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***Synthetic Biology Workshop:
From Science to Governance
18/19 March 2010***

EC Initiatives on the governance and ethics of new and emerging technologies: the case of Synthetic Biology

**European Commission
Research DG**

**RTD-L3 - Governance and Ethics
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Content:

- What policy instruments to address emerging technologies?
- The Research DG approach to governance and ethics
- Current activities and a prominent example addressing another emerging technology: the Code of Conduct for Responsible Nanosciences and Nanotechnologies Research
- Some challenges for policy makers in addressing the governance and ethics of Synthetic Biology





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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?**





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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 be aspirational as well





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Converging Technologies (3):

- Past experiences with e.g. genetic engineering 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.





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The approach of the Research DG

General philosophy behind the governance approach of the Research DG:

- *'Upstream' two-way dialogue with and engagement of 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*





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The approach of the Research DG

Actions supporting the engagement 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





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

SYNTH-ETHICS

- ❖ 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**





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

SYBHEL

- ❖ 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





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- *'Support Actions'* focusing on capacity building, infrastructures, networking, exchange of best practice
(Not specifically focused on synbio!)

- ❖ Forum of National Ethics Councils; in dialogue with EGE and International Dialogue on ethics (:Bureau of European Policy Advisors, BEPA activities)

- ❖ 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.





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The approach of the Research DG

Actions supporting the soft-law approach:

(Not specifically focused on synbio!)

- 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





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An example that addresses another emerging technology:

The Commission's Recommendation on a
**Code of Conduct for Responsible Nanosciences and
Nanotechnologies Research**

- 1. Chronology: Main Milestones**
- 2. Content of the Recommendation**
- 3. Next steps**
- 4. Administrative requirements**





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The Commission's Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research

1- CHRONOLOGY: Main Milestones

2004: Towards a European Strategy for Nanotechnology, COM(2004) 338, 12.5.2004

2005: Nanotechnologies Action Plan, COM(2005) 243, 7.6.2005

2008: Recommendation on a Code of Conduct, C(2008) 424, 07.02.2008

2008: Regulatory Aspects of Nanomaterials, COM(2008) 366, 17.6.2008

2008: Council Conclusions on Responsible Nanotechnologies, 26.09.2008

2009: Resolution of the European Parliament, 24.04.2009





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The Commission's Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research

2- CONTENT OF THE RECOMMENDATION

GENERAL PRINCIPLES

- (1) **Meaning**
- (2) **Sustainability**
- (3) **Precaution**
- (4) **Inclusiveness**
- (5) **Excellence**
- (6) **Innovation**
- (7) **Responsibility**





The Commission's Recommendation on a
Code of Conduct for Responsible Nanosciences and Nanotechnologies Research

ACTIONS TO BE TAKEN (27)

– Good governance of the N&N research (17)

- Stakeholders awareness, (7)
- Favours an inclusive approach (3)
- Key priorities (4)
- Prohibition, restrictions or limitations (3)

– Due respect of precaution (7)

- Protection of people (4)
- Reduction of uncertainty (3)

– Wide dissemination and monitoring (3)





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The Commission's Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research

To sum up:

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





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The Commission's Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research

3- NEXT STEPS

The Code of Conduct will be **reviewed every 2 years**, therefore beginning of 2010:

Series of **seminars** with Member States (Berlin, Brussels, Bucharest, Paris), Sept.-Oct. 2009

EC Public **consultation** (21/10/2009 up to 03/01/2010 – 49 answers)

Revision of Commission 'Nano' **Strategy and Action Plan** in 2010?

Implementation of **NANOCODE** project (SiS-2009-244521 – 23 months)





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Some challenges for engagement and soft law approaches in Synthetic Biology





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The Achilles' heel of public debate/dialogue

Timing and Framing:

- **Timing** (*:reflecting Collingridge's 'dilemma of control'*)
 - too early: little societal and political interest (e.g. Rathenau efforts in the NL on Synbio?!)
 - too late: too much polarisation and vested interest to have an open debate 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*





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

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? Risk? Dual use? 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 (:by the synbio community) that is insensitive or, worse, irresponsive to societal concerns





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

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





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A Code of Conduct for Synthetic Biology?

Calls for a Code of Conduct, e.g. by EGE Opinion on Synthetic Biology (No 25, 17/11/2009):

“A Code of Conduct for research on synthetic microorganisms should be prepared by the EC”

Two Codes have been developed by synbio industry, but for gene synthesis only: are these adequate and sufficient?

- If not, what justifies 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?)
- Do we require a more `general` Code like the Nanocode?
 - Do synbio and nanotechnology merit a similar Code?
 - Should we then have a Code (or even one Code?) for each emerging technology?





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A Code of Conduct for Synthetic Biology? (2)

How effective can any Code of Conduct, addressing mainly professionals, be in an age of '**DIY**', '**garage**' synthetic biology?

- If synthetic biology truly becomes "citizens' science", then wider engagement/communicative actions become even more justified





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Governance and ethics 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 in general, but also concretely in addressing risk assessment and future regulation (: binding law)





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