

# **SynBio Governance approaches : Lessons from nanotechnology**

1

**Synthetic Biology Workshop : From Science to Governance**

**European Commission, DG for Health and Consumers**

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# From Nano to SynBio : Why ?(1)

## Transformative, platform technologies

2

- Nanotechnology relies on an **evolving** « **toolbox** » (enables to see, interpret, act, control, deliver with atomic precision, at a femtosecond time pace, including DNA applications)
- Nanotechnology has pervasive industrial applications (energy, chemistry, electronics, safety), from materials to heterogeneous systems,
- Nano-bio combination already has its own scientific and industrial roadmap (medicine, agriculture and food, energy...)
- Increasing use of Digital components, equipments and systems *for the engineering of the living*, with databases, simulation, process., CAD tools
- STANDARDS matter at all level.

## From Nano to SynBio : Why ?(2)

Also linked by high levels of complexity and uncertainty

3

- Assessment methodologies of Risks stay fragmented
- Reduction to exposure not fully monitored so that the Risk issue stays unclear
- Ethical, legal and societal risks
- A Better understanding of the **systemic approach** by communities dealing with the « Living » ( systemic Risk stays underestimated by some nanotechnology stakeholders)
- Benefits in securing energy supply and improved therapies as well as for clean technologies, understood in both case
- Shared Low level of public awareness at the beginning of the « Hype »Curve

## From Nano to SynBio : Why ? (3)

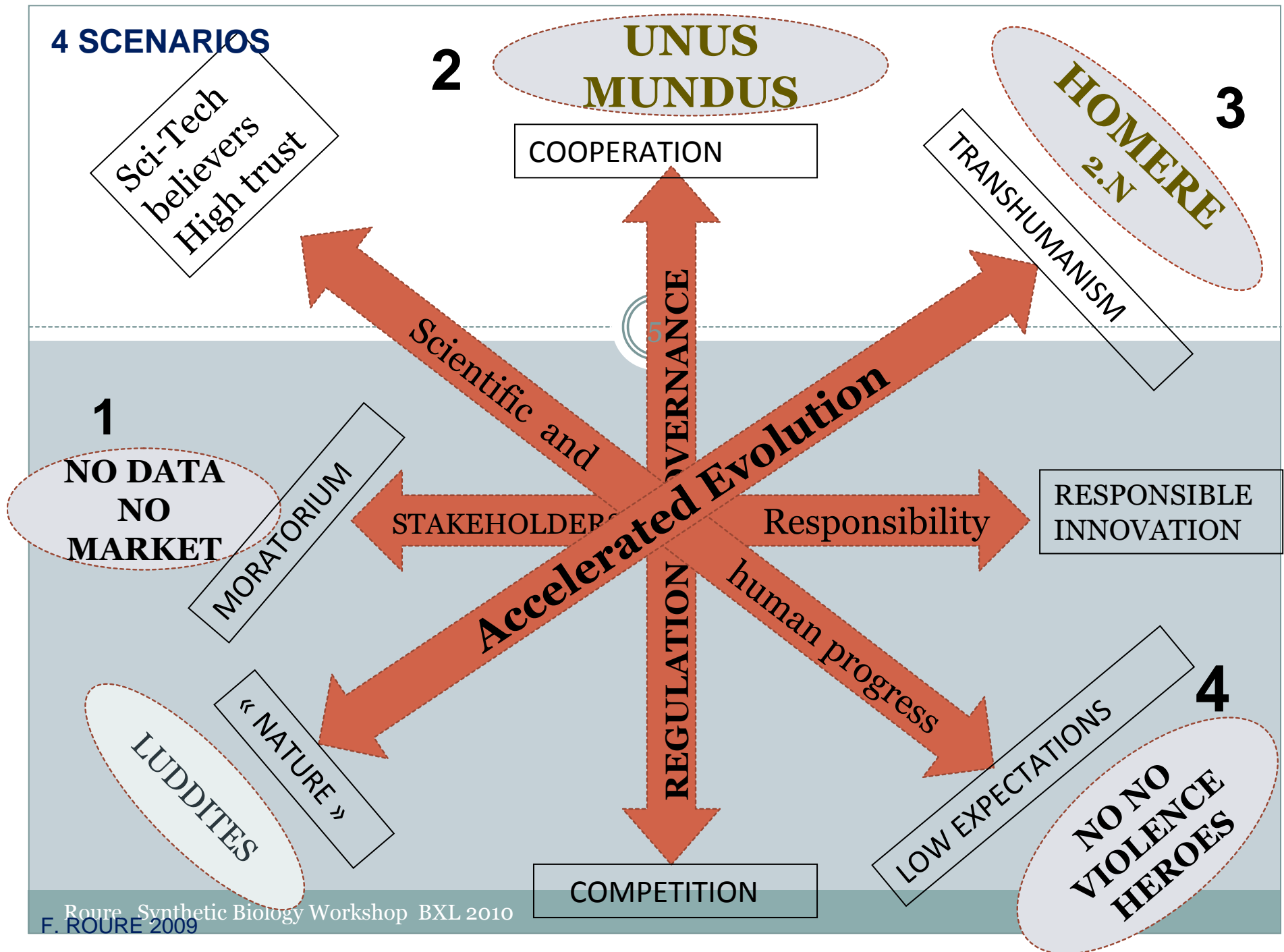
Linked ethical and governance issues in a context where  
« concerns are voiced OFF the Institutions »

4

**Debate on « Nano » for Society at large with low level of information, ends in questions for ... SynBio :**

- **FINALITY** and **PRIORITIES** for **BENEFITS** (SHARED, AFFORDABLE)
- **SOCIETY INVOLVEMENT IN CHOICE AND POWER SHARING ISSUES**  
GOVERNANCE definition (EU 2001)
- **DEMOCRATIC, ON GOING ASSESSMENT AND CONTROL** with **MEANS** adapted to Applications ( including bio-error, bio-terror)
- **OVER ALL, expression of FEARS ABOUT POTENTIALLY « Extreme » ENGINEERED DIFFERENCES AMONG HUMANS BY TECHNOLOGY**  
( Converging technologies, *SynBio*, Including concerns about MECHANISATION, or even *CUSTOMIZATION*, OF THE MIND )

4 SCENARIOS



# The European Code of Conduct (CoC) for responsible development of Nanoscience : implentation at stake

6

- Adopted by the European Commission as a recommendation, it is **hortatory**, not mandatory.
- In this CoC, Human enhancement for other reasons than therapeutics to recover from disease or accident, or maintain well being while ageing, should not be supported, and the precautionary principle should guide decisions.
- Rountable in Nov. 2008– EU DG Research with Canada, the US, Argentina,...:

« **No matter one or different Codes of conduct, if the same purpose is chosen.** »

Voluntary industrial codes of conduct for nanotechnologies stay fragmented and , except some significant exceptions, not really implemented, increasing demand of regulation from consumers.

## NSF Report on Ethics of Human enhancement

- « To be clear, there presumably will be benefits to society from enhanced persons. We can expect greater **productivity** or more creative and **intellectual breakthroughs**, which is why individuals would want to be enhanced in the first place.
- “But what remains difficult to calculate is whether these gains outweigh the costs or risks, or even the likelihood of either gains or costs—which is needed **if** we do find it sensible to use a precautionary principle to guide our policymaking.”

Source : [http://www.humanenhance.com/NSF\\_report.pdf](http://www.humanenhance.com/NSF_report.pdf) 31 August 2009

# Nano-enhanced technologies 2020 ? + CAD+BIO...

## Involvement of Technology Areas in Top 16 Technology Applications

Technology Applications	Bio	Nano	Materials	Information
Cheap solar energy	X	X	X	
Rural wireless communications		X	X	X
Ubiquitous information access		X	X	X
GM crops	X	X		
Rapid bioassays	X	X	X	X
Filters and catalysts	X	X	X	
Targeted drug delivery	X	X	X	X
Cheap autonomous housing	X	X	X	X
Green manufacturing	X	X	X	X
Ubiquitous RFID tagging			X	X
Hybrid vehicles		X	X	X
Pervasive sensors	X	X	X	X
Tissue engineering	X	X	X	
Improved diagnostic and surgical methods	X	X	X	X
Wearable computers		X	X	X
Quantum cryptography		X	X	X



# Synthetic biology, 4th generation of nanotechnology roadmap? Definitions matter for governance issues.

9

- Referring to NSF/ Mihail Roco presentation about the technological roadmap: Syn Bio as part of the 4th and following generations of nanotechnology applications (heterogeneous systems)
- Synthetic biology has been defined by the European Consortium Synbiology in 2006 as « the engineering of biological components and systems that do not exist in nature and the re-engineering of existing biological elements ».

The British Royal Academy of Engineering has adopted in May 2009 the following definition: « Synthetic biology aims to design and engineer biologically based parts, novel devices and systems as well as redesigning existing, natural biological systems »

Semantics, language and terms are recognized as an issue by OECD/CSTP/WPB, with possible international cooperation.

Inappropriate definitions can lead to inappropriate, divergent regulations.

# Governance Approaches: Points for consideration

10

Learning from the past : elaborating on governance failures and experience

- Trade, Trust, and Safety at the origin of international dialogues addressing Nanotechnology Governance

- Metrology, Characterization and Standards issues, relevant for Nano at International level, the same for Synthetic Biology emerging dialogues in in a context of highly Concentrated Industries and dual use strategic issues.

- Societal Conflicts as well as *overlapping* research are costly and inefficient.

- What have we learned from international dialogues on nanotechnology governance issues ?
- Nature of International dialogues for Synthetic Biology ?
- Could and Should the European Union move forward? How?

# Matters of concerns/interest at the origin of International Dialogues in Nano and Synbio

11

- Tariff and non tariff barriers to international trade.
- Fears of unknown Toxicity and EcoToxicity of synthesized nanoparticles / Bioparts and networks...
- Knowledge Gaps and Perception gaps
- Scientific deadlocks and missing tools for international cooperation
- Standardization as a key factor to dramatically decreasing production costs and foster industrialisation, jobs, sustainable markets, qualitative growth.
- Intellectual property protection *versus* open innovation.
- Vertical *versus* horizontal regulations
- **The specific ELSA issues inherited from Nano-bio-IT convergence : Synthetic Biology and beyond:**
  - Time to rewrite the code of Life ? Diversity *versus* Conformism...
  - Setting new boundaries for the « common heritage of humankind »?
  - Benchmarking existing frameworks
  - Drawing the relevant Cascade of Responsibilities among stakeholders.
  - Accessing the THE KNOWNNS WE DON'T KNOW ( *i.e don't share*) for some voluntary ( biosafety and terror, defense and security, industrial secrets) or involuntary reasons (ex : fragmentation of initiatives for Databases)

# **Informed Trust:** a pre-requisite for responsible development of applications and related markets (nano, synbio)

12

- Technical and industrial roadmaps must meet a market to be successful;
- Markets depend on the willingness of customers to adopt and buy innovative products and processes;
- This willingness on the demand side relies on the level of trust given to supply side; then on economic conditions: lowering price, lowering scarcity.
- In an open, globalized market, international, Multistakeholders Dialogues , provide a unique opportunity to improve the conditions of an informed trust.
- **Co-evolution of Science, technology and Society is Key for the successful development of opportunities open by nanotechnologies and SynBio.**

For Nano as well as for SynBio, unlike the « engineering of consent » ([Edward Bernays](#)), Informed Trust is an answer to the « Heuristics of Fear » ([Hans Jonas](#))

# The typology of Pre-normative, Governance Dialogues :

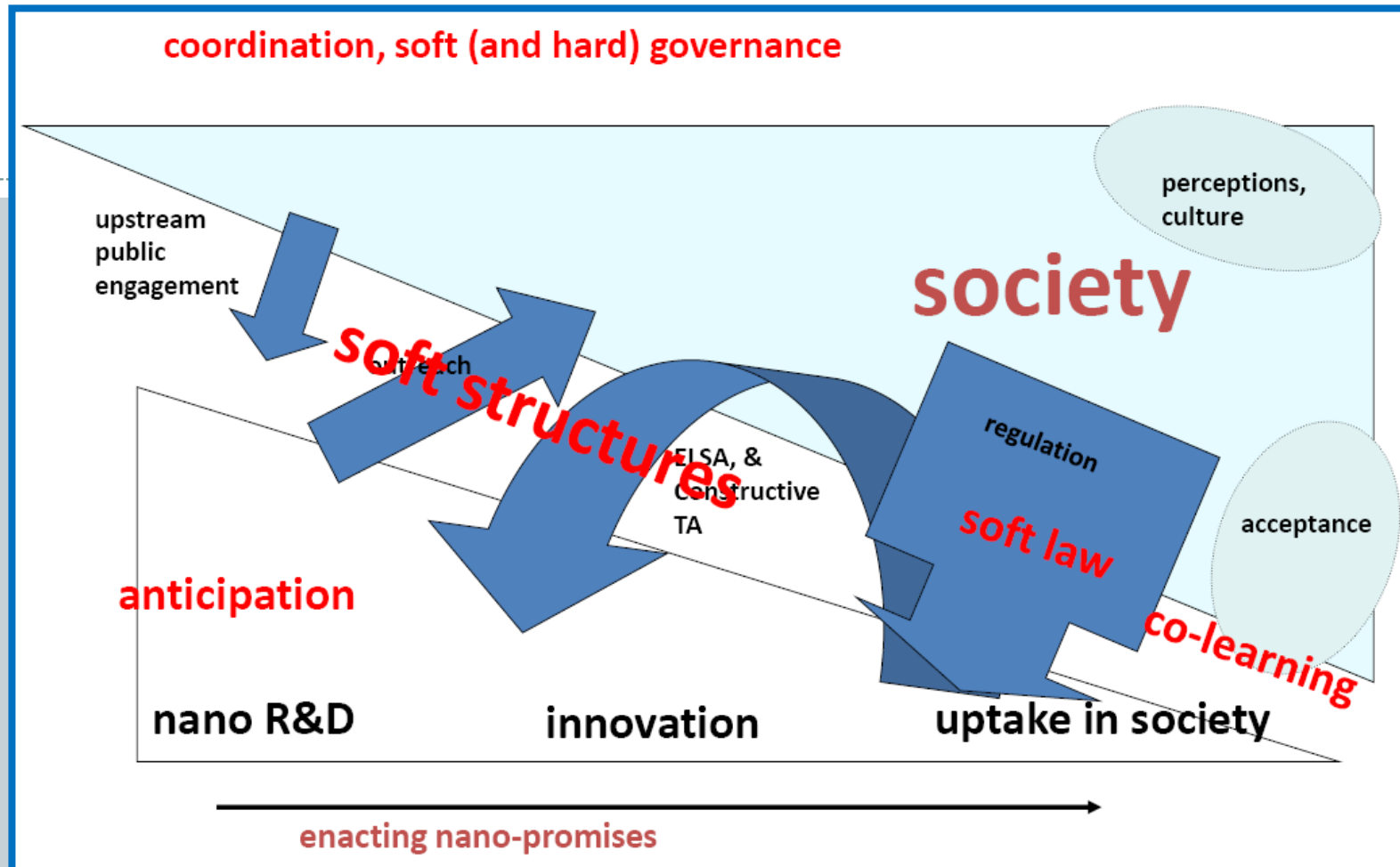
13

## Some criteria for clarifying the nature of Pre-Normative, International «Dialogues »:

- - Inclusive, *versus* restricted to « Club » membership
- - Formal ( legal basis, Treaty, Agreement ), *versus* Informal
- - Focused, *versus* valuing Broader issues
- - Short term, *versus* Long term, Foresight oriented
- - Public (Hard Law and incentives), *versus* Private (Soft Law)
- - Consensus oriented , *versus* voluntarily designed for expression of diversity and differences (conflicting views and interests) as a valuable approach for public policy decision makers.
- - Global *versus* local, by all relevant levels of subsidiarity
- - Reflexive, *versus* of hierarchical type

# What do we mean by « Reflexive governance » ? (Arie RIP, NL)

14



**Reflexive ethics, prerequisite for a reflexive governance**

# Inclusiveness, as a long lasting challenge in International Dialogues dealing with Nano Governance issues

15

- Inclusiveness has been challenged by « DIVIDES »
  - language as a barrier for access to knowledge and consequently as a barrier for taking active part to Dialogues themselves
  - level of awareness on benefits and challenges coming from the systemic nature of risks , stay related to the level of economic and scientific development
  - Patent thickets exclude innovative players
  - Financial cost of participation to International Fora (ex: ISO)
  - North-South Divide takes time to bridge by **Lack of Understanding of potential benefits from a coordinated, synchronized agenda between UN specialized international organizations having an interest in Nanotechnologies for development / green new deal...**

# International Dialogues including Nano Governance issues, SYN BIO without Structured Dialogue for Governance.

16

1. INTERNATIONAL DIALOGUE FOR RESPONSIBLE DEVELOPMENT OF NANOSCIENCES AND NANOTECHNOLOGIES ( GLOBAL)
1. ISO TC 229 (ISO IS AN OPEN NGO!) (STANDARDS)
2. OECD (WPMN, WPN) (ECONOMY AND POLICY), WPB (biotech)
3. UN / UNESCO (Nano-ethics), + UNEP, UNIDO, UNITAR, UNDP...FAO, ILO, and Liaison with NGOs at UN Headquarters
4. IFCS (NANOMATERIALS, INTERGOVERNMENTAL FORUM ON CHEMICAL SAFETY)
5. OTHER DIALOGUES ( ICON, GNN, IRGC, GDNP, REGIONAL DIALOGUES IN EUROPE, ASIA, SPECIFIC DIALOGUES , EX:–INDIA-SOUTH AFRICA-BRAZIL), BETWEEN SCIENTISTS, INDUSTRY,...

For SYN BIO, fragmented Fora (IASB, US-NAS/OECD-WPB...)



# Results of the 3rd International Dialogue on responsible development of N&N 2008

17

Intergovernmental, Inclusive, informal Dialogue, AKA the « AlexandriaProcess » since 2004

- “**Nano**” issues stay **locked** in the « **chemical agenda** » : nanomaterials of 1st generation
- Call for an inclusive dialogue for a structured dialogue on responsible development of nanotechnology, including patent aspects, dynamic assessment,...**Proposal of the creation of an Intergovernmental Panel on nanotechnology-induced change**, expressed in a Keynote lecture related to nanotechnology global governance.
- Presentation of the European **Code of Conduct for Research, towards its internationalization**. Interest for this non legally binding, but nevertheless « aspiring » document, from several countries
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# Nano Standards: Main issues within ISO TC 229

18

- ❑ WG 1 : Terminology and nomenclature (Canada),
- ❑ WG 2 : Measures et characterization (Japan),
- ❑ WG 3 : Health, security and environmental aspects (USA),
- ❑ WG 4 : Nanomaterials specifications (China)

## Examples of Specific tasks :

- ✓ Terminology and nomenclature , the questions of Ontology and Nomenclature
- ✓ Metrology, test methods on cooperation with OECD
- ✓ Modelisation and simulation
  
- ✓ Specific Task Group for Consumers and Citizens expectations from Nano-standards ( US NNCO lead : Clayton Teague).




Inspiring a potential International standardization initiative for SynBio? ISO+CEN ?

# Main challenges faced by ISO for Nano, relevance for SynBio

19

- A limited mandate in time : to be renewed.
- A great difficulty with **terminology** issues, highly dependant of instruments and tools for metrology and characterization
- **Absence of a knowledge tree** for interoperable ontology and taxonomies in different fields of application (*IT, Food, Materials, Energy, Pharmaceuticals, Clothing, Aerospace and automotive industries, Forest and paper products....SYNBIO ?*). **DICOM concept could be helpful here.**
- **« Pollution » of discussions among stakeholders by the regulatory uncertainties as regards definitions**
- **IPR conflicts of interest for definitions and characterizations**

 Prefiguration of a deeper and harder debate for synthetic biology standardization (Parts, Processes, Networks and Systems + Dynamics 4D)

- An early interaction with Scientists is crucial integrate new knowledge. *Otherwise, even teaching will be a challenge...*

# The specific question of Taxonomy at the center of international standardization for Nano. Challenge for SynBio.

20

## The Logic Cascade :

- ontology

-taxonomy

-terminology

-definitions

-representation

must be set in a fully coherent, participative and dynamic way.

Stakes : the capacity of teach, design, research, innovate, regulate, protect (IP), produce, evaluate, cooperate, even compete...on a level playing field.

Avoiding conflicts and overlappings means saving time and money.

# International Standards for empowering the engineering of useful synthetic biological systems ? Conditions ?

21

## **Standardization for reducing time and cost for industrialization:**

« the biological engineering community would **benefit** from the development of technologies and the promulgation of standards that support the definition, description and characterization of the basic biological parts » (Drew Endy, MIT 2005, « Foundations for engineering biology », Nature.

The Registry of Standard Biological Parts was relying on initial open source concept. « Naïve » approach or Sustainable approach?

How coming to an agreement on the perimeter of open source and the one covered by IPR? Parts? Devices? Beyond?

## The « Registry »? : Towards an integrated , generic model available for all stakeholders ?

22

- In Synthetic Biology, simulation and modeling are used as the basis of engineering applications.
- Is a single international Registry for standard biological parts needed ?
- If yes, the question of a **good governance** for meeting public interest is at stake: transparency, ethics, participation to decision making, independance, control.
- **This governance should be designed at the international level on an inclusive way, ensuring a fair representation and balance of power along stakeholders.**
- Learning from the ICANN-IANA Global Internet Governance *reference* ...

## Outcomes and Limits to OECD efficiency in dealing with global nano /synbio global governance issues :

23

- OECD is **not fully inclusive** and WPN develops among voluntary contributions : not all country members are involved;
- OECD generally considers that there is no need for a global regulatory framework specific to nanotechnologies; this position is challenged by civil society represented by well known NGOs ( for example, Friends of the Earth, ETC Group, ...)
- OECD can influence policies by **recommendations** , by adoption of standards, by creation of specific agencies , and as a « Pace setter ». No legislative and enforcement powers, but well-known **ability to provide Benchmarking** and homogeneous indicators
- **OECD position about traditional IPR issues is challenged by the ‘open innovation’ concept, and ‘reflexive governance’ societal aspirations.**
- OECD organization splits nanotechnology and biotechnology in separate areas , which prevents it from creating an institutional, intergovernmental anticipation for synthetic biology policy issues. This could be changed...

# Risks related to Synthetic Biology expressed by public debates/ Fora

24

- **1. The Human factor :**

- Biohackers , illicit bioeconomy of synthetic drugs, Bioterror
- « Garage » Biology
- DIY Do-It-Yourself Biology: naïve or under due training and control ?

- **2. The Unknowns / Bio errors**

Toxicity

Ecotoxicity

Reversibility

Resilience and predictability of behaviour

Proliferation

- **3. The systemic, long term nature of risks from Nano, CTs and Synthetic biology with ethical, societal issues**



# Preliminary lessons for SynBio Global Governance learned from SynBio Fora and Projects

25

- Synthetic biology, combining the inert and the living, has a **potential huge return on investment**
- **Constructing the public sphere** is necessary before public engagement in a reflexive governance
- Synthetic biology is part of a broader, dynamic, multidisciplinary Risk **Assessment Methodology**
- Controlling DNA Synthesis must be achieved international, relying on screening tools of orders, to be effective. (Companies, IASB...)

Key words *heard* for a successful international model of SynBio governance :

**Responsibility, Equity, Ownership, Security, Humanity**

# The Review related to EHS Transatlantic NANO regulations (LSE report 2009)

26

- Principles tested to coordinate EHS Regulatory approaches
  - Regulatory flexibility
  - Precautionary principle : only a tool for « practitioners? »
  - Technological innovation
  - Mutual recognition' in international trade
  - Disclosure of EHS-relevant data and test methods
  - Voluntary or mandatory labeling schemes
  - Equity with respect to access to nanotechnologies in developing countries
  - Public involvement

And : « *Is there a need to create new institutions or Fora for an adequate Transatlantic Dialogue?* » NO, BUT... (strong limits observed to existing structures)

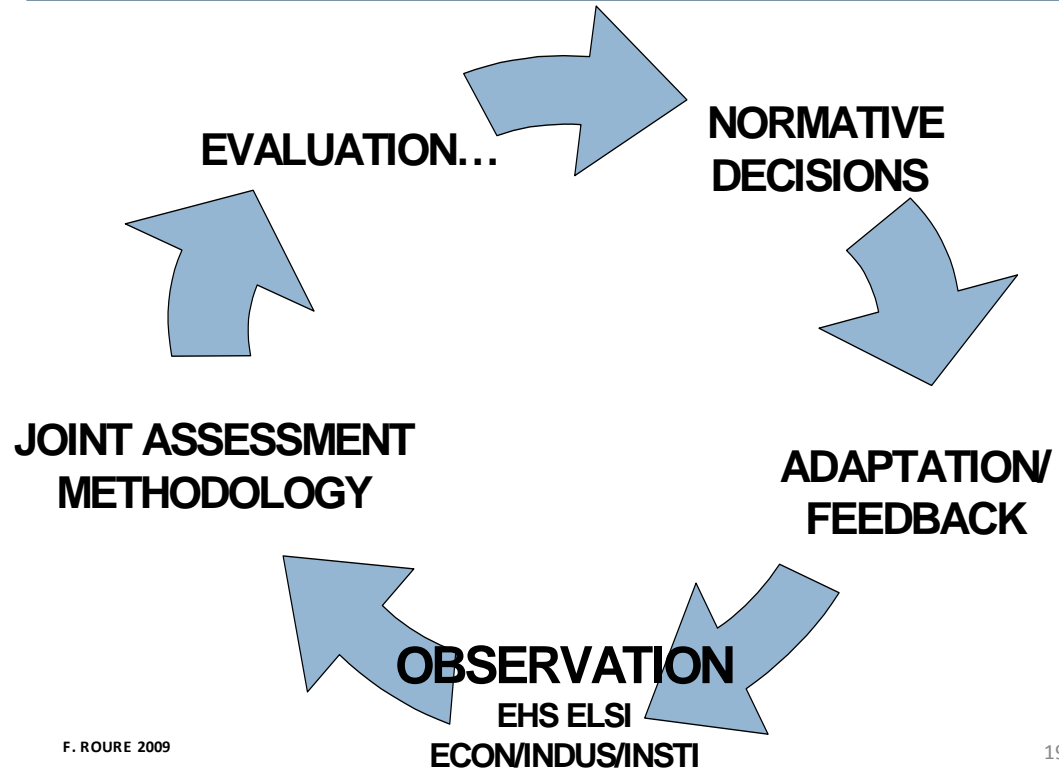
# The Nanotechnology Governance Continuum to be considered as a generic concept for Synbio Governance ?

27

What we have learned from

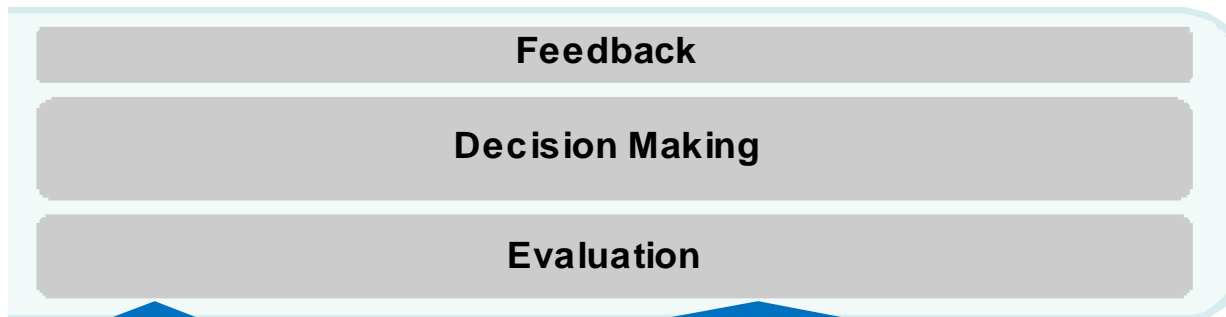
**FramingNano  
and  
ObservatoryNano**

## The Nanotechnology Continuum for a sustainable Governance Model



19

D  
M  
B



Provide  
Common  
Assessment  
Methodology

Provide Advice, Visions and Actions

### Advisory

Develop Advice for Decision-Makers

Provide State of the Art Observations

### Observatory

Identification of the State-of-the-Art Knowledge  
on Nanotechnology-Induced Change

TECH EHS ELSA ECO SEC ...

Peer-Reviewed  
Scientific, Technical and  
Socio-Economic  
information

### Common Assessment Methodology

Identification of Relevant Priorities,  
Principles & Values (ex. risk/benefit evaluation, EHS and ELSA priorities, societal  
desirability, etc.) to Assess Nanotechnology Induced Change

Stakeholders and Public  
engagement

DELIB.  
PANEL

## CONCLUSION for Nano and Synbio Governance approach

29

- 1) **Addressing the Governance issues with Dialogues, at all levels of subsidiarity, lowers the global level of uncertainty and secures investments**
- 2) **Inclusiveness and Information sharing are critical**: What « we-don't-know- we- know » will be a liability for innovation and trust :
- 3) **Investing in a Governance Continuum is safer and cheaper** for all stakeholders : joint assessment, « designed for differences » methodologies are key for success. *Conflicts can destroy markets.*
- 4) **Industry, skilled jobs, safety and security stakes require a high level of awareness** from public policy makers.

In the EU, with the societal impact of unemployment, opting for a **new paradigm in Emerging technologies such as Nano and SynBio Governance can pave the way for an attractive model of re-industrialisation and qualitative green growth**, for its citizens, and a reference in a globalized, multipolar World.

# **SynBio Governance approaches : Lessons from nanotechnology**

30

**Thank you for your attention**

**Synthetic Biology Workshop,  
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## Disclaimer

31

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