

# Governance of Innovative Technologies for Agriculture

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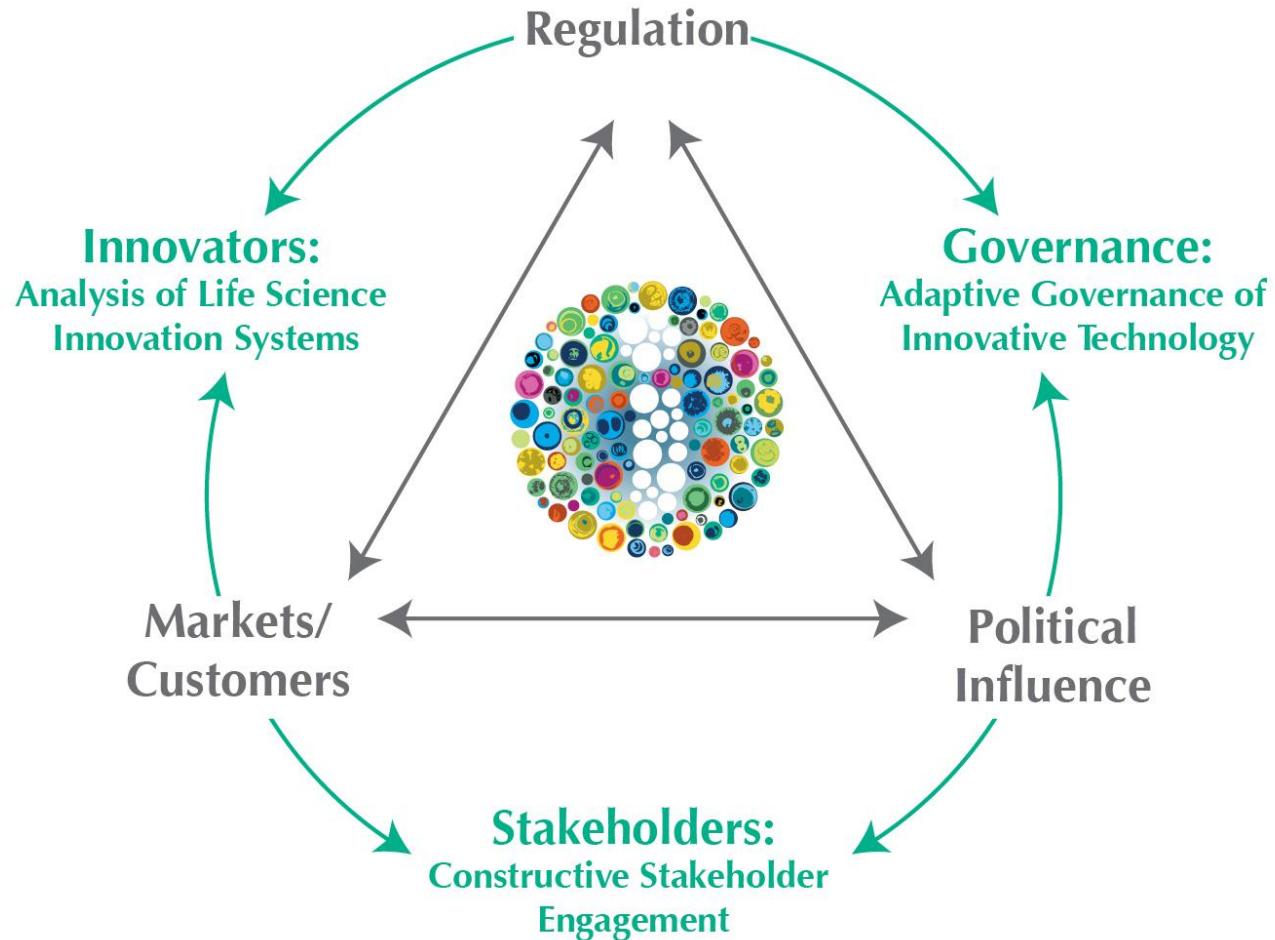


The Open University



# What we do

## INNOGEN INSTITUTE



# Where we do it

**Bio-  
economy –  
green, red,  
white, blue**

**Diagnostics**

**Sustainable  
food production**

**Biofuels**

**Pesticides**

**Pandemics**

**GM crops**

**Pharmaceuticals**

**Industrial  
Biotechnology**

**Stratified  
Medicine**

**Cell  
Therapies**

**Synthetic Biology**

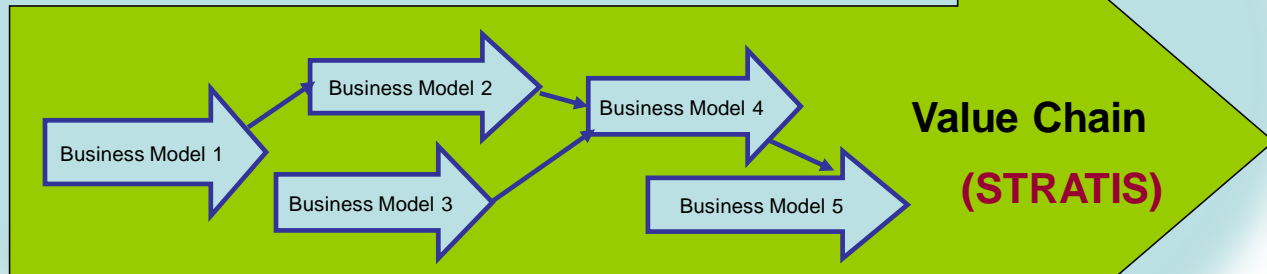
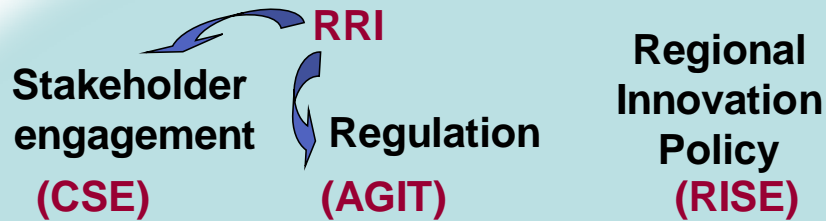
**Genetic  
Databases**

# How we do it

Conceptual scenarios

Quantitative scenarios

## Innovation Ecosystem



IP Regimes      Markets  
Funding Models      Industrial Dynamics  
(GIDA)





# INNOVATION PRESSURES ON COMPANIES

# The agrochemical industry in the 1980s

- **Agrochemicals a maturing industry**
- **Pipeline of new products could no longer support R&D costs**
- **Global markets could support fewer companies**
- **Predictions of waves of mergers/acquisitions**  
(John Braunholtz, ICI, BCPC Conference 1977)

• **The industry needs a new high value-added R&D trajectory to take us into the 21<sup>st</sup> Century – GM crops (Monsanto)**

# Disruptive and Incremental Innovation: Link to Regulation

## Disruptive innovation:

- Has the potential to create new types of product and even to create whole new industry sectors.
- But it cannot be accommodated within a company's current business model. It needs new areas of R&D; new modes of production; new routes to market. **There is often no clear regulatory precedent.**

## Incremental innovation:

- Enables stepwise improvements in a company's current innovation system, creating competitive advantage within the same sector without challenging the prevailing business models. **There is usually a clear regulatory precedent.**



An innovation that is path-breaking for one industry sector can be path dependent for another.



# EU REGULATION



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# Frustration with the EU Regulatory System

## Three reports from ACRE (2013)

1. Highlights inconsistencies in the approach to GMO regulation ... [and reflects] concern that the operation of this regulatory system is becoming increasingly untenable
2. Discusses the scientific validity of adopting the current approach to regulation, which is to control organisms based on how they were produced rather than on their novel characteristics
3. Considers a more effective approach to environmental risk assessment within the constraints of the principles set out in the current legislation

<https://www.gov.uk/government/publications/genetically-modified-organisms-review-of-current-eu-regulations>



# EASAC

A new independent expert report from the European Academies Science Advisory Council warns of the grave scientific, economic and social consequences of current European Union policy towards GM crops. In the strongest terms, the report also argues that Europe must reassess the accumulated evidence and the new advances since EU policy affects not only Europe, but also the developing world and Africa in particular.

<http://www.easac.eu/home/press-releases/detail-view/article/easac-warns.html>



# The politicisation of regulatory systems

- **The EU regulatory system for GM crops is widely regarded as a failure of evidence based risk governance**
- **It is overly dominated by political considerations, particularly environmental NGO pressures in a way that is anti-democratic**
- **Using the regulatory system to mitigate public fears, rather than to deal with real risks, is bad governance practice and leads to the destruction of innovative industries**

Mittra, J., Mastroeni, M. and Tait, J. (2014) *Engaging with uncertainty and risk in agricultural biotechnology regulation*. Innogen Institute Research Report, [http://www.innogen.ac.uk/downloads/Final-Report\\_140429.pdf](http://www.innogen.ac.uk/downloads/Final-Report_140429.pdf)

## *Two perspectives on the EU approach to regulation for agriculture-related products*

1. The EU has the most rigorous approach to regulation globally. This will attract industry to locate in the EU rather than in other countries or regions with less onerous regulatory systems. Other countries will be stimulated to follow the lead of the EU.
2. The EU has the most bureaucratic, time consuming and expensive regulatory systems globally. Companies will increasingly choose to locate or re-locate in other regions so as not to lose competitive advantage.



# Opportunities created for others

BGI, formerly the Beijing Genomics Institute, were too independent for Beijing University – their expulsion is claimed to be the key to their success. They now produce 25% of the world's total genomic data and have already processed the genomes of fifty-seven thousand people. BGI also has sequenced many strains of rice, the cucumber, the chickpea, the giant panda, the Arabian camel, the yak, a chicken, and forty types of silkworm.

"In the United States and in the West, you have a certain way," [BGI President Jian Wang] continued, smiling and waving his arms merrily. "You feel you are advanced and you are the best. Blah, blah, blah. You follow all these rules and have all these protocols and laws and regulations. You need somebody to change it. To blow it up. For the last five hundred years, you have been leading the way with innovation. We are no longer interested in following." □



[http://www.synthesis.cc/cgi-bin/mt/mt-search.cgi?blog\\_id=1&tag=synthetic%20biology&limit=20](http://www.synthesis.cc/cgi-bin/mt/mt-search.cgi?blog_id=1&tag=synthetic%20biology&limit=20)



# HOW DID WE GET INTO THIS MESS? SOCIAL SCIENCE AND 'GOVERNANCE'



# A Policy Revolution: from “Government” to “Governance”

## Government

- Pre 1980s – “Powers over”
- A top-down legislative approach
- Attempts to regulate the behaviour of people and institutions in detailed and compartmentalised ways

## Governance

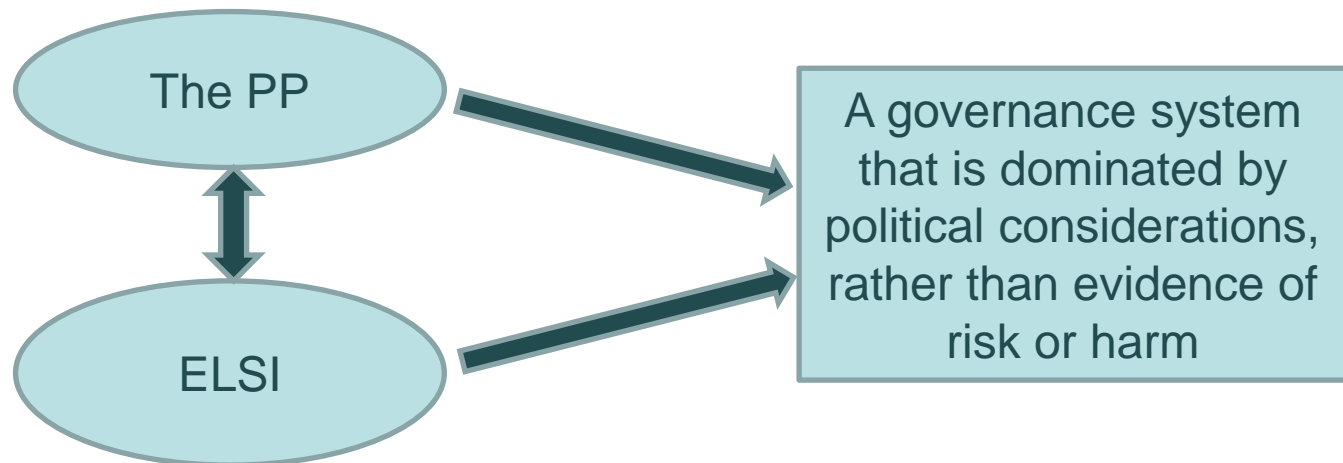
- Post 1980s - “Powers to”
- Sets the parameters of the system within which people and institutions behave so that self-regulation achieves the desired outcomes



# The new governance agenda and the precautionary principle (PP)

New governance approach (1980s) – dominant research agenda in the social sciences:

- Bottom-up consultative approach, built on ‘upstream engagement’
- More open
- More public involvement in decision making
- Focuses on ‘ethical, legal and socio-economic aspects (or implications)’ (ELSA/ELSI)

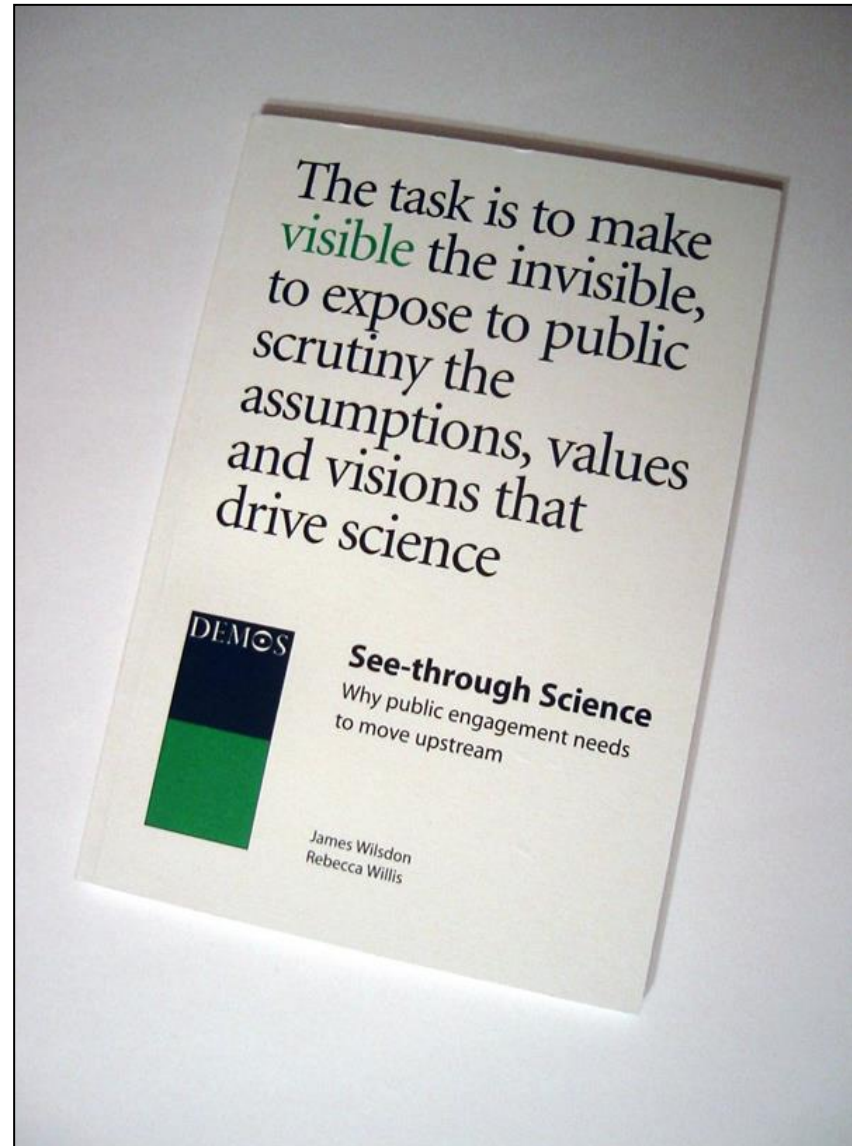




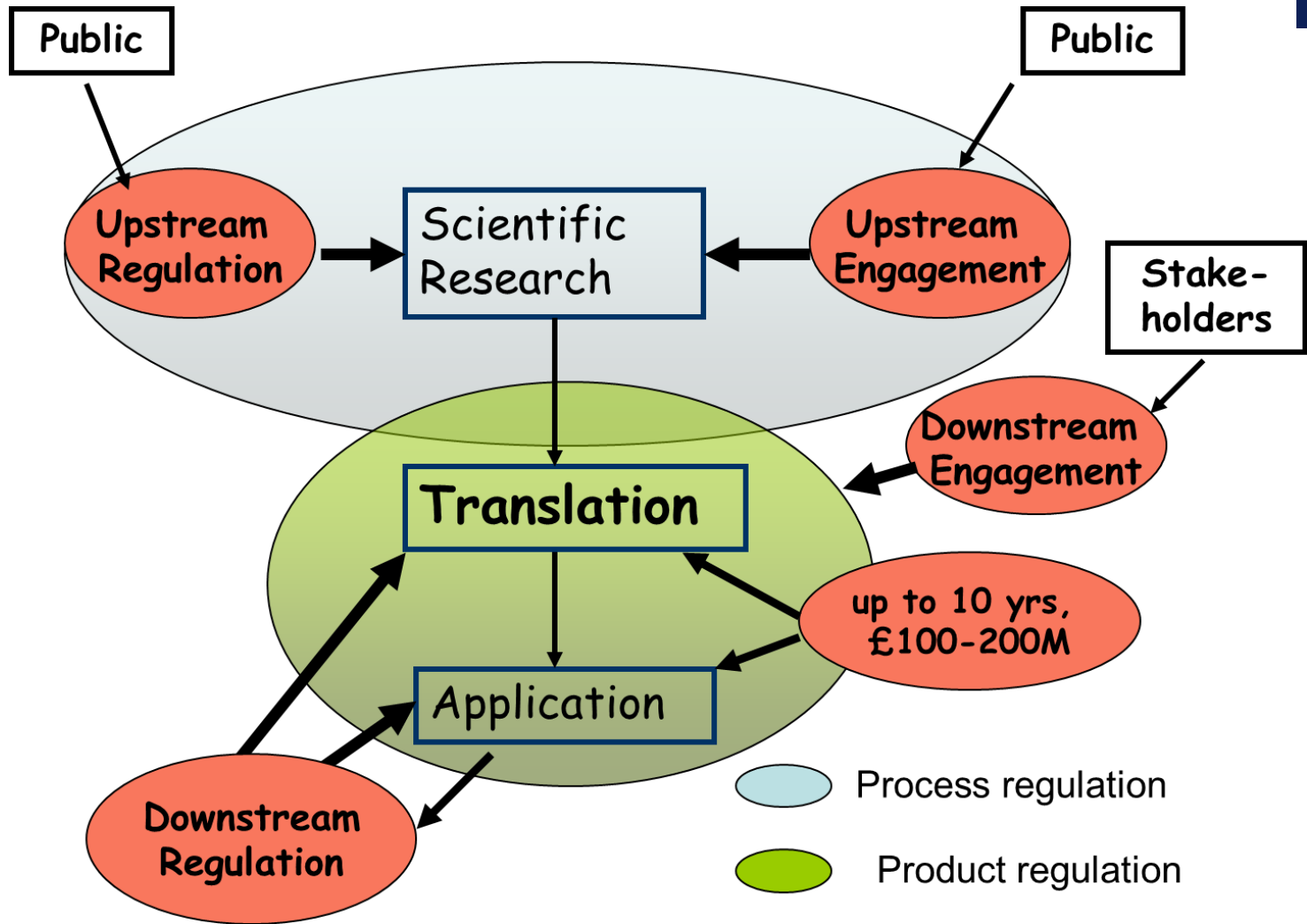
The ambition was political.

Demos expected this initiative to have profound implications for the future of science and to reshape the way that science relates to public decision making.

This aim has largely been achieved, at least partly through the influence of Demos, with an ELSI component attached to most major research projects on advanced innovative technologies in the EU and USA, and a major influence on science and regulatory policy.



# Governance / Innovation Interactions: from Science to Market Place



# Defects in the assumptions behind upstream engagement

- **Ignores generations of socio-economic research**
  - **Assumes perfect foresight**
  - **Assumes we know nothing about “the assumptions, values and visions that drive science”**
  - **Fails to challenge the assumptions, values and visions that drive social sciences**
- **Assumes that those who wish to engage in the process will be impartial and unbiased**
- **Assumes the possibility of a broad public consensus on desired future outputs from life science innovation**



# Defects in the conduct of upstream engagement

- **Small groups easily swayed by strong opinions**
- **Given ignorance of the future – engagement becomes a process of fictitiously framing the technology in the public mind**
- **Uncommitted citizens have better things to do with their time**
- **Can lead to polarisation and increased conflict**
- **Engagement fatigue**
- **Labile public opinion**
- **Pressure to act on results of engagement**



# Defects in the outcomes of upstream engagement

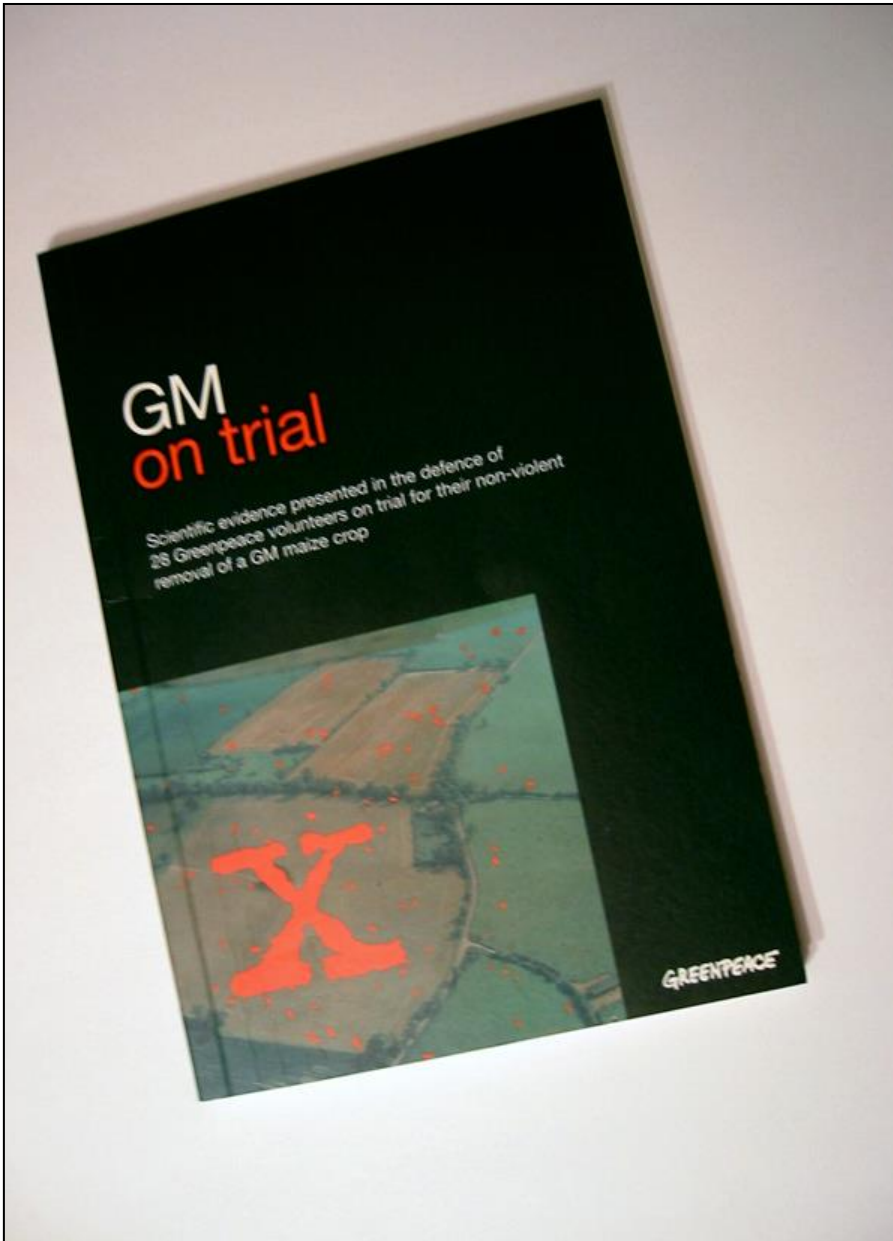
- Has blocked the development of some potentially valuable products
- Will not prevent the development of products that are unacceptable to the public or that harm health or the environment
- Will prevent us from learning from experience
- Rather than supporting democratic decision making it is still largely undemocratic



# Technology related conflicts – hearts and minds



Tait, J. (2001) More Faust than Frankenstein: the European Debate about Risk Regulation for Genetically Modified Crops. *Journal of Risk Research*, 4(2), 175-189. <sup>22</sup>



**“corrupting  
public  
understanding  
of science for  
political ends”**

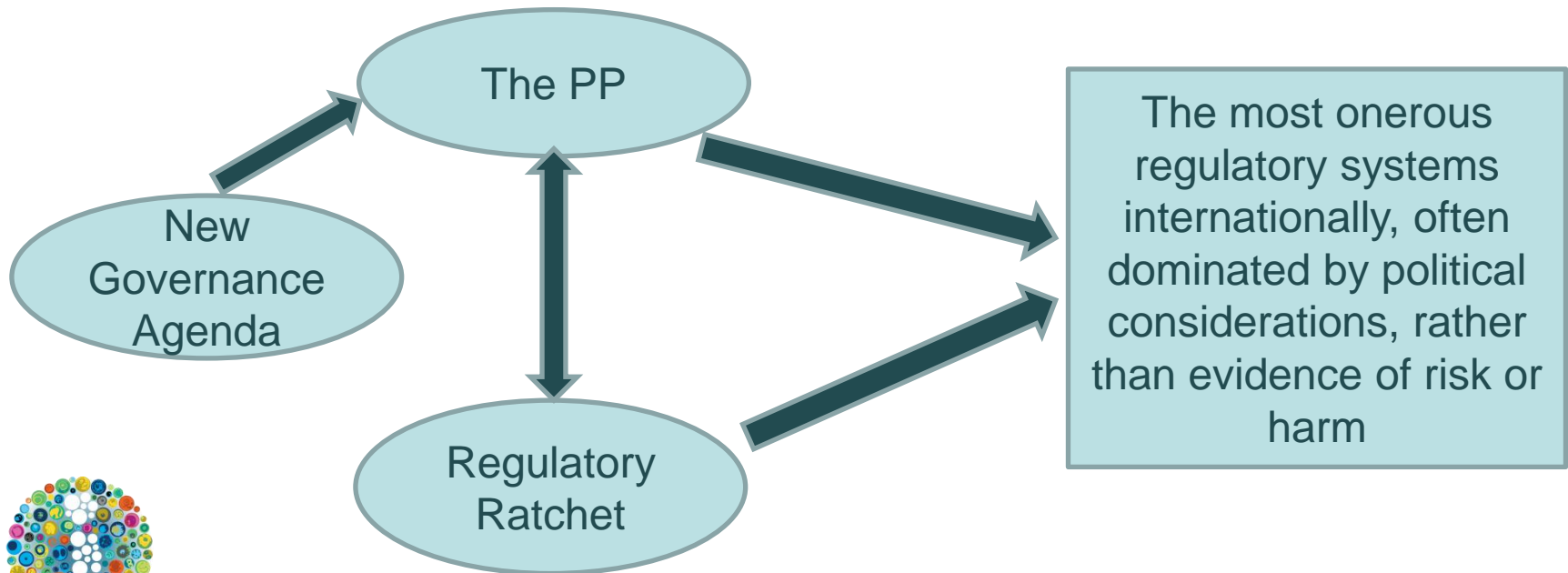
<http://www.greenpeace.org.uk/files/pdfs/migrated/MultimediaFiles/Live/FullReport/1766.pdf>



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# Regulation, the precautionary principle (PP) and the new governance agenda

- Regulatory Ratchet
- Precaution – action taken in advance of evidence of harm
- **New governance approach in the 1980s - emphasis on public consultation and involvement in decision making**





## The outcome of the new governance agenda for life sciences:

The new governance agenda claims to be lighter-touch, less top-down, but in effect it has extended the regulatory process into areas that used to be left to market forces. It claims to be more democratic, involving a wider range of stakeholders in the decision making process, but in effect it has merely led to a shift in power relations away from industry and commerce and in favour of advocacy groups with equally limited claims to represent 'society'.



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Tait, J. and Barker, G., (2011) Global food security and the governance of modern biotechnologies: opportunities and challenges for Europe  
*EMBO Reports*, 12, pp763-768

# Regulation needs to be enabling of innovation

Roles of large and small companies - evolution in the context of a lengthy and expensive regulatory system



Thanks to Christopher Milne, Tufts Centre for Drug Development



**WHAT TO DO ABOUT IT?**

**CONSTRUCTIVE STAKEHOLDER  
ENGAGEMENT  
AND ADAPTIVE GOVERNANCE**

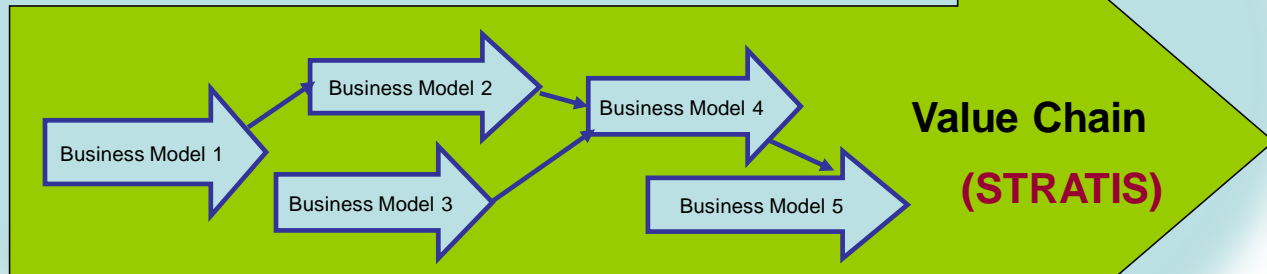
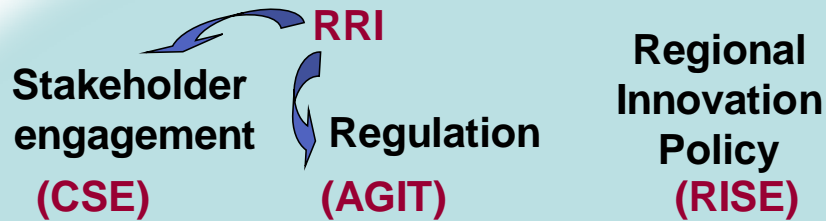


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Industrial Dynamics (GIDA)



# Debunking Myths



John Cook  
Stephan Lewandowsky

- It's not just what people think but how they think
- Focus on the facts you wish to communicate
- For those who are strongly fixed in their views, counter arguments can cause them to strengthen their views
- When you debunk a myth you create a gap in the person's mind ... your debunking must fill that gap

<http://www.skepticalscience.com/Debunking-Handbook-now-freely-available-download.html>

# Effective debunking requires three major elements

1. The refutation must focus on core facts rather than the myth to avoid the misinformation becoming more familiar
2. Any mention of a myth should be preceded by explicit warnings to notify the reader that the upcoming information is false
3. The refutation should include an alternative explanation that accounts for important qualities in the original misinformation



# Constructive Stakeholder Engagement-1

- Be equitably skeptical about the motivations of those with whom you engage
- Consider innovation and regulatory processes, as well as science
- Consider benefits of the technology and balance against costs and risks
- Develop standards for engagement including standards for the quality of evidence on which decisions are based
- In a plural democracy, maintain choice as far as possible



Tait, J. and Barker, G., (2011) *EMBO Reports*, 12, pp763-768.  
Tait, J. (2009) *EMBO Reports*. , 10, pp 18-22

## Constructive Stakeholder Engagement-2

- Open discussion accommodating of the full range of relevant opinions (general public/citizens, scientists, industry, users of the technology, consumers)
- No single perspective should dominate other opinions.
- Manage expectations - unlikely that all stakeholder views can be accommodated
- Careful timing – too early and its value will be undermined by the level of uncertainty around the nature of future developments; too late and stakeholder opinions and political positions may have become entrenched so that accommodation will be more difficult to achieve.



# Watch out for ‘stealth advocacy’

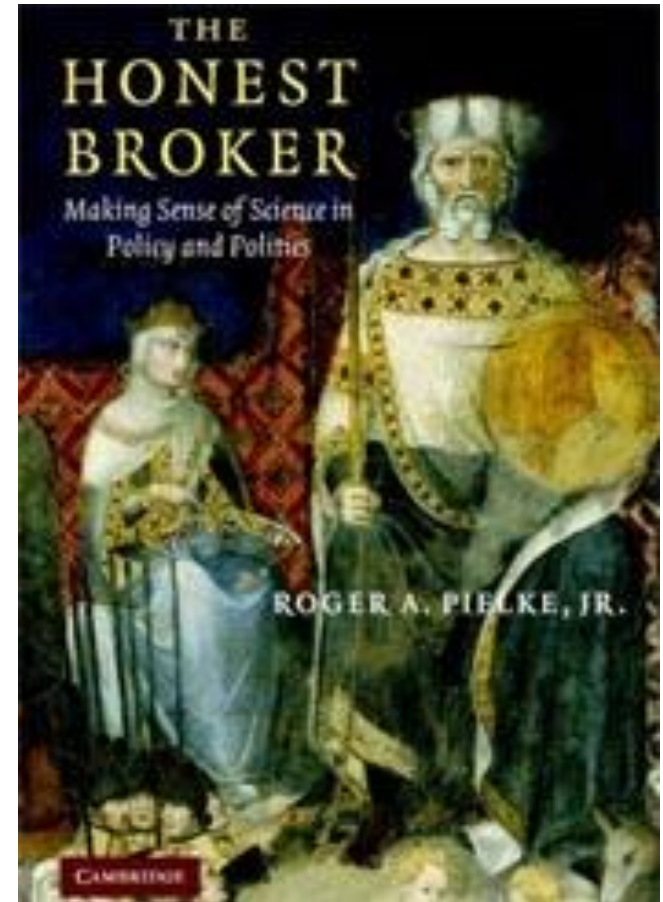
## Scientists as policy advisers – roles

- Pure scientist
- Science arbiter
- Issue Advocate
- **Honest broker** (seeks to expand the choices available to decision makers, but to refrain from advocating any particular course of action)

## Plus ‘stealth advocate’:

- allows an adviser to claim to be “...above the fray, invoking the historical authority of science while working to restrict the scope of choice”.

(Also applies to social scientists)



Pielke R.A. (2007) *The Honest Broker: Making Sense of Science in Policy and Politics*. Cambridge, UK: Cambridge University Press

# *European regulatory systems need to be more adaptive*



An adaptive risk governance approach is *enabling* of innovation, *minimises* risk to people and the environment, and *balances* the interests and values of all relevant stakeholders. It provides for trade-offs between these factors and supports smarter regulatory approaches that seek to balance potential social benefits and potential risks, particularly where both are uncertain in the early stages of technology development.



# Smart, Adaptive Governance of Innovative Technology – Focus on Balance

- Regulation can be modified in the light of changes in risk assessment e.g. improved scientific understanding of the technology and its impacts and the levels of uncertainty associated with them, or changes in the policy and political context.
- Recognises its role in enabling innovation
- Balances the risks and benefits to people and the environment
- Balances the interests and values of ALL relevant stakeholders
- Is explicit about political influences on policy decisions
- **REGULATORY SCIENCE** - Is able to consider ‘technical fixes’ as an alternative or complement to regulation



# Important not to over-react

- Our regulatory systems do need to become more *adaptive* than they have been in the past, and also more intelligently anticipatory
- Our engagement with stakeholders does not necessarily need to be lessened – it needs to be more targeted and constructive than it has been in the past
- Innovators need to behave responsibly, but so do regulators, stakeholders and social science researchers
- Significant improvements in developing more adaptive regulatory systems are being made in health care areas – agriculture could learn from them



## Eduardo Paolozzi - Master of the Universe



**How can we  
master this  
universe?**



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