Rathenau Instituut

14 July 2010 RoSBNet Workshop Oxford UK

Technology Assessment

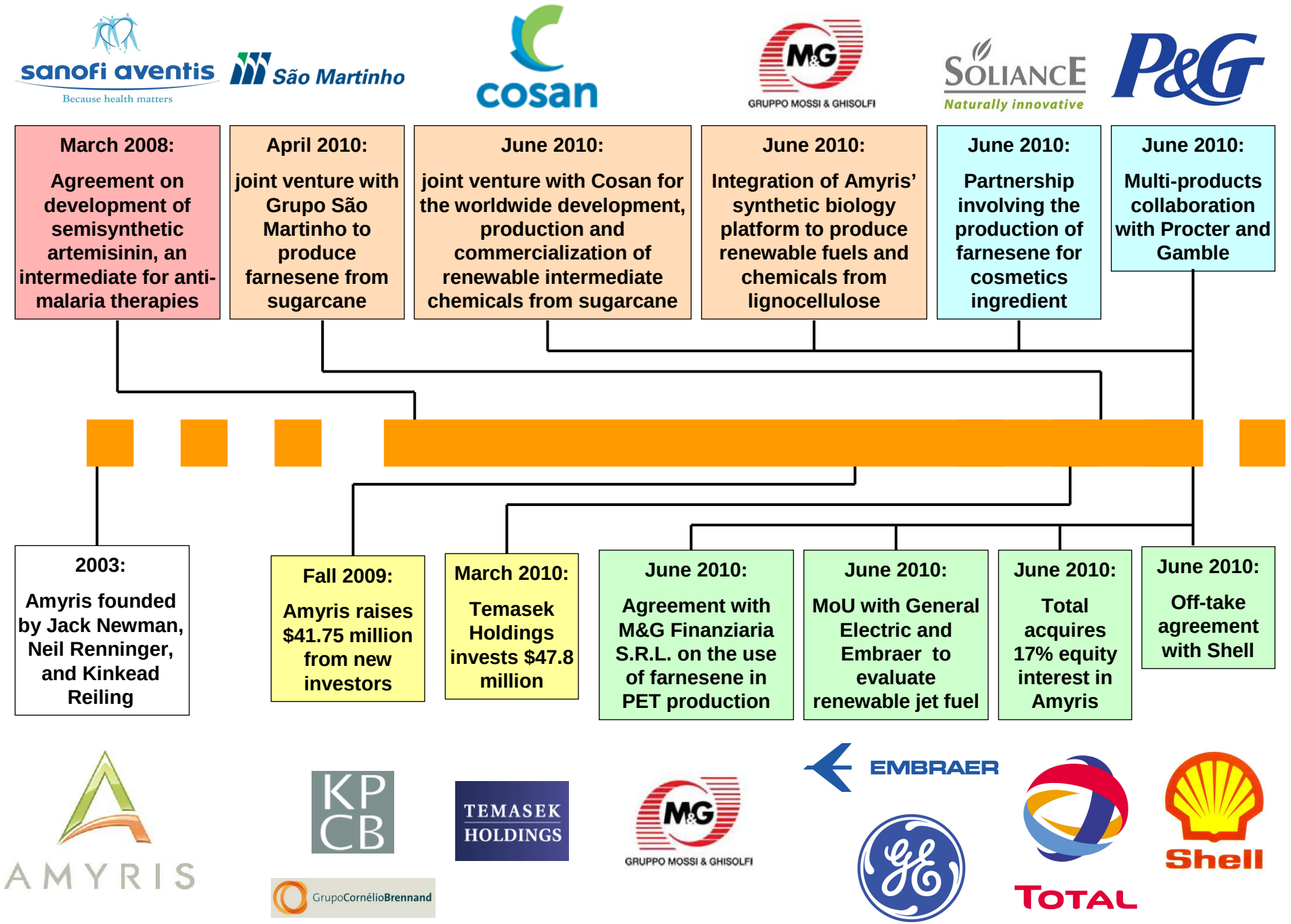
Societal implications of synthetic biology: the challenge of 'responsible innovation'

DIRK STEMERDING

Structure of my presentation

Rathenau Instituut

- Activities of Rathenau Institute relating to technology assessment of synthetic biology
- Technology assessment as contribution to ‘responsible innovation’ in the field of emerging technologies
- Challenges for responsible innovation in synthetic biology


March 2008:
Agreement on development of semisynthetic artemisinin, an intermediate for anti-malaria therapies
April 2010:
joint venture with Grupo São Martinho to produce farnesene from sugarcane
June 2010:
joint venture with Cosan for the worldwide development, production and commercialization of renewable intermediate chemicals from sugarcane
June 2010:
Integration of Amyris' synthetic biology platform to produce renewable fuels and chemicals from lignocellulose
June 2010:
Partnership involving the production of farnesene for cosmetics ingredient
June 2010:
Multi-products collaboration with Procter and Gamble
2003:
Amyris founded by Jack Newman, Neil Renninger, and Kinkead Reiling
Fall 2009:
Amyris raises $41.75 million from new investors
March 2010:
Temasek Holdings invests $47.8 million
June 2010:
Agreement with M&G Finanziaria S.R.L. on the use of farnesene in PET production
June 2010:
MoU with General Electric and Embraer to evaluate renewable jet fuel
June 2010:
Total acquires 17% equity interest in Amyris
June 2010:
Off-take agreement with Shell
sanofi aventis
Because health matters
São Martinho
cosan
GRUPPO MOSSI & GHISOLFI
SOLIANCE
Naturally innovative
P&G
AMYRIS
KPCB
GrupoCornélioBrennand
TEMASEK HOLDINGS
GRUPPO MOSSI & GHISOLFI
EMBRAER
TOTAL
Shell

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Emerging Technologies

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Emerging technologies as a potentially transforming power in society:

growing capabilities to engineer (human) life through a *convergence* of nano-, bio-, info-, and cognitive sciences

- Making Perfect Life: collaborative project for European Parliament (2009-2011)
- Nanotechnology: Dutch nano-dialogue (2010)
- *Synthetic biology*: work in progress

SynBio on the political agenda

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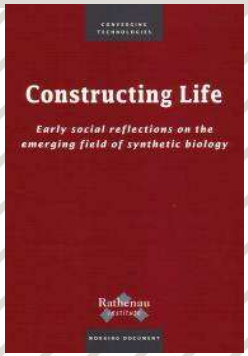
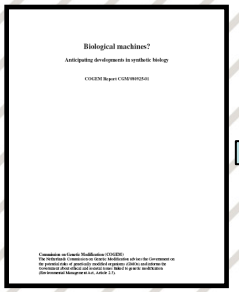
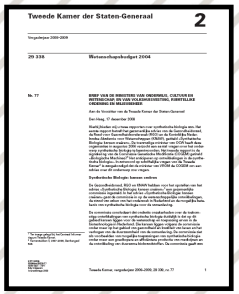
- Exploring



- Participating:
  synbio 2.0 & 3.0 / public debate

- Putting in context:
  convergence





- Agenda setting

Message to the Parliament

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- Biosafety
  - Consider need for revisions of current GMO regulation (COGEM)
- Misuse & bioterrorism
  - Pay attention to international regulation of DNA-synthesis
  - Increase awareness of researchers (code of conduct)
- Patenting
  - Consider options for ‘open source’ approaches
- Ethics & society
  - Create space for public involvement

TA of SynBio:
current and future activities

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Publications

- Constructing Life. Early social reflections on the emerging field of SB (2006)
- SB and the role of civil society organisations. Shaping the agenda and the arena of the public debate (2009)

  (*Synthetic Biology. The technoscience and its societal consequences* Schmidt et al.)
- Life as a do-it-yourself kit (2009)

  (*NanoEthics* Vol 3, No 3)
- Ten Lessons for a nanodialogue (2008)

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Activities

- Making Perfect Life: Bioengineering (in) the 21st century (2009-2011)

  (STOA project European Parliament)
- Synthetic Genomics: Scientist's understanding of society's concerns; society's understanding of the science and scientists (2009-2010)

  (J. Craig Venter Institute, US)
- Exploring SB in Japan (2010)

  (Dutch Embassy. Office for Science and Technology)
- SB for Human Health: ethical and legal issues (SYBHEL: 2009-2012)

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Responsible innovation

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- Emerging technologies are perceived in terms of opportunities (by promoters) and concerns (by critial responders)
- Move in (EU) policy-making to 'responsible innovation' in an attempt to avoid antagonistic contestation (as in the case of GMO's)
- Government institutions in Europe (and US) propose to integrate 'ELSI' research into Nanoscience and SynBio technology programmes:
  - Understanding Public Debate on Nanotechnologies – Options for Framing Public Policy (Von Schomberg & Davies 2010)
  - SynBioSafe, SyntEthics, SYBHEL (EU funded projects)

TA as ‘anticipatory governance’

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Anticipation

Emerging technologies are shaped by visions of the future which can be made subject of TA with the aim to:

- articulate and reflect on choices in technological innovation
- understand potential future implications of emerging technological developments as a result of complex interactions between technological and societal developments (co-evolution)

Governance

Emerging technologies are shaped by a variety of actors rather than by top-down government, which means that TA should involve a variety of expert and lay stakeholders in a collective process of learning and assessment

Adressing different concerns

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Potentially disruptive nature of emerging technologies, challenging:

- established regimes of regulation
- normative conceptions in society and cultural frames of meaning

TA may contribute to the anticipatory governance of synthetic biology through:

- regulation-oriented activities, adressing issues of bio-safety, bio-security and ownership
- deliberation-oriented activities, adressing normative issues of choice, (global) justice, and (public) conceptions of 'life' and 'nature'

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Issues of SB regulation

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To what extent can we trust established regimes of regulation in governing synthetic biology?

Biosafety

Biological Machines (COGEM 2008):

For the time being no need for new safety legislation…future developments may challenge current risk analysis methods

New Life, Old Bottles: risk research urgent requirement parallel to product development (Rodemeyer 2009)

European Group of Ethics (2009): initiate study on current risk assessment procedures

Biosecurity

Code of conduct for biosecurity (KNAW 2008):

Many of the rules of the code of conduct already implemented by virtue of biosafety measures?!

- Dual-use research
- Regulating DNA synthesis
- Do-it-yourself biology as a new context

EGE (2009): define comprehensive security framework for SB

Patenting

Patenting system as a challenge for SB (Oye & Wellhausen 2009):

- Problem of 'anti-commons'
- How to draw a line between public sharing and private ownership of biological parts and design principles?

EGE (2009): launch debate on most appropriate ways to ensure public access to results of SB

What about deliberation…?

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Involving social scientists, ethicists, civil society organisations and publics in deliberations about wider normative issues of choice, (global) justice, and conceptions of 'life' and 'nature'

Consultation (surveys, focus groups)

Pauwels (2009): *US public perceptions of synthetic biology*

- Ambivalence and uneasiness about the 'engineering' nature of SB and the goal of redesigning life forms and 'creating life'
- Applications matter (!): attitudes more positive about energy than health applications
- Appropriate controls and regulations should be in place and enforced

Royal Academy of Engineering (UK 2009): *Public dialogue on synthetic biology*

Kronberger et al. 2009: *Communicating synthetic biology*

Engagement

Schuurbiers & Fisher (2009): *Lab-scale intervention*

- Attempting to integrate societal and humanistic considerations into the laboratory and other techno-scientific design processes as a form of 'constructive technology assessment'
- Engaging publics with choices and considerations in research (Nanojury UK) and with socio-technical scenario's of futures-in-the-making (Nanologue EU)

Rabinow & Bennet (2009): *Synthetic biology, ethical ramifications*

Lessons for responsible innovation in synthetic biology

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Three lessons:

1. Regulatory concerns hould be actively adressed by the government: lack of public trust and confidence in the way in which risks are governed will undermine public support for the opportunities of SB.

2. Broaden the agenda of the public debate to the opportunities of SB: create ways to involve various stakeholders, civil society organisations, and the public in discussions about societal priorities of research and development ('social pathway engineering')

3. Make sense of broader concerns in society about 'soft impacts':
   - in the context of particular opportunities and fields of application of SB (energy, food, medicine, …)
   - in the context of more general developments and trends (converging technologies, increasing 'makeability' of life itself, …)