Risk Governance of Synthetic Biology: International Risk Governance Council Project

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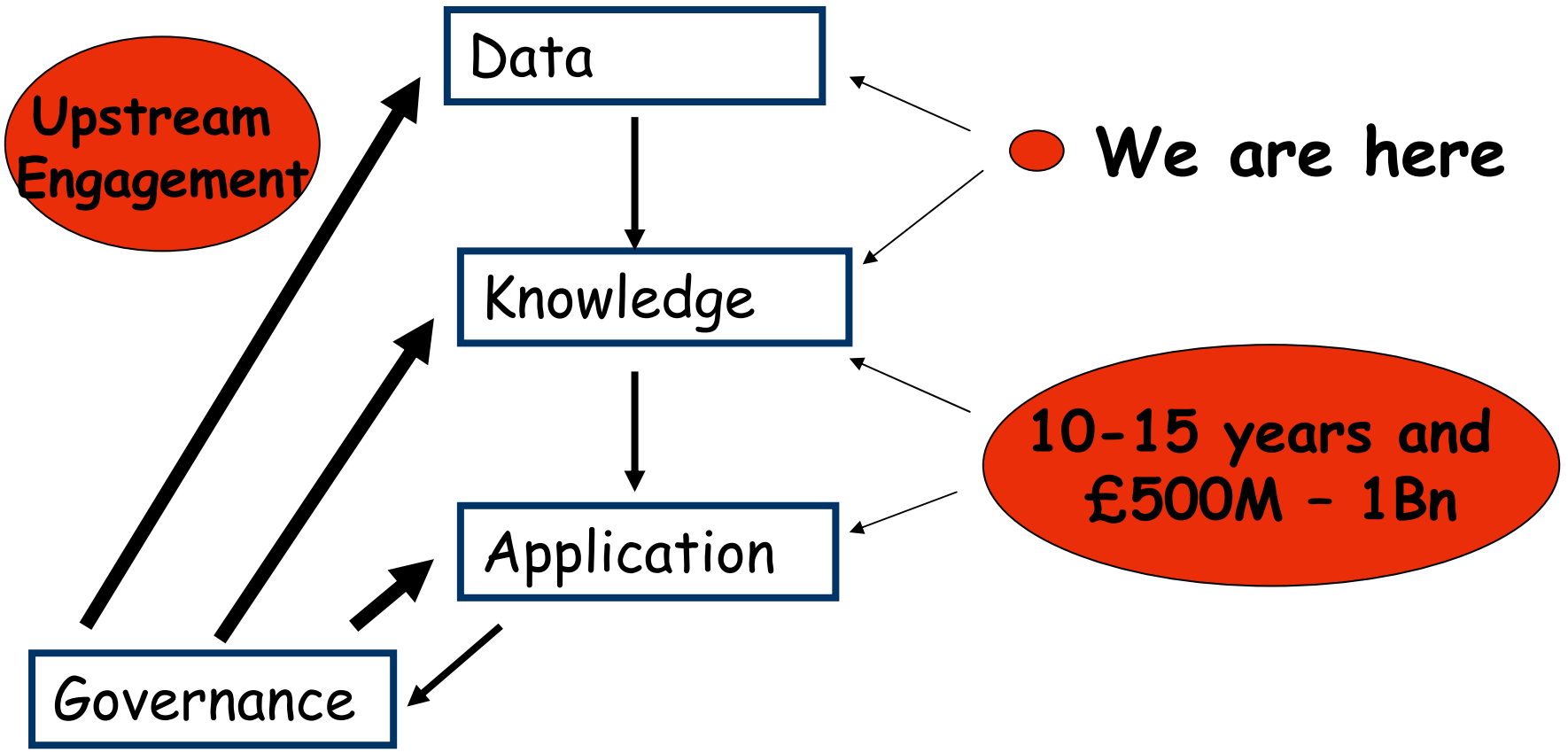
E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL


Big profits
Public benefits
So far so good ……..

But things are going to get complicated!

Progress from Science to Market Place



IRGC: Appropriate Risk Governance of Innovative Technology

An ‘appropriate’ approach to risk governance would be one that is enabling of innovation, minimises risk to people and the environment, and balances the interests and values of relevant stakeholders.

Tait, J., Chataway, J. and Wield, D., “Appropriate Governance of the Life Sciences – 2: The Case for Smart Regulation”, Innogen Policy Brief, http://www.genomicsnetwork.ac.uk/innogen/

Governance issues for Synthetic Biology

Process - related issues

Involves the production of novel, self replicating living organisms

Techniques readily acceptable with no specialist training

Ability to develop potential human, animal or plant pathogens

Patenting of novel life forms

Morality of creating novel life forms

Product – related issues

Choice of regulatory precedent will be critical

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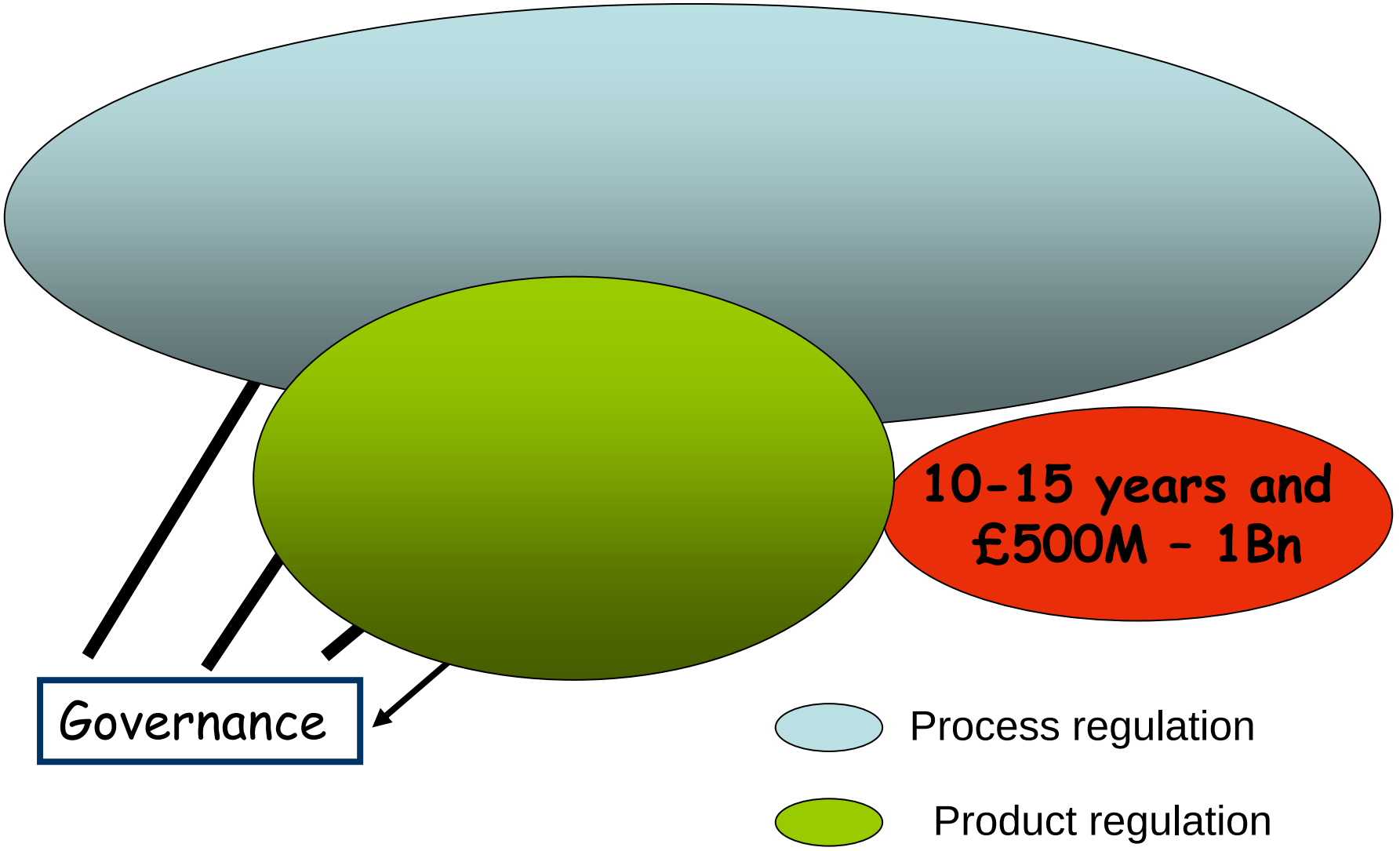


Key features of the IRGC approach*

Linking risk governance to innovation systems:

- **The need for regulatory certainty to stimulate commercial investment**
- **The need for 'smarter' regulation to enable innovation without compromising safety**

Reconciling conflicting stakeholder needs and concerns:

- **Ignorance/uncertainty about future benefits and risks**
- **Volatile public opinion over a long time scale**
- **Irreconcilable conflict over the technology and its applications**

*Concept Note: Risk Governance of Synthetic Biology. www.irgc.org

The IRGC family of approaches

1. IRGC Risk Governance Framework – dealing with existing risks
2. Risk Governance Deficits (RGDs) – avoiding deficiencies or failures in risk governance, weak spots in how risks are assessed and managed
3. Emerging Systemic Risks

Potential risk governance deficits

Examples from previous technology governance decisions:

- **GM crops**
- **Stem cell therapies**

Potential RGDs in Synthetic Biology

Technology Development:

- Investments made with public benefits in mind, but a failure to think through how they will be delivered.
- Early developments likely to be an extension of GM technology, particularly for bio-fuels
- Re medical benefits, pharma are reluctant to invest – benefits not yet obvious
- No clear value chain for most Synthetic biology developments

Potential RGDs in Synthetic Biology

Policy and Regulation – early process stage

- Don’t waste regulatory effort on developments which will not stand the test of time
- Remain alert to potential RGDs from future developments
- Need for a robust and flexible regulatory approach, given the range of future uncertainties
- Need for international dialogue on the appropriate scale and timing of regulatory oversight

Potential RGDs in Synthetic Biology

Policy and Regulation – product development stage

- Difficult to handle the joint goals – deliver public benefits, avoid unacceptable risks, enable commercially viable activity in a future-oriented context
- Collaborate in the development of regulatory systems for foreseeable risks
- Be ready with effective responses to unforeseen risks or rogue behaviour
- Enable heterogeneity in a field with many different techniques and applications

Potential RGDs in Synthetic Biology

Public and Stakeholder Engagement

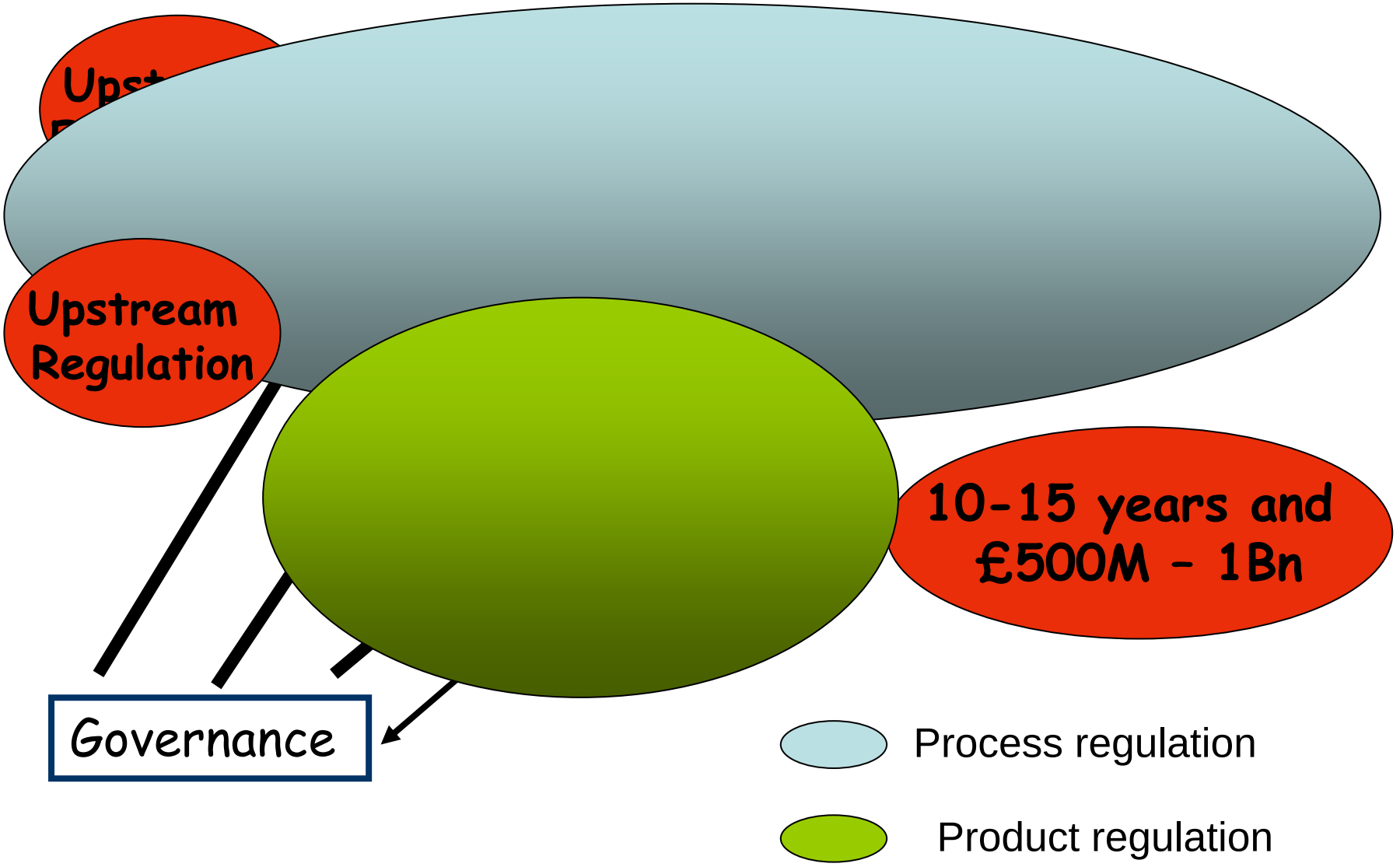
- Develop a strategy on how and when to incorporate stakeholder inputs into governance decision making
- Consider RGDs inherent in the process of ‘upstream engagement’
- Consider whether engagement will resolve the societal issues raised by synthetic biology
- Adopt an equitable approach to pressure groups arguing for and against particular developments

Implications for regulation and governance: from upstream engagement to upstream regulation

Regulation dictates the shape of the industry sector that develops the technology e.g. GM crops and stem cells

If regulation moves upstream flexibility to change will be vitally important – we don’t yet know how to do this

Progress from Science to Market Place



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