This response was submitted to the consultation held by the Nuffield Council on Bioethics on Emerging biotechnologies between April 2011 and June 2011. The views expressed are solely those of the respondent(s) and not those of the Council.

The University of Manchester Institute for Science Ethics and Innovation and The Centre for Social Ethics and Policy.

Response to Nuffield Council Consultation on Emerging Biotechnologies

NOTE: Having carefully considered the questions posed by the Nuffield Council Consultation we feel the most constructive response is that given below in the form of a general statement. Specifically answering the seventeen questions posed in the consultation paper would be repetitive, and would, to complete them conscientiously, require a treatise of considerable length and complexity. That said, many of the questions are answered, or at least addressed, within this statement.

The term 'emerging biotechnologies' covers a multitude of research interests; the scope of this response is limited to genetically modified crops, nanotechnology and synthetic biology, as the debates surrounding these technologies share common themes and concerns. Indeed the Biblical idiom 'there is nothing new under the sun' (Ecclesiastes 1:9) resonates strongly when assessing the history of biotechnological advances.

The ethical and sociological debates that arose vis-à-vis genetically modified crops, resurfaced when nanotechnology took centre stage, and have been revived yet again in the context of synthetic biology. These technologies, which seek to manipulate the natural world at its most rudimentary level, have repeatedly attracted the same arguments from critics. Doomsday scenarios, such as ecophagy, are peddled as all but certain, and the scientists working on the technologies are accused of recklessly 'playing God'. Yet, we humans have always 'meddled with Nature' altering the world around us to suit our convenience, and all technologies can be operated for malevolent ends as well good. And, plenty of technologies in current existence have the capacity to wreak devastation on a scale comparable to the fictitious 'grey goo'. These arguments and counterarguments are well established in the bioethical literature, and need not be repeated here.

However, the repetitive nature of this discourse points towards a need to think afresh about the way in which these issues are framed for the purposes of discussion, and the process of the discourse itself. Needless to say, the benefit of hindsight should not be underestimated. Despite significant (and continuing) opposition, genetically modified crops are arguably a success story of emerging biotechnologies; the benefits of cultivating genetically modified crops (higher yields, the ability to grow crops in difficult terrain or in hostile weather conditions which can and do facilitate food security) should not be confused with problems that have arisen as a result of an unsatisfactory regulatory regime and poor oversight (which may for example, sometimes compromise species purity in crops).

By emphasizing the lack of novelty in the ethical discourse concerning emerging biotechnologies, we do not intend to undermine the unique challenges each strand of technology encompasses. Rather, these idiosyncrasies ought to be managed through appropriate regulatory measures. Indeed, what is truly novel is the challenge faced by those charged with the task of (re)designing a sustainable, coherent framework of governance in which these technologies can develop safely.

Regulatory theory and mechanisms have developed significantly since the inception of the field of 'biotechnology'. Contemporary discourses on regulatory theory should be consulted; current architects of the regulatory regime have at their disposal a spectrum of mechanisms that may be used to construct a clear and nuanced 'mixed model' appropriate to emerging biotechnologies. A simple regulator-regulatee relationship as the basis for strategy will not suffice as the power and responsibilities of the network third party interest groups, financial stakeholders and so forth also need to be addressed in terms of the principles of better regulation (accountability, transparency, proportionate, consistent, and targeted). Furthermore, there must be a regulatory fit between the method of regulation and the stage of development of any given technology. Flexibility is crucial, for a technology might outgrow the regulatory regime as it develops and moves from being in the exploratory stages to being in the trial stage, and finally to being of practical utility – and in all likelihood, highly profitable. Careful thought must be given to the longevity of a chosen regulatory strategy, be it a traditional 'command and control' structure, principles-based regulation or an Open Source model – to name a few.

Global channels of information exchange mean that national regulations must be contextualized, regionally (European Union) and internationally. Transnational dialogue is important not only for the purpose of streamlining methods of collaborating on research and development, but also developing policies to control/monitor the future use of technologies that will dramatically alter the nature of international relations vis-a-vis security and warfare (e.g. through nano-surveillance and bioweapons) and indeed, trade, development and human rights.

The issue of risk is central to discussions on emerging biotechnologies – perhaps because despite sophisticated risk assessment models available today, the full nature and extent of risk in this context is ultimately unknowable. However, this should not be reason enough to halt research. Innovation will always carry some degree of risk; the issue is not that risk exists (many existing technologies are risky, from household appliances to nuclear power stations), but rather, how to cope with the risk, through developing mechanisms to reduce and absorb risk. Between the extremes of precautionary and proactionary approaches is a vast middle-ground. The challenge lies in designing a balanced framework of governance that facilitates research, ensures safety, and inspires public confidence.

The importance of consultations such as this one cannot be overestimated. The Human Fertilization and Embryology Authority (HFEA) is seen worldwide as model of good governance. It was established following lengthy, extensive debate and consultation with all interested parties including the general public. Thus, by the time the HFEA was created, despite the controversial nature of the research and therapies regulated by the Authority, there was little dissent over the HFEA itself. A similar process ought to be followed in the process of establishing a regulatory framework for emerging biotechnologies: addressing the asymmetry of information is the first step in beginning a worthwhile dialogue. The opportunity to engage in dialogue is itself an important step in establishing trust between all parties – and trust is the cornerstone of a successful regulatory regime.