

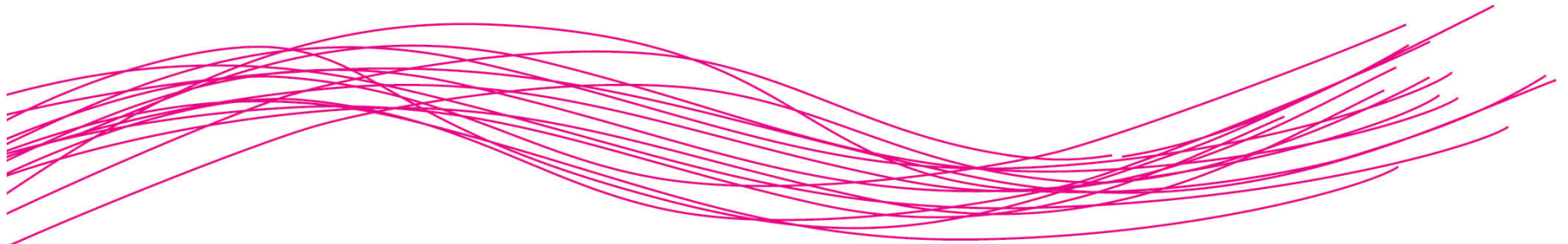


EUROPEAN
COMMISSION

Community research

Woodrow Wilson Center, Synbio project, 12-05-10

EC Initiatives on the governance and ethics of Synthetic Biology



**European Commission
Research DG
RTD-L3 - Governance and Ethics
Dr. Lino Paula, Policy Officer***

**The views expressed are those of the speaker and do not necessarily reflect the official opinion of the European Communities*





EUROPEAN
COMMISSION

Community research

Content:

- What policy instruments to address emerging technologies?
- New forms of collaboration: the Research DG approach to governance and ethics
- Current activities relevant to Synthetic Biology
- Some challenges for policy makers (and scientists) in addressing governance and ethics issues of Synthetic Biology





EUROPEAN
COMMISSION

Community research

Converging Technologies:

- New technologies such as nanotechnology, ICT and synthetic biology have in common that they operate at the convergence of ‘traditional’ disciplines, which make them **inherently complex** both in terms of scientific and societal impact.
- Converging technologies are also rapidly ‘**moving targets**’ which are hard to confine and define
- How can such rapid and complex developments be **timely and adequately regulated?**





EUROPEAN
COMMISSION

Community research

Converging Technologies (2):

- How can such rapid and complex developments be timely and adequately regulated:

Instruments available:

- Binding law (Conventions, Directives, Regulations)
 - “Soft” law (code of conduct, guidelines, ‘Open Method of Coordination’ – best practice benchmarking)
 - Engagement approaches (‘upstream’ engagement, stakeholder dialogue, societal deliberation)
- Soft law and engagement ≠ binding law without sanctions!
- Soft law and engagement can address a wider range of issues (ethical, social), with a wider involvement, than binding law can.- and can be aspirational





EUROPEAN
COMMISSION

Community research

Converging Technologies (3):

- Past experiences in Europe with e.g. genetic modification also show that regulating via binding law alone does not suffice
- For a complex technology a complex mix of instruments is warranted, ideally starting with engagement approaches and moving via soft law towards – if needed – binding law





EUROPEAN
COMMISSION

Community research

The approach of the Research DG

General philosophy behind the governance approach of the Research DG:

- *'Upstream' two-way dialogue with all stakeholders to internalise ethical and social aspects in the design of new products and practises*
 - *Materialising in support for **engagement** and **soft-law** approaches;*
 - *Which deal with a **wider range of issues** than risk assessment only*





EUROPEAN
COMMUNITY

Community research

FP7 2007-2013

Cooperation
mio € 32,365

Ideas
mio € 7460

People
mio € 4728

Capacities
mio € 4217

+ JRC (nuclear & non-nuclear) + Euratom

Infrastructures
mio € 1700

SME
mio € 1336

Regions
mio € 126

Potential
mio € 370

Science in Society
mio € 330

International
mio € 185





EUROPEAN
COMMISSION

Community research

Science in Society

3 action lines:

**More dynamic
governance of the
science and society
relationship**

**Place of science and
technology in
society**

**Society's
engagement on
science issues**

**Our science system,
its professional
codes, expertise**

**Role of the
universities in the
social fabric**

**Gender and
research**

**Strengthening potentials,
broadening horizons**

**Young people
between science
education and
research careers**

**Science and society
communicate**

**Two-way
communication of
science and the
public, and role of
the media**





EUROPEAN
COMMISSION

Community research

The approach of the Research DG

Actions supporting the soft-law approach:

(NOT SPECIFICALLY FOCUSED ON SYN BIO!)

■ EC Ethical Review

- Carried out on all EC funded research projects that are ethically 'sensitive', providing guidance to researchers

■ European Group on Ethics (:BEPA)

- advisory body to the President of the European Commission
- Opinions provide guidance to EC funded research and beyond

■ Code of Conduct for Responsible Nanotechnology

- Adhering to general principles like sustainability, precaution, inclusiveness, responsibility





EUROPEAN
COMMISSION

Community research

“Introduction to the Commission’s Recommendation on a
Code of Conduct for Responsible Nanosciences and Nanotechnologies Research”

■ Code of Conduct for Responsible Nanotechnology

- Recommendation to the **Member States**
- Political signal to all **stakeholders**
- **Principles** (meaning, inclusiveness,...)
- **Actions** (good governance, precaution)
- **Process** (monitoring, feedback, revision...)





EUROPEAN
COMMISSION

Community research

The approach of the Research DG

Actions supporting the communicative approach:

EC's Framework Programme for Research (currently FP7):

- 'ELSA'/Governance research projects on synthetic biology – their impact and frameworks for assessment
- '*Support Actions*' focusing on capacity building, infrastructures, networking, exchange of best practice
- '*Mobilisation and Mutual Learning action plans*' - MML





EUROPEAN
COMMISSION

Community research

■ 'ELSA' research projects on synthetic biology (FP7)

SYNTH-ETHICS; synthetics.eu

- ❖ addresses ethical, legal and social implications with a special focus on biosafety, biosecurity and on notions of life;
- ❖ In close collaboration with the **synthetic biology community**;
- ❖ Analysing **public debate** and current ethical and regulative frameworks existing in synthetic biology - and closely related fields like nanobiotechnology and genetic engineering;
- ❖ Identifying challenges for current regulatory and ethical frameworks and recommendations for dealing with them, targeted at 1) the synthetic biology community, 2) EU policy makers and 3) **NGOs/the public**





EUROPEAN
COMMISSION

Community research

■ 'ELSA' research projects on synthetic biology (FP7)

SYBHEL; sybhel.org

- ❖ Evaluation of the impact of SynBio on human health/well-being;
- ❖ Research on cross-cutting themes: the definition of SynBio, scientific research, safety and justice;
- ❖ Create a hub for all researchers and policy-makers interested in ethical, legal and social issues arising in SynBio as it applies to human health **to meet and exchange ideas**;
- ❖ Recommendations for regulation and commercialisation of SynBio as it applies to human health and well-being;
- ❖ Determine a strategy for **policy deliberation** on SynBio





EUROPEAN
COMMISSION

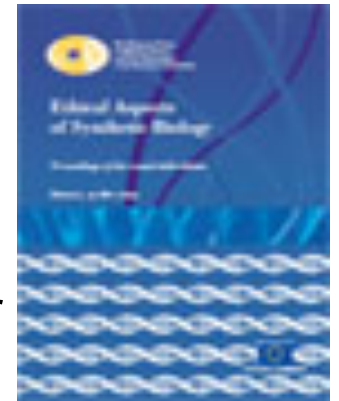
Community research

■ *'Support Actions'* focusing on capacity building, infrastructures, networking, exchange of best practice
(NOT SPECIFICALLY FOCUSED ON SYN BIO)

❖ Forum of National Ethics Councils; in dialogue with the EGE and International Dialogue on ethics

❖ European Network of Research Ethics Committees (EUREC)

Networking and providing training for members of Research Ethics Committees (RECs)



❖ Specific actions, e.g. *EC-UNESCO Conference 'Joint Action for Capacity Building in Bioethics'* , *Global Forum on Bioethics in Research*, etc.





EUROPEAN
COMMISSION

Community research

■ 'Mobilisation and Mutual Learning action plans' - MML

(NOT SPECIFICALLY FOCUSED ON SYN BIO)

- ❖ To bring together trans-disciplinary consortia
- ❖ To develop and implement multi-annual Mobilisation and Mutual Learning Action Plans
- ❖ Oriented towards a Societal Challenge
- ❖ Encompassing a series of 'Science in Society' actions





EUROPEAN
COMMISSION

Community research

Some challenges for communicative and soft law approaches in Synthetic Biology





EUROPEAN
COMMISSION

Community research

A Code of Conduct for Synthetic Biology?

A code has been developed by industry, but for DNA synthesis only: is this adequate and sufficient?

- If not, what warrants an additional specific Code for Synthetic Biology? – i.e. what should such a code address? (is there a need for a specific synbio governance and ethics?)

But how effective can a Code of Conduct, addressing mainly (self-identified!) professionals, be in an age of '**DIY**', '**garage**' **synthetic biology**?

- If synthetic biology truly becomes 'citizens' science', then wider engagement actions become even more warranted

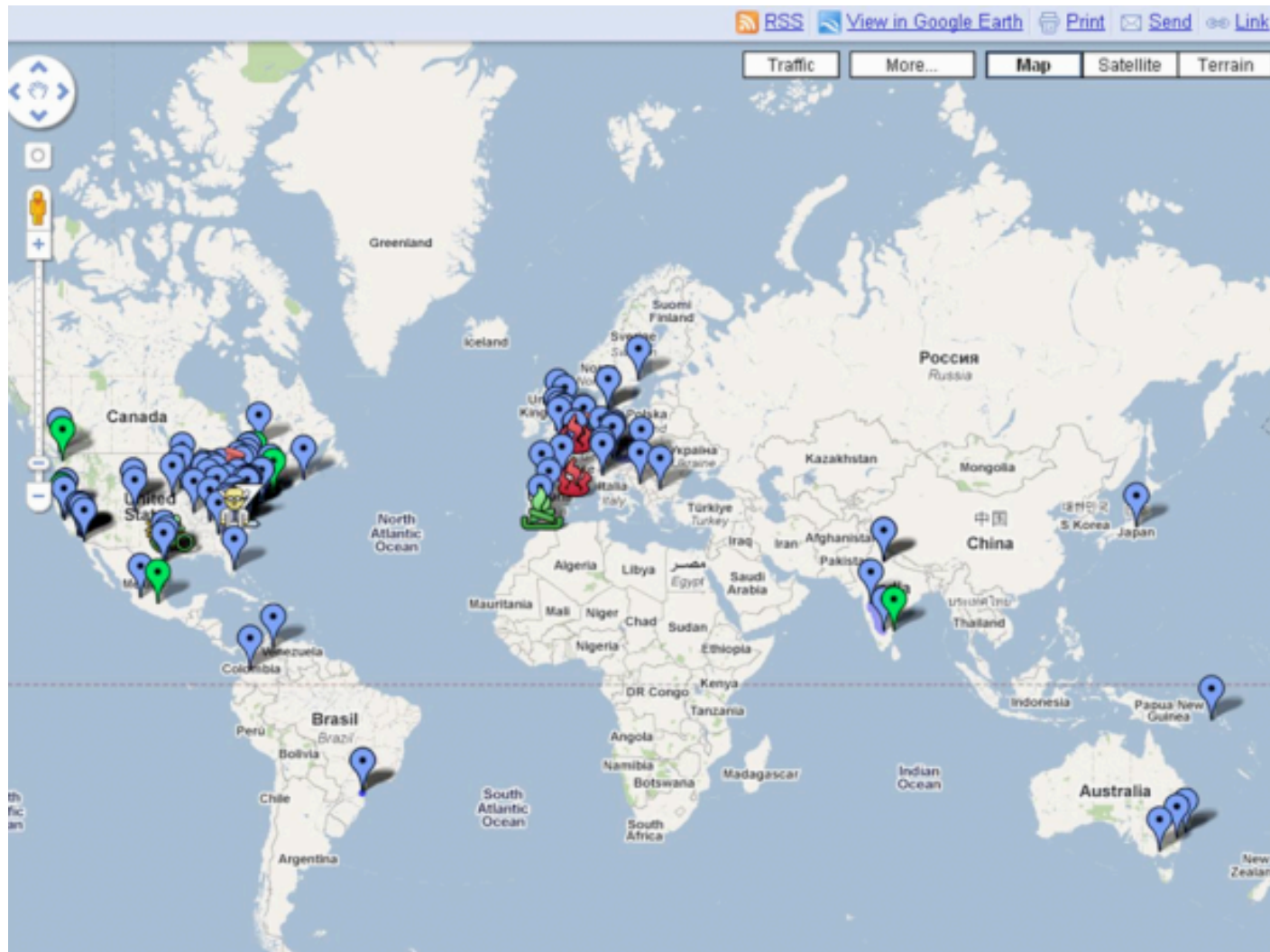




EUROPEAN
COMMISSION

Community research

Diybio.org:





EUROPEAN
COMMISSION

Community research

The Achilles' heel of public engagement/ dialogue

Timing and Framing:

■ **Timing** (:reflecting Collingridge's dilemma)

- too early: little societal and political interest (e.g. dialogue efforts in NL on Synbio)
- too late: too much polarisation and vested interest to have an open dialogue that can still give direction to policy decisions

■ **Framing**

- *Top Down*: danger of government control, limited connection to public concerns
- *Bottom up*: danger of stakeholder hijacking, limited connection to policy decision making





EUROPEAN
COMMISSION

Community research

The Achilles' heel of public engagement/ dialogue (2)



MIND THE GAP

in framing and language when collaboration between:

- *Synbio scientists and civil society/citizens*
- *Synbio scientists and social scientists/ethicists*
- *ethicists and civil society/citizens ("playing God")*

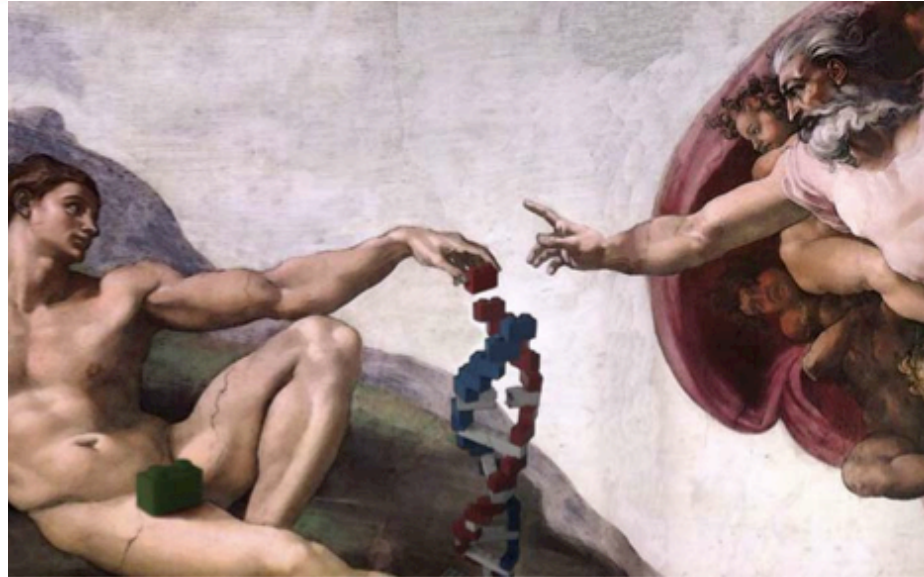




EUROPEAN
COMMISSION

Community research

“Playing God”



EXTREME GENETIC ENGINEERING

An Introduction to Synthetic Biology

January 2007





The Achilles' heel of public engagement/ dialogue (3)

Both timing and framing of societal dialogue on synbio require careful consideration:

➤ When?

- Society is largely still unaware about synbio and;
- No 'real' synbio consumer products on the market

➤ About what?

- Biosecurity? Health and environmental safety? Sanctity of life? Scientific hubris? Equity?
- At this point societal concerns are not well identified, let alone focalised
- But terms like 'designing life' or even 'synthetic biology' itself can become perceived as reflecting a framing (:on the part of the synbio community) that is insensitive to societal concerns



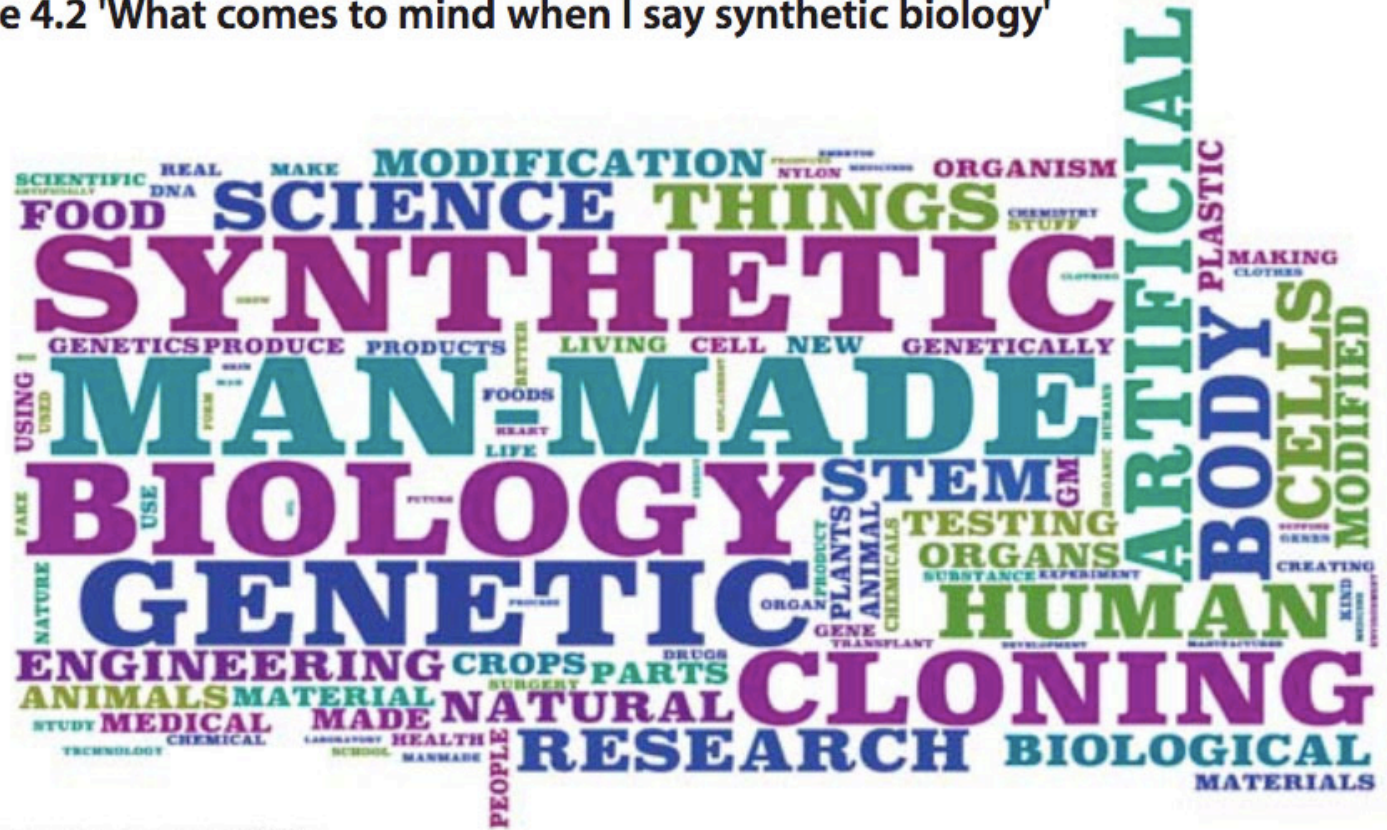


EUROPEAN COMMISSION

Community research

2009 UK Royal Academy of Engineering public opinion survey:

Figure 4.2 'What comes to mind when I say synthetic biology'



Base: All respondents (1,005)





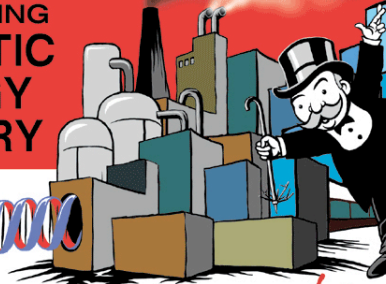
EUROPEAN COMMISSION

Community research

SYNDUSTRY

The news of "Synthia," the world's first human-made species, is just the latest from a rapidly growing artificial life industry. Synthetic biology (or "Syn Bio") aims to profit from the design and construction of industrially useful life-forms.

THE EMERGING SYNTHETIC BIOLOGY INDUSTRY



Syn Bio's Big Shots

Global corporations are investing in synthetic biology labs and partnering with start-up companies.

"Over the next 20 years synthetic genomics is going to become the standard for making anything." - Craig Venter

Cargill
Agribusiness giant. Supports synthetic biology R&D.

BP Energy giant. \$500 million partnership on synthetic biology with University of California Berkeley; holds equity stake in Craig Venter's Synthetic Genomics, Inc.

Du Pont
Chemical giant. Developed first commercial syn bio product with Genencor and sugar giant Tate & Lyle - a fibre called Sorona.

Pfizer
Pharma giant. Conducts in-house syn bio research for drug development.

Virgin Group
Includes Virgin Fuels, investor in synthetic biology. Controlled by celebrity billionaire Richard Branson.

Synthetic Startups

A bevy of 'pure play' syn bio companies is attempting to design synthetic microbes for fuel, chemicals and drugs. Many are university spin-offs.

gevo
(USA) Developing synthetic biofuels with support from Virgin.

Mascoma (USA)
Developing synthetic biofuels.

Synthetic Genomics (USA)
Constructing synthetic life forms for biofuels and carbon sequestration.

LS9 (USA)
Developing synthetic biofuels and industrial chemicals.

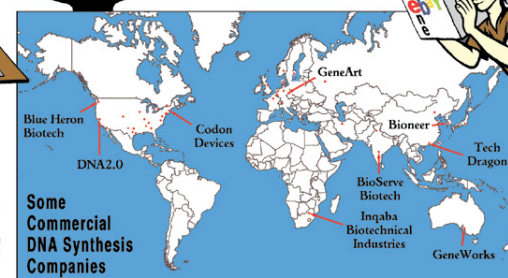
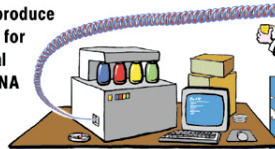
AMYRIS BIOTECHNOLOGIES
(USA) Developing cellular factories to produce drugs, fuels and industrial chemicals.

ProtoLife
(Italy) Developing synthetic living systems.

DNA Synthesis Foundries

DNA foundries produce the raw material for creating artificial life: synthetic DNA (sDNA). Over 70 DNA foundries

worldwide manufacture sDNA for genetic engineers and synthetic biologists. The market for sDNA already exceeds a billion dollars annually. Even long DNA sequences - entire genes, for example - can be ordered over the Internet and delivered within two weeks. The speed of producing accurate DNA sequences is doubling every two years and costs are halving even faster.



Published by ETC Group Dec 2007 Artwork by Shtig
www.etcgroup.org



'wild cards' in public framing





EUROPEAN
COMMISSION

Community research

The Achilles' heel of public engagement/ dialogue (4)

- To answer the `when` and the `what` question, further research on public and stakeholder concerns is needed





EUROPEAN
COMMISSION

Community research

Engagement necessary to realise the societal potential of Synthetic Biology

Summarising:

- Research, dialogue and policy action about concerns beyond risk assessment are warranted;
- Engagement approaches have to play an important role in addressing the governance and ethics challenges of synthetic biology





EUROPEAN
COMMISSION

Community research

Thank you for your attention

Contact:

Dr. Lino Paula

Policy Officer, Governance and Ethics Unit

European Commission, Research Directorate-General

Directorate L: Science, Economy and Society

SDME 7/80

Tel. (+32-2) 2963873 Fax. 2984694

lino.paula@ec.europa.eu