INTRODUCTION

1.1 Field specific ecosystem

Synthetic biology is the application of science, technology and engineering to facilitate and accelerate the design, manufacture, and/or modification of genetic materials in living organisms. Hence, synthetic biology goes a significant step beyond genetic modification techniques associated with GMO (genetically modified organisms), and in contrast aims to systematically de-code in order to programme (and accurately build) biological entities from their constituent genetic elements. A key feature of synthetic biology is 'the de novo synthesis of genetic material and an engineering-based approach to develop components, organisms and products'.

The current and proposed future applications of synthetic biology range across medical and health (the prevention and treatment of diseases and medical conditions); bio-energy with the potential to substitute fossil fuels; bio-environmental diagnostics and remediation and with the potential to treat environmental pollution; agriculture through the development of disease and pest-resistant crops and the genetic modification of pests themselves; and consumer goods through the bio-synthesized production of fragrances and flavourings.

In common with earlier debates around genetically modified organisms (GMOs) and nanotechnology the way synthetically produced organisms (where DNA has been manipulated) interact with natural environments cannot be fully known or predicted until they are actually released into natural environments (for example in late-stage field trials). Once this has happened, the 'Genie' cannot be put back in the 'bottle'. Building-in self-destruction properties to the organism is one scientific option but regulatory bio-toxicology will also have an important role in providing sound answers to emerging questions. Although the biological engineering metaphor is used frequently when defining synthetic biology, this metaphor can be misleading, because it assumes a level of engineering control which may apply in chemical or mechanical disciplines – ie 'knowing with certainty and predictability how components of an engineered device function in contact with each other in an engineered 'system' – but that this is not yet the case in bio and bio-chemical settings.

Designing this level of certainty occupies the minds of synthetic biology researchers currently but is still very much a 'work in progress'. In the meantime, we have to admit that synthetic biology is a new and promising field, with potentially great benefits but also with possible risks which we are not yet able to assess with full certitude. Managing this uncertainty (common to each new and emerging technology) while advancing synthetic biology for the benefit of the whole society is one of the greatest challenges of this field.

In contrast with earlier rounds of GMO research and commercialization, which required high levels of investment in expensive specialist equipment, and as a result GMO was manufactured within predominantly large organizations, the rapidly falling cost of equipment has had the benefit of making synthetic biology research, testing and commercialization opportunities accessible to a wider, more globally geographically distributed, and smaller biotech companies, and indeed small 'garage' or 'DIY' entities. Whilst this has benefits also to enable general publics to access and de-mystify synthetic biology, it also brings regulatory and responsibility challenges, including increased risks of the production of new unregulated bio-entities and 'bio-hacking'.

Compared to the other technologies considered within SMART-Map, synthetic biology is defined by its 'platform' characteristic meaning it does, and will in the future, impact a far wider diversity of applications and products. This has a number of implications not least the field does not compose 'one' ecosystem of actors but many. Further the societal and environmental impacts and debates are far more multi-faceted, and perhaps need to be disaggregated to a greater degree than the SMART-Map project was able to do within its terms of reference and its focus mainly on medical/health applications.

Advancing synthetic biology brings together stakeholders at the intersection of different domains.[1] **Academia and research centers** are part of these groups as they are the site of basic and applied research, but also an important link between research and innovation carried out in **industrial context**. In the private sector, pharmaceutical companies and biotech companies play a key role, alongside equipment producers, procurement

[1] For a detailed account on the country specific ecosystems we worked with in SMART map see MS12 document

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companies, advanced material producers, SMEs producing market applications, as well as affected traditional industries. The technological developments in the field are supported and accelerated through **financial investment**, from both public and private sources across the world. The **regulatory framework and political system** involves various regulators, including ethics commissions, risk assessment institutions, regulatory bio-toxicology settings, drug and food safety authorities and other oversight bodies. All these stakeholders are fundamental in bringing synthetic biology innovations to market, while the key **beneficiaries** of synthetic biology vary depending on the specific field of application.

The present document, a SMART Map for the responsible advancement of Synthetic Biology is the joint product of an inclusive process of co-design, involving representatives from relevant industries, research institutions, the public sector, civil society, and 'grass-roots' synthetic biology social enterprises.

1.2 Responsible Research and Innovation & the European Commission

The European Commission describes Responsible Research and Innovation (RRI) as an approach which "implies that societal **actors** (researchers, citizens, policy makers, business, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society".

Demonstrating how responsible innovation can be implemented in an industrial context is an open task, as is providing evidence that responsible innovation is an effective approach to opening up of the innovation process to social actors, ensuring the quality of products and processes. The European Commission sees a need for an improved business governance that deeply embeds creativity, scalability, responsiveness, circularity and societal engagement. To achieve these goals, it supports actions that aim to increase public-private partnership in the innovation process, to increase the social value and acceptability of innovation, and facilitate the emergence of new business models that embed sustainability and social responsibility throughout the entire business process. It is in this context that SMART-map operates.

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