Nuffield Council on Bioethics
Emerging Biotechnologies
Consultation Paper
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Responses to Questions

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(Note: personal response, NOT representing the University)

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Question 1: How would you define an 'emerging technology' and an 'emerging biotechnology'? How have these terms been used by others?

This is rather outside my expertise (I am a laboratory researcher interested in synthetic biology.) However, to the extent that I have thought about it, I would say that an emerging technology is a technology of which the importance cannot yet be judged accurately - that is, it clearly has a large potential importance but has not yet shown any sign of 'peaking' in terms of adoption, new applications, etc. In this sense it is like an island which is emerging from the sea, of which the final size and significance cannot yet be judged accurately. An emerging biotechnology is such a technology which is related in some way to biological systems, most particularly to alterations to biological systems or generation of new biological systems (as opposed to new physical methods for assaying or analysing biological systems, although these are clearly very important in biotechnology.)

Question 2: Do you think that there are features that are essential or common to emerging biotechnologies? (If so, please indicate what you think these are.)

This is a difficult question. All biological systems have many features in common. Thus it could be argued that there is only one emerging biotechnology, with all the applications you mention being simply facets of our increasing understanding of biological systems and ability to manipulate them; that is, they are application areas rather than separate biotechnologies. So, our increasing understanding of how biological systems work (via high throughput sequencing, single molecule microscopy, systems biology analysis, etc.) and ability to modify this (to introduce new DNA using viral vectors, edit using zinc finger nucleases, design and synthesise large pieces of DNA, etc.) allow us to modify living

systems, with applications in agriculture, medicine, human enhancement, etc. depending on which organism we choose to modify and what changes we choose to make.

Question 3: What currently emerging biotechnologies do you consider have the most important implications ethically, socially and legally?

My particular interest is in synthetic biology. To my mind, synthetic biology is a fundamental technology (or set of techniques) which can be applied to many applications including 'next generation' GM crops (those with more extensive modifications than addition of a single gene for insect or herbicide resistance), medical applications (such as constructs for induced pluripotent stem cells, correction of genetic disorders, etc) and biocatalysts (for example, for preparation of next generation biofuels). Synthetic biology is so broadly (or poorly) defined, that almost any new development in any of these areas could be classed as synthetic biology. In terms of applications, those which are related to human health seem likely to pose the most obvious ethical issues (in terms of access, risk, ownership, etc.) but I think that agricultural developments ultimately pose deeper issues, in terms of the requirement to feed a growing human population in a sustainable way. In this context, it is important to remember that failure to adopt a particular technology can also have severe consequences.

Question 4: Are there examples where social, cultural and geographical factors have influenced the development of emerging biotechnologies (either in the past or currently)?

In addition to the examples discussed in the consultation document, we can also look at examples from the past. One of the simplest 'biotechnologies' is that of wastewater treatment, which has been available for more than 150 years; nevertheless, many people in the world still do not have access to clean drinking water, and some millions of children still die each year from diarrheal diseases. This appears to be due to various combinations of war, inept government, poor infrastructure, poverty, corruption, geographical and climate issues, and no doubt other factors of which I am not aware. Given that many governments still can not provide all of their citizens with so basic a requirement as clean drinking water, can we really expect that the benefits of more advanced technologies will be widely available? Is it reasonable to expect this?

Question 5: Are there examples where social, cultural and geographical factors have influenced public acceptance or rejection of emerging biotechnologies?

The most obvious recent examples are those cited in the Consultation Document, viz, GM crops in Europe, and stem cell research in the USA. Also, the decisions made by one group may have unfortunate and unanticipated effects on another - for example, it was reported (though I can not vouch for the truth of this) that the government of Zambia refused to allow imports of GM food aid from the USA, although people were starving, as they were concerned that this would affect

their later ability to export food to the EU, where such foods were not permitted. Other well-known examples are the resistance to polio vaccination in Nigeria (though this was not really a new technology), which was attributed to suspicions about Christian motivations among the Muslim population, and the resistance by certain NGOs to the introduction of 'Golden Rice' fortified with vitamin A, although proponents of this technology claimed that it could greatly reduce blindness and death among children in developing nations.

Question 6: Are there examples where internationalization or globalisation of research, markets and regulation have influenced the development of emerging biotechnologies?

This one is really a bit outside my expertise. One could consider the tightening of IP rights in China and India and its influence on the generic drug industry, along with the increased willingness of multinational entities to invest in R&D in jurisdictions with a robust approach to the enforcement of intellectual property laws.

Question 7: How have political traditions (such as liberal democracy) and political conditions (eg war) influenced the emergence of biotechnologies?

Various philosophers and historians have (to the extent that I understand their positions) argued that liberal democracies provide a uniquely suitable environment for science and technology, in that the development of novel concepts and methods requires questioning of previously held concepts, and a failure to accept without question the authority of existing experts. One might expect in this case that immediate post-revolutionary conditions might be ideal for the development of new advances, but the influence of ideology can be pervasive, with Lysenko being the obvious example. An interesting counter-example is the development of a strong biotechnology industry in communist Cuba, which (as I understand it) was specifically promoted by the government. Other governments of various degrees of democracy have also made biotechnology a priority development area, generally by offering generous incentives to attract overseas experts and to encourage the return of expatriates, although it remains to be seen how successful this will be. The government-encouraged development of large and influential organizations such as BGI (formerly Beijing Genomics Institute) certainly bears watching. Another interesting example is the development of the sugarcane bioethanol industry in Brazil during the 1970s (although this arguably did not really require the development of new technology). During the late 1980s, I was taught that this required large market-distorting subsidies and was an example of inappropriate government intervention, but in the light of subsequent developments it seems rather prescient. As for war, it is well known that many of the early milestones in biotechnology were directly related to the major wars of the 20th century. For example, during the First World War, the Neuberg process was developed in Germany for manufacture of glycerol for use in nitroglycerine manufacture, since the normal source, tropical plant oils, was not available due to British naval blockades. Likewise, in Britain, the Weizmann process (ABE fermentation) was developed for manufacture of acetone, for use in cordite manufacture, since the

chemical industry of Germany was no longer a viable source. The influence this gave to Chaim Weizmann was reportedly important in leading to the establishment of the modern state of Israel. The Weizmann process was also important in the Second World War for the manufacture of butanol required for artificial rubber, and is said to have been used in South Africa as late as the 1980s due to apartheid-related embargos on imports. The development of modern stirred-tank bioreactors, still the mainstay of the microbial biotechnology industry, was related to the citric acid and penicillin fermentation processes. The rise of the citric acid fermentation industry in the USA is often said to be due to the reduced availability of citric acid derived from lemons in southern Italy due to the First World War, and penicillin development was transferred from Oxford to NRRL in the USA due to certain bombing-related issues prevalent in the UK during the early 1940s. We should also not ignore the development of biological weapons, especially anthrax, in the UK and USA during the war, and (allegedly) in the Soviet Union for some considerable time afterward. Although it is not clear whether this really had a significant effect on the development of subsequent biotechnologies, it must certainly have affected the thinking of those in power when new developments in recombinant DNA technology became available in the 1970s, and arguably is still colouring the thinking of many people regarding the current development of synthetic biology.

Question 8: Are there ethical or policy issues that are common to most or many emerging biotechnologies? Are there ethical or policy issues that are specific to emerging biotechnologies? Which of these, if any, are the most important?

I can't really think of anything useful to say here. Potentially, biotechnologies raise issues of human or animal 'dignity' (however this is defined) which are not a feature of most other areas of technology; however, public views on such issues can change quickly, as in the case of *in vitro* fertilization, which was initially very controversial but now is generally accepted as benign. With regard to emerging biotechnologies, one might wonder how much human DNA could be inserted into a non-human organism before it might start to acquire a modified status in peoples' minds. A particular issue with biotechnologies is their ability to self-replicate in the environment, a feature not shared by other technologies (though nanotechnology may develop such abilities in the future, if science fiction writers are to be believed.) This could pose a threat to ecosystems, making any mistakes or errors irreversible to a degree not seen with other disastrous system failures such as nuclear meltdowns, chemical spills etc. I don't consider myself competent to argue as to the relative importance of ethical issues.

Question 9: Do you think that some social and ethical themes are commonly overlooked in discussions about emerging biotechnologies? If so, what are they?

As the consultation document points out, failure to adopt a technology can have adverse consequences just as surely as its adoption. This is an issue with advanced medical technologies, but potentially much more so with agricultural biotechnologies and renewable or low-carbon energy technologies, as it is

generally agreed that the current situation is not sustainable, and the status quo can not be maintained indefinitely.

Question 10: What evidence is there that ethical, social and policy issues have affected decisions in (i) setting research priorities, (ii) setting priorities for technological development, and (iii) deploying emerging biotechnologies, in either the public or private sector?

I'm afraid that this question lies outside my expertise.

Question 11: What ethical principles should be taken into account when considering emerging biotechnologies? Are any of these specific to emerging biotechnologies? Which are the most important?

I can only refer back to my answers to questions 8 and 9 - that the potential consequences of failure to adopt a technology should be considered as well as the potential consequences of adopting it, and that the greatest of caution should be taken when considering uncontained use of organisms capable of competing successfully with 'natural' organisms in the environment (current GM crops and genetically modified microorganisms are not likely to compete successfully in the environment without human intervention.)

Question 12: Who should bear responsibility for decision making at each stage of the development of an emerging biotechnology? Is there a clear chain of accountability if a risk of adverse effects is realised?

I'm afraid that this question lies outside my expertise.

Question 13: What roles have 'risk' and 'precaution' played in policy decisions concerning emerging biotechnologies?

I'm afraid that this question lies outside my expertise.

Question 14: To what extent is it possible or desirable to regulate emerging biotechnologies via a single framework as opposed to individually or in small clusters?

Probably different frameworks are appropriate for:(i) medical or other human interventions which affect only a single person and cannot spread; (ii) agricultural and similar interventions which can potentially affect large numbers of people in a 'common-source' way; (iii) contained use of modified organisms as biocatalysts for industrial processes such as biofuel production; and (iv) release of genetically modified organisms, especially microorganisms, which are potentially capable of replicating and surviving indefinitely in the environment (eg, for bioremediation).

Question 15: What role should public opinion play in the development of policy around emerging biotechnologies?

As far as I understand the situation, public opinion is built into the working of democracies.

Question 16: What public engagement activities are, or are not, particularly valuable with respect to emerging biotechnologies? How should we evaluate public engagement activities?

I'm afraid that this question lies outside my expertise.

Question 17: Is there something unique about emerging biotechnologies, relative to other complex areas of government policy making, that requires special kinds of public engagement outside the normal democratic channels?

I don't see any such features, but this is really outside my expertise.