

Responsible Innovation Framework for commercialisation of research findings

For use in synthetic biology feasibility studies competition 2012:

Advancing the Industrial Application of Synthetic Biology

Driving responsible innovation

The Technology Strategy Board is the UK's innovation agency and a non-departmental body working under the sponsorship of the Department for Business, Innovation and Skills of the UK Government. Our role is to help UK businesses to develop new products, processes and services to generate wealth and grow the economy.

Synthetic biology is a technology which, if used appropriately and responsibly, has the potential to address major societal and environmental challenges and help grow the economy. It has the potential to contribute to the creation of a sustainable economy in which there is universal and continuous access for current and future generations to the resources and opportunities needed to live well.

Technology Strategy Board and its partners are keen to ensure that all the projects they fund in this area use innovation responsibly and are using this Responsible Innovation Framework as part of this competition.

Responsible innovation issues in carrying out and commercialising R&D

Responsible innovation requires careful consideration of ethical, societal and regulatory issues and appropriate response throughout the process, including (i) during the process of carrying out the R&D, and (ii) for commercial use of the findings.

(i) Conduct of the research: Research undertaken by universities, institutes or independent research organisations should follow good scientific practices in accordance with research council policies. Research projects that raise potential ethical issues must first seek approval from their institutions' own committees, and academics applying as part of a business-led consortium have a duty to

highlight potential ethical issues via the JeS form. Where such institutions are not involved, or some experimental work is to be done outside the jurisdiction of such processes, project leaders must notify Technology Strategy Board and demonstrate that they have considered whether there are any ethical issues associated with the conduct of the research, and if so, that they have addressed them.

The Technology Strategy Board's responsible innovation process described below relates to the development and commercial use of the technology.

(ii) Application of the research findings: The intention is to fund projects where the 'anticipated commercial use' of the project outcomes meets, on the balance of positive and negative drivers, the standards outlined below for responsible innovation. All project applications that successfully pass the Technology Strategy Board's normal independent assessment process and qualify, in principle, for funding will also be reviewed to ensure that they meet the standards set out for responsible innovation.

Why this framework is important

This framework is intended to help companies ***anticipate and give responsible consideration*** to the ***intended*** and ***potential unintended*** impacts of the commercial development and use of the technology, including the potential for misuse, ***before the work begins***. It encourages competition applicants to ***reflect*** upon the possible impact of their project, to identify any important knowledge gaps, and to propose appropriate action to ***prevent or mitigate*** adverse impacts.

Companies and others undertaking projects, approved for funding by Technology Strategy Board and its partners under the Responsible Innovation Framework, will be expected to demonstrate that the policies and procedures that they have in place, or are proposing to develop, are appropriate for the issues raised by the framework. Merely identifying the issues is not enough; the ability to manage them effectively is of paramount importance.

Where applicants are not – at the point of application – fully aware of all the potential issues raised within the framework, we expect them to design their project to seek answers to these questions. This is allowable within the project funding.

There is an obligation on applicants and their partners to disclose any potentially high-risk applications. Project partners will be expected to monitor, and notify Technology Strategy Board of, any developments during the course of the project that lead to, or could lead to, a substantive change in the responsible innovation assessment. These issues will be part of the project monitoring conducted by Technology Strategy Board, and companies will be expected to take this into account and act upon it as they carry out their commercialisation.

Derivation of the Responsible Innovation Framework

This framework is based on the processes used by the ethical investment, ethical finance and other responsible innovation communities, and consultation with staff in organisations such as Standard Life Investments and Triodos Bank. Organisations such as these use similar criteria to decide whether or not to invest (e.g. buy shares) in or lend money (provide debt finance) to companies. It also benefited from the input of social scientists with expertise in synthetic biology. Our framework is intended to ensure that Technology Strategy Board, and its partners, grant funding to projects in a responsible way. In developing the framework, account was also taken of the Sustainable Economy Framework (SEF) model developed by Technology Strategy Board in conjunction with Forum For The Future, the responsible innovation work of MATTER, the Engineering and Physical Sciences Research Council (EPSRC) and the Economic and Social Sciences Research Council (ESRC) Innogen Centre, and the synthetic biology public engagement work of the Biotechnology and Biological Sciences Research Council (BBSRC).

Part 1: Ethical and social

The Nuffield Council for Bioethics have articulated the overarching principles of responsible innovation in their publication *Biofuels: Ethical Issues* (2011). Here it states: (1) the development should not be at the expense of people's essential rights (including their access to sufficient food and water, health rights, work rights, and land entitlements); (2) the development should be environmentally sustainable; (3) the development should contribute to a net environmental benefit and should not exacerbate environmental degradation; (4) products should be developed in accordance with trade principles that are fair and that recognise the rights of people to just reward (including labour rights and intellectual property rights); (5) the costs and benefits of a development should be distributed in an equitable way; and (6) if the first five principles are respected and if the development can play a crucial role in mitigating environmental and social harm, then depending on key market and economic considerations, there is a duty to undertake the development.

Applicants are encouraged to be mindful of the above principles when considering the proposed projects. For the purposes of illustration we have attempted below to indicate some of the ethical and social factors that companies and project partners should consider in assessing their proposed responsible innovation. This is not an exhaustive list and project leads are encouraged to identify and raise any other relevant factors.

A. The positive drivers – factors in favour of supporting projects

Projects funded under this competition should indicate how, if successful, their **commercial use of the project's outcomes** will make a **positive contribution** in the areas of **human well-being, society and the environment**. The following are examples of positive drivers.

Products and services that benefit society and/or human well-being

Projects are encouraged that will lead to products, processes or services of benefit to the community (such as education, arts and culture, housing and employment) or life-saving and life-enhancing products (such as medicines, medical devices and safety equipment). Projects should seek to identify key stakeholders for their commercialisation activity, and are encouraged to engage with them.

Making a positive contribution to the environment

Projects that will lead to products, processes or services that enhance and support the environment. Projects should indicate any environmentally beneficial impacts, for example green transport, waste minimisation, improving efficiency of water use and resilience of water systems, minimal use of non-renewable resources, increased use of renewable resources including energy, pollution control, improved nutrient cycle and the conservation of natural resources. Projects are encouraged to consider entire lifecycle impacts, including second and third-order effects.

Promoting sound practices in employment, business behaviour and ethics

Project outputs should be taken forward by companies that encourage principles of good business behaviour and ethics. Good practice should be observed in areas such as responsible sourcing, fairness, human rights, privacy, the avoidance of child or coerced labour and accountable governance. In terms of health and safety, they may provide clear evidence of excellent health and safety systems and a good track record on health and safety issues. Account will be taken of the size and resources of the company.

B. The negative drivers – factors against supporting projects

The responsible innovation assessment of a project will also take into consideration, balancing against the positive drivers, the following ethical and social issues.

End uses leading to social damage

These include the use of technologies which result in social damage, for instance certain communities bearing disproportionate risk or experiencing economic or social disadvantage; that result in a reduction in human dignity; or that increase the likelihood of misuse or the causing of deliberate harm.

End uses leading to environmental damage or pollution, including:

- potential adverse climate impact (such as that caused by greenhouse gas emissions, ozone depleting substances, atmospheric aerosols etc.)
- potential adverse impact on ocean acidification
- unsafe use of chemicals; poor chemical safety, increased pollution
- unsustainable or inappropriate land use
- applications likely to lead to unsustainable use of water
- applications involving the non-sustainable use of biomass
- potential adverse impact on natural biodiversity
- applications likely to have an adverse effect on other environmental boundaries.

The absence of clear policies and procedures on bribery and corruption

All companies taking projects forward should have appropriate policies in place, and instruct their employees not to engage in, support or permit any corrupt practices, such as bribery, in their work for the company.

Inappropriate use of human or animal products and substitutes

Inappropriate production, use and/or marketing of human or animal products and substitutes such as human breast milk, animal fur and the like, where partners do not commit to adopting the appropriate codes and regulations are discouraged.

Testing products on animals

Applications in which testing on animals, either by the companies themselves or their suppliers, is not kept to an absolute minimum in line with Home Office guidelines and using best practice techniques and technologies.

Business in countries that violate the political and civil rights of their people

Projects where the anticipated market, or significant components of the supply chain involve one or more countries rated poorly in respect of human rights worldwide, unless the companies have effective policies on human rights.

Production or sale of weapons

Projects intending to derive revenues from the production or sale of weapons outwith the appropriate international treaties and/or for non-defence purposes are discouraged.

Addictive substances and behaviours

Projects are discouraged if they lead to the consumption of addictive substances or the encouragement of addictive behaviours; for example, alcoholic drinks, tobacco products (other than for the treatment of addiction or helping smokers to give up) and gambling.

Part 2: Regulatory

It is expected that organisations undertaking projects demonstrate that they are (or intend to become) familiar with the regulations relevant to the projects that they are undertaking. They should make it clear in their proposal what regulations will apply to the product, process or service being developed and how they intend to comply with these regulations. They should also commit to making regular reassessments of regulatory requirements as the project develops and to implementing any necessary regulatory changes. Legislation potentially applicable to this competition includes:

- Genetically Modified Organisms (contained use) Regulations
- Genetically Modified Organisms (Risk Assessment)(Records and Exemptions) Regulations 1996
- Genetically Modified Organisms (Deliberate Release) 2002
- GM Food and Feed Regulation (EC) 1829/2003
- Biological and Toxin Weapons Convention (BTWC)
- Medicines for Human Use (Clinical Trials) Regulation 2004

Companies convicted of an offence under any of these Acts in the last three years must declare this fact and are not eligible for funding in any competition where this framework is applied.

Footnote: In this framework, Technology Strategy Board has attempted to articulate the major ethical, societal and regulatory issues to be taken into account, and managed, to ensure responsible innovation in this area. It is a framework to guide thinking, not an exhaustive checklist of criteria. Competition entrants are invited to draw to our attention additional issues relevant to their projects. We intend to review and update the Responsible Innovation Framework as necessary based on experience gained through its use.

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