)	0.000*** (–2.28)	0.000*** (–2.34)
Trade – Consumer	0.07 (–1.35)	0.004** (–2.11)	0.02* (–1.60)	0.06 (–1.57)
Industry – Government	0.08 (–1.17)	0.000*** (–2.33)	0.02* (–1.40)	0.02 (–1.53)
Trade – Government	0.43 (–0.87)	0.16 (–1.29)	0.53 (–0.80)	0.62 (0.00)
Trade – Industry	0.96 (0.30)	0.21 (1.04)	0.65 (0.60)	0.55 (0.00)
F(Sig.)	4.42 (0.003**)	11.36 (0.000***)	7.69 (0.000***)	5.80 (0.000***)

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

Significant barriers to meaningful public engagement

Roberts, Herkert & Kuzma, *Elementa*, 2020
Kuzma & Cummings in prep



- Philosophical Barriers
  - Cultural world views about structure of society and our relationships to others
  - Egalitarian views influence views on need for public engagement
  - Hierarchical and Individualistic views may not
- Practical Barriers
  - "Academic capitalism"
  - Pressures of funding and competition
  - Undesirable to slow innovation

How do we overcome these attitudinal and cultural barriers posed by which "coalition" we inhabit or world views we have?

Momentum against Public Engagement therefore…

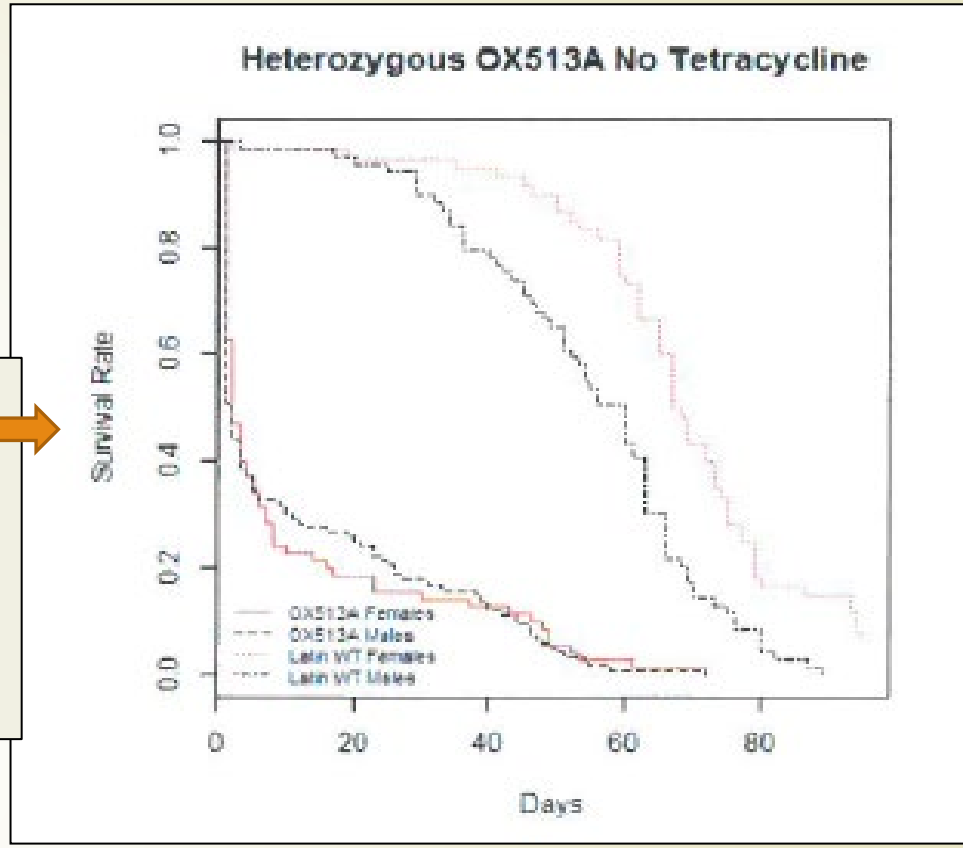
- **Often burden of proof is on the public engagement community to show evidence that "it works" or to show "benefits of engagement"**
  - For whose ends is it supposed to work?
  - What "benefits "? To Whom?
  - Should public engagement be held to a same or higher standard than GDO science? ("field trials" without certainty they will work in broader ecosystem)
  - Should we be willing to experiment with PE (while using best practices we've already learned)?

- **Flipping the question….What suffers without engagement?**
  - Democracy, informed consent, social equity, procedural justice
  - But also risk assessment and DM—strong objectivity (Harding 2004)

Value Judgements in RA for GE insects (OX513A)

Meghani & Kuzma 2017; Kuzma 2019

- Discounted emergence of significant % females from leaky Tet operon
- Dismissed the data in the same document on survival time
- Downplayed # of mosquitos released
- No attempt to quantify # biting females survival over time
- Characterized passive transport as negligible
  - (even though document states it happened from FL to CA)
- Did not measure Tet in the environment of release (made assumptions instead)

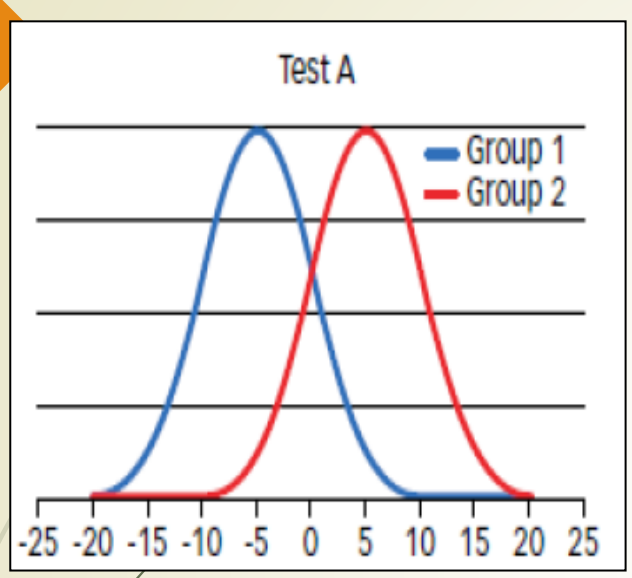


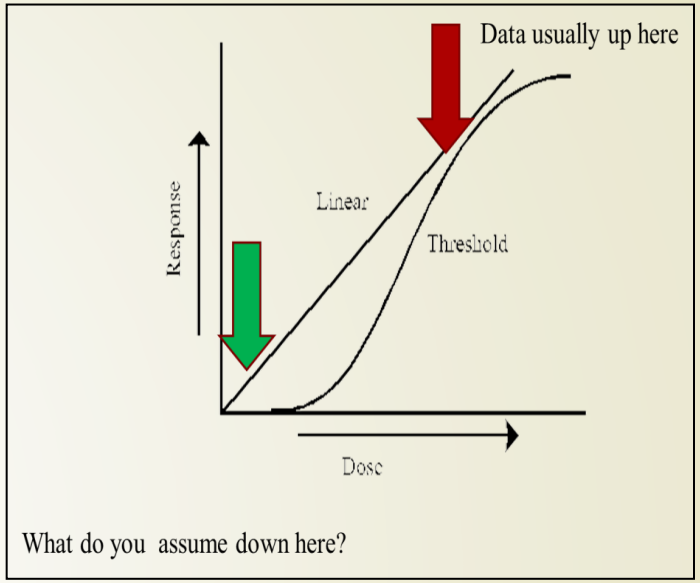
FDA Conclusion

FDA found that it is highly unlikely that release of OX513A male mosquitoes would contribute to the increase in transmission of dengue or other diseases transmitted by mosquitoes. Male mosquitoes do not bite humans or other animals and therefore do not transmit diseases. Further, their environmental lifetimes are short (~2 days), limiting their ability to interact with humans.

FDA FONSI & Oxitec EA 2016

VALUES in risk assessment





- Who gets to decide the alternatives (baseline or other options) for considering risk-risk, risk-benefit tradeoffs?
- Who gets to define what a "risk" is? (endpoints for assessment
- Who gets to decide when there is enough information?
- Who gets to decide whether to err on the side of avoiding false positives (promotion) or negatives (precaution)?
- Who gets to define what level is "safe"?

Case of Gene Drives

- **Dilemma:**
  - *Significant uncertainties associated with field trial decisions for gene drive insects, but need field trials to amass data*
- **Serious deficiencies in the regulatory risk assessment approach for GE insects (FDA and EPA)**
  - *Stems from approach of "hubris" not humility*
  - *Systematic bias in interpretations of uncertainty*
    - (Meghani & Kuzma 2017; Kuzma 2019)
- **Substantive Validity of RA is significantly challenged**
- **Procedural Validity is all the more important**
- ***Greater public, stakeholder, outside-expert and community engagement is NECESSARY to correct for bias of techno-optimism and improve the risk assessment process for GDOs***

Without engagement—risk of techno-optimism in RA

INFECTIOUS DISEASES

GM mosquito study draws fire

Release of altered strain spread DNA to local mosquitoes

- **Judge orders FDA to analyze risks of escape by genetically engineered salmon**
- By Food Safety News Desk on November 6, 2020
- On Thursday, the U.S. District Court for the Northern District of California judge ruled the FDA violated core environmental laws in approving "AquAdvantage" salmon.
- Failed to consider risks of escapees adequately in EIS

Regulation & Governance

Regulation & Governance (2019) doi:10.1111/rego.12245

Procedurally Robust Risk Assessment Framework for Novel Genetically Engineered Organisms and Gene Drives

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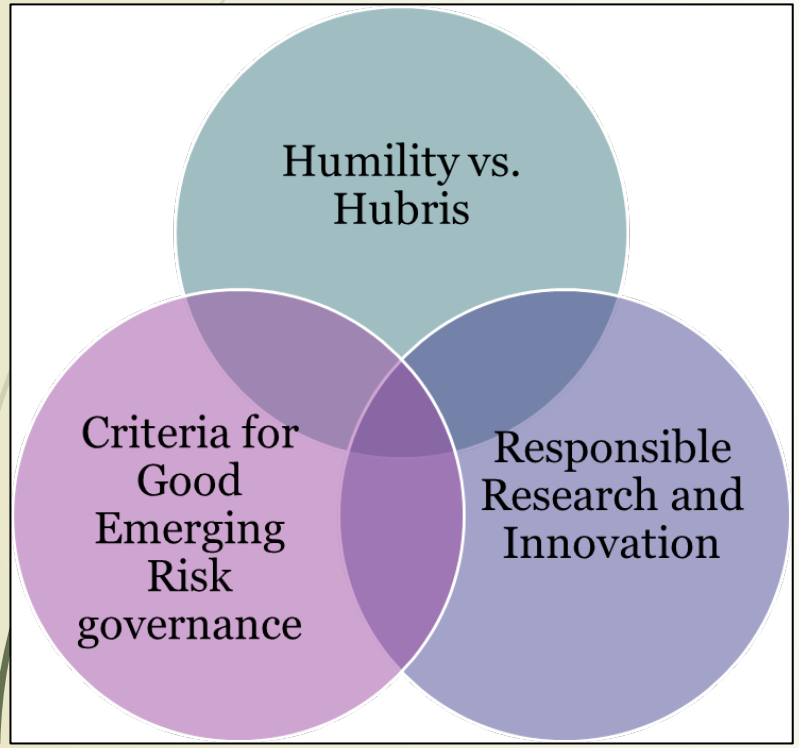
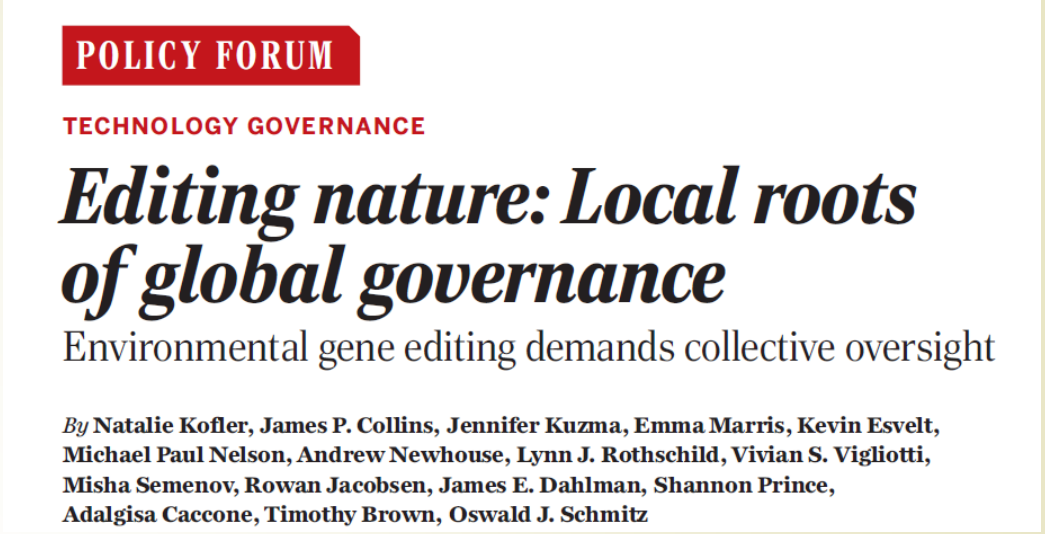


How?
PRRAF: Principles for RA

Table 1 Evaluation of the FDA-Oxitec risk analysis of the Oxitec GE mosquito

Criteria • Principles	Final FDA-Oxitec EA & FONSI
Principle of Humility†	Minimal to none
• Assess social and behavioral foundations of vulnerability to risk	*Minimal*
• Consider the ethical, political, and other social dimensions of the distributive impact of risks among different groups and communities	*Minimal*
• Elicit public input into framing of risk analysis that is open to non-technological alternatives	*None*
• Promote mutual learning as object of deliberation in risk analysis	*None*
Principle of Inclusion†	Minimal to none
• Engage multiple interested and affected parties in discussion of ends and means of innovation	*None*
• Elicit the input of interested and affected parties to scope the risk problem and at key junctures in risk assessment	*Minimal*‡
Principle of Reflexivity	Minimal to none
• Examine assumptions and framing in risk analysis	*Minimal*
• Acknowledge alternative explanations to the data and analysis	*None*
• Reflect on quality of organizational processes used for risk analysis	*None*
• Reflect on meaning of errors to outcomes and reputations of assessors	*None*
Principle of Procedural Validity	Minimal to none
• Assess the quality of the risk analysis process that led to the outcomes	*None*
• Evaluate scientific validity of the approaches used in risk analysis	*Minimal*
• Proceed with openness and transparency in conduct of risk analysis	*Minimal*
• Ensure consistency in interpretations of data and information	*Minimal*
• Use all available, relevant information including subjective probabilities	*None*
• Consider the acceptability of the results and interpretations to those who provide inputs to the analysis	*None*
Principle of Anticipation	Minimal to None
• Consider contingencies of what is known, plausible, possible, and unknown for the future	*Minimal*
• Account for changing future conditions at different timescales	*None*

How?
Principles for "Collective Oversight"



POLICY FORUM

TECHNOLOGY GOVERNANCE

Editing nature: Local roots of global governance

Environmental gene editing demands collective oversight

By Natalie Kofler, James P. Collins, Jennifer Kuzma, Emma Marris, Kevin Esvelt, Michael Paul Nelson, Andrew Newhouse, Lynn J. Rothschild, Vivian S. Vigliotti, Misha Semenov, Rowan Jacobsen, James E. Dahlman, Shannon Prince, Adalgisa Caccone, Timothy Brown, Oswald J. Schmitz

- **Groups with Conflict of Interest (i.e. part of overall research team, funders, developers, etc.) should not be in charge of engagement**
- **Put independent groups in charge of process of engagement**
  - Community groups without strong "stake" in the issue ("Local Roots")
    - (Kofler et al. 2018)

Additional Key Questions for Public Engagement in DM

- **How should a decision be made (or consent given) under a public engagement framework?**
  - What would be a legitimate sociopolitical process?
  - Local referendum (ala Key Haven)? Majority rule? Threshold of concern? Minority veto? Consensus?
- **How to give voice to the voiceless?**
  - Environmental species?
  - Communities that cannot participate, or outside initial "who" boundaries?
- **How can social equity be achieved?**
  - How can we give special consideration and voice to historically marginalized and indigenous communities?

Thank you!