Ministry of Infrastructure and the Environment

In search of synbio-policy fit for purpose and future proof

Workshop on Synthetic Biology:
From science to policy and societal challenges

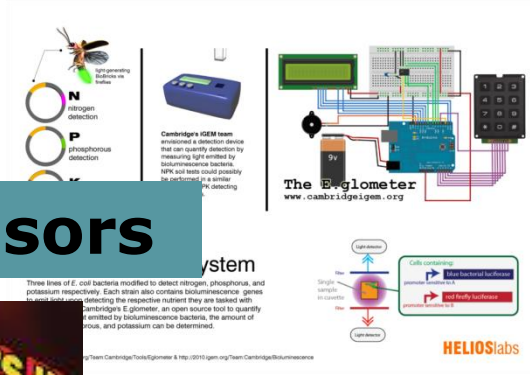
10 December 2015
Esch-Sur-Alzette, Luxembourg

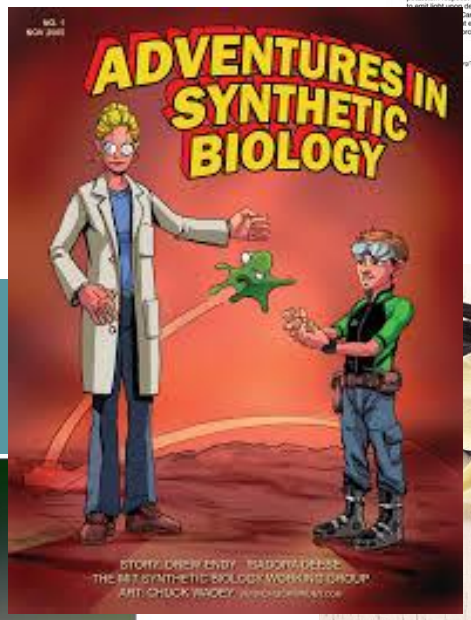
Synthetic Biology Creates New Drug Development

New drug development pathways. One of the avenues of synthetic biology that has wide application is the development of alternative production routes for useful compou… most dis… construc… metabol… and yea… precursor (arteminisin) for an antimalarial drug (Martin et al. 2003, Ro et al. 2006).

Medicine

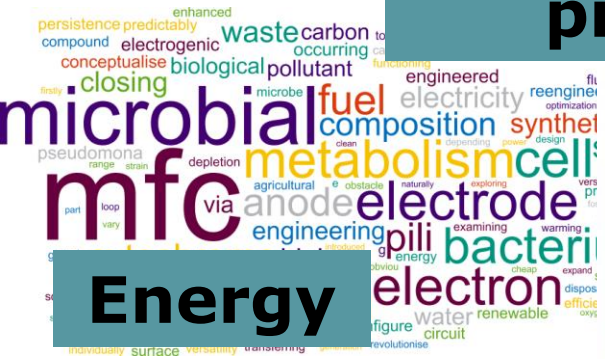
biosensors





Consumer products

Food

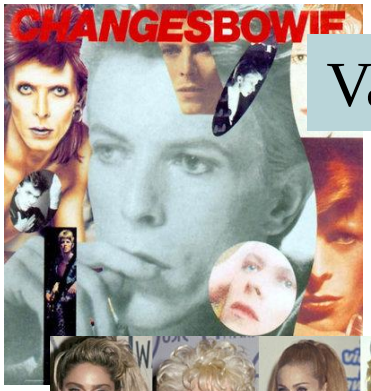


Energy

Synbio potentials for policy makers

From early genetic modification to synbio:
What kind of changes are there and what are the consequences?

What kind of changes are we dealing with?



Variations on a theme

Changes with a huge societal impact

Characteristics of the synbio changes

- Fast
- Many
- Complex
  (due to e.g. NBIC convergence)

Opportunities & Benefits

Synbio applications raise questions
from a safe & secure perspective

- What's it about?
- Can the risk assessors assess the risks?
- Does our (EU) regulation cover the developments?
- How can policy makers assure safe and secure use while at the same time working on innovations
- What policy measures do we policy makers have to take?

And more fundamental questions

- What are the ethical and moral issues
- What will be the impact on society
- What does that imply
- How is society to be involved?

Policy makers confronted with new applications example gene drive

Policy maker

Sciencexpress Policy Forum

Safeguarding gene drive experiments in the laboratory

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Multiple strategies are needed to ensure safe gene drive experiments.

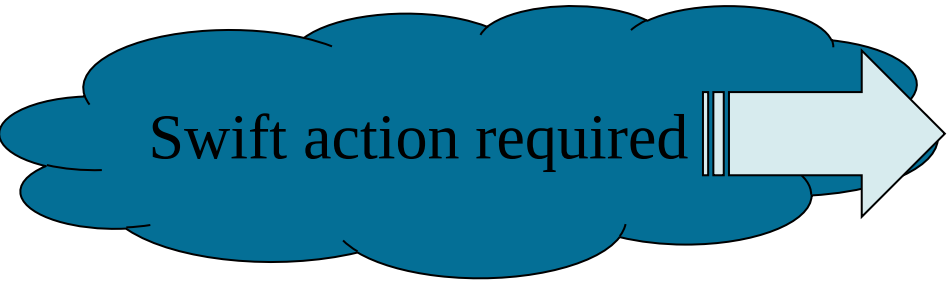
Gene drive systems promote the spread of genetic elements through populations by assuring they are inherited more often than Mendelian segregation would predict (see the figure). Natural examples of gene drive from *Drosophila* include sex-ratio meiotic drive, segregation distortion, and replicative transposition. Synthetic drive systems based on selective embryonic lethality or homing endonucleases have been described previously in *Drosophila melanogaster* (*1*–*3*), but they are difficult to build or are limited to transgenic populations. In contrast, RNA-guided gene drives based on the CRISPR/Cas9 nuclease can, in principle, be constructed by any laboratory capable of making transgenic organisms (*4*). They have tremendous potential to address global problems in health, agriculture, and conservation, but their capacity to alter wild populations outside the laboratory demands caution (*4*–*7*). Just as researchers working with self-propagating pathogens must ensure that these agents do not escape to the outside world, scientists working in the laboratory with gene drive constructs are responsible for keeping them confined (*4*, *6*, *7*).

Two of us recently used a CRISPR/Cas9-based gene drive system to generate a *Drosophila* strain homozygous for a loss-of-function mutation [the mutagenic chain reaction (*6*)] (see the figure). Even though *D. melanogaster* ordinarily poses no threat to human health or agriculture, the accidental release of flies carrying gene drive constructs [illegible] unpredictable ecological consequences. This study therefore used institutionally approved stringent barrier methods. Only one experimenter handled the flies, inside an Arthropod Containment Level 2 insectary suitable for work with mosquitoes carrying human pathogens. Because barrier protocols can be vulnerable to human error (*8*), these authors suggested (*6*) that additional molecular confinement methods described (*4*) and used by others of us in budding yeast (*9*) could further reduce risks. That these studies documented highly efficient RNA-guided gene drive in flies and yeast underscores the potential of the technology and the risk resulting from an accidental release.

As concerned scientists working in related areas, we engaged in collective discussions to identify and publicize interim safety recommendations for laboratory research involving potential gene drive systems while formal national guidelines are developed. Although we cannot claim to represent all researchers, we share a commitment to the safe and responsible development of gene drive technology. Although we differ in our assessments of the types of precaution needed, we recognize that any single confinement strategy could fail. We therefore unanimously recommend that future studies use a combination of stringent confinement strategies (see the table) whenever possible and always use safeguards adequate for preventing the

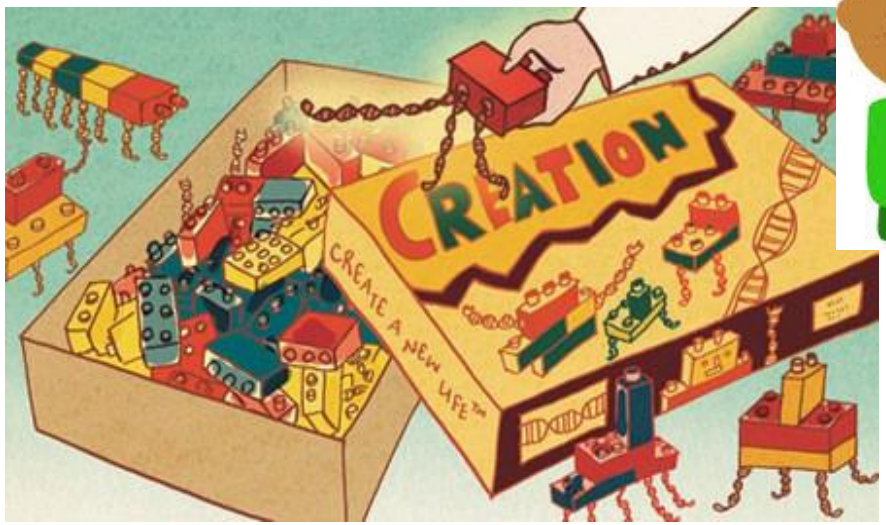
Gene drive

- Aims at inserting a new characteristic permanently in an entire population of an organism.
- By inserting a genetic characteristic along with a “copy machine”
- Which is subsequently passed to **all** of it’s offspring
- Resulting within a few generations in a changed population.

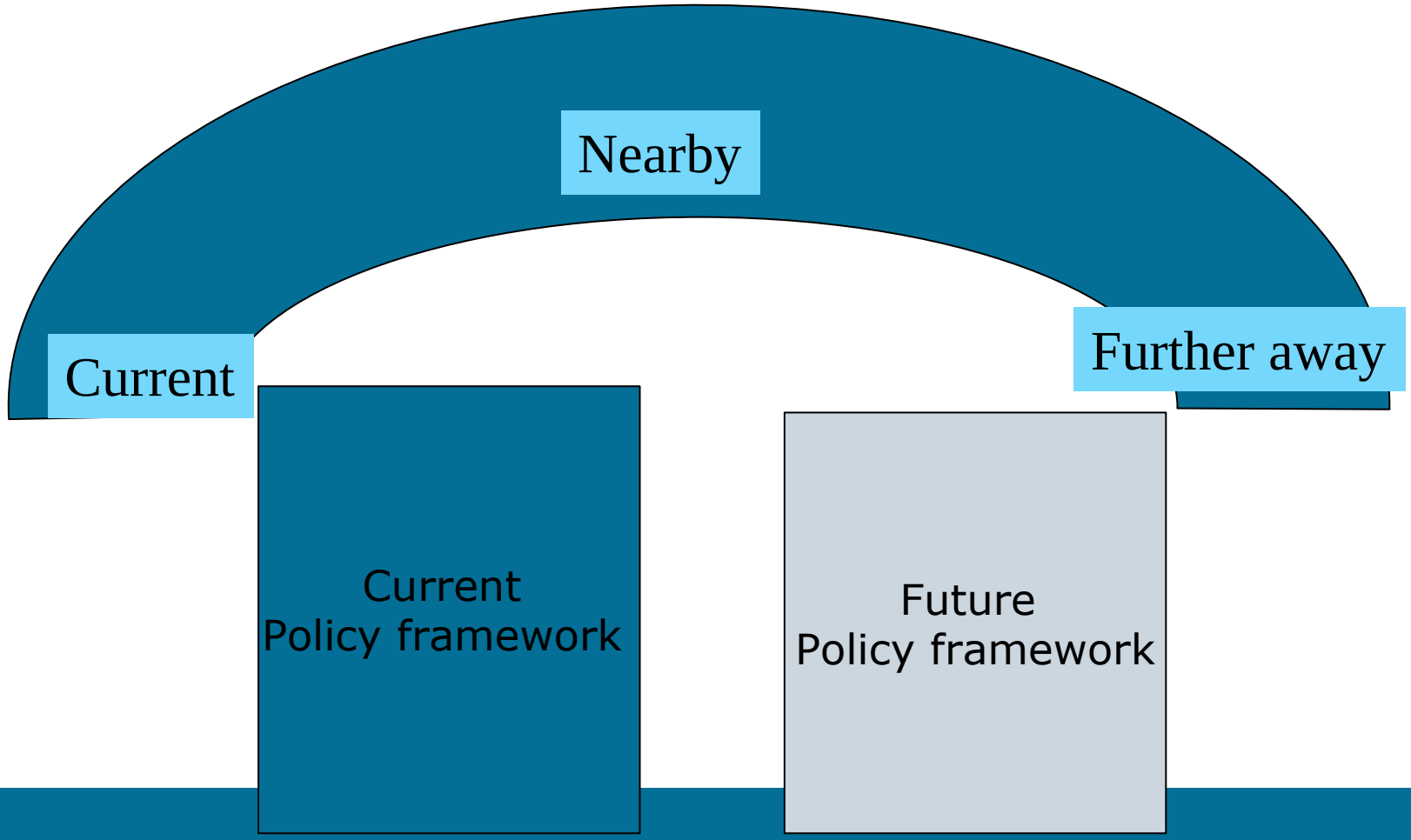


- Assessment not entirely possible
- System not entirely suitable
- Society’s opinion?

The swift and major changes ask for adaptation of our policy on biotechnology

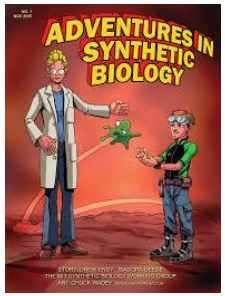


Cover the horizon of biotechnological developments



Relevant themes to cover

A. The developments: their benefits and concerns



B. (Innovative) policy instruments

C. Involvement stakeholders and the public

D. EU and international framework

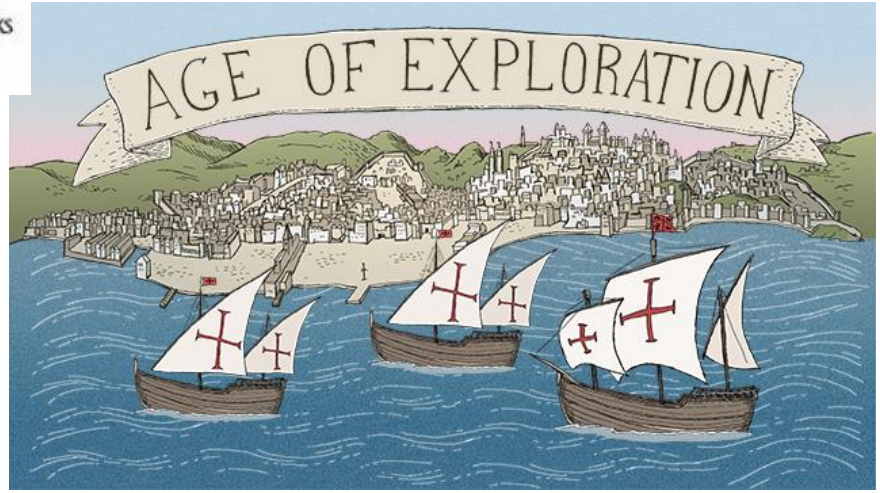
CBD
Convention of Biological Diversity

At the same time

- A lot of work is already in progress:

Scientific Committees
- on consumer safety
- on emerging and newly identified health risks
- on health and environmental risks

CBD
Convention of Biological Diversity



Developing EU policy, initial steps:

- Agenda setting
- Providing tools/input:
  - Research
  - Policy instruments

BE GREAT.
BE STRONGER TOGETHER

Towards agenda setting

- What are the requirements for a new policy framework
- Give a closer look at our current system
- Then draw conclusions and set the agenda

Input for policy development

- Research agenda based on the 3 opinions
  - What EU priorities do we have?
  - What is already done where?
  - What will be the EU research agenda
- Policy instruments
  - What are the requirements?
  - What policy instruments can be suitable

    (Are we able to find/create suitable instruments?)

Let’s start