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.

Nuffield Council on Bioethics: Consultation paper on emerging biotechnologies

Science and Innovation Network Canada response

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

An 'emerging technology' is a practical, marketable application of research and development that has either only recently been realised, or has barriers to realisation. An 'emerging biotechnology' is an emerging technology with a biological basis or application. These terms are generally used by investors to refer to unproven technologies, or to those that have good potential (in a similar way to 'emerging market' and 'emerging economy').

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

The essential/common features match with the definition of an emerging biotechnology from Q1: the technology is not mature or has barriers to implementation, and has a biological basis, component or application.

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

Almost all emerging biotechnologies lend themselves to media sensationalism; the ones with the most important implications (positive and negative) would be biochemicals (human health, land use, technological advancement), biofuels (energy security, food security, land use), cloning (ethics, human health), genetically modified crops and animals (animal health, environmental hazards, food security, human health), nanotechnology (advanced materials, human health, technological advancement) and regenerative medicine (human health).

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

There are many examples of social, cultural and geographic factors influencing the development of emerging biotechnologies. In Canada, the harsh environment, short growing season and high level of agriculture and farming have been a driver of the genetically modified crops biotechnology field. This has led to work on heartier varieties of grains, as well as pest-resistant strains. Furthermore, the greater

cultural acceptance of GMOs within the community has lead to Canada being a leader in the production of GMOs internationally.

There are also instances where socioeconomical and geographical factors have influenced the development of research into tropical diseases. This has been seen be driven by commercial and financial factors where the countries that are affected do not have the resources to mount research programmes and the countries/industry players that do have those resources don't have the economic incentive to develop them. Higher-profile examples include sleeping sickness (human African trypanosomiasis) and Chagas disease (American trypanosomiasis).

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

In some developed and developing countries, there is widespread public opposition to genetically modified crops and animals. One particularly apt example is Europe. It is difficult to pin down specific social/cultural factors that have caused this public opposition (or even whether it is driven by social-cultural factors), however, it could be hypothesised that there is a general mistrust in industry and commercially-driven motives that come at the expense of the public interest. In a similar vein, western Europeans are generally accepting of IVF and stem cell research, which for cultural/religious reasons has been extremely contentious in the US. The Canadian acceptance of GMOs, resulting in part from a perceived necessity, has also resulted in a broader acceptance of their value and use than is found in other countries.

6. **Are there examples where internationalisation or globalisation of research, markets and regulation have influenced the development of emerging biotechnologies?**

Internationalisation and globalisation of research, markets and regulations has influenced the development of emerging biotechnologies, in part by increasing the competition/competitors, speeding up certain processes, increasing the number of potential participants to large scale clinical trials, etc. The outsourcing of clinical trials to developing countries in order to reduce costs and bureaucracy has influenced the development of some drugs and vaccines, and the public perception (trust) of the development process. Examples include Pfizer's testing of trovafloxacin in Nigeria in 1996 and Johnson and Johnson's testing of risperidone in India in 2003.

7. **How have political traditions (such as liberal democracy) and political conditions (e.g. war) influenced the emergence of biotechnologies?**

Liberal democracy as an identifier of Western political regimes and within it the unfolding of various forms of capitalism, economic growth and wealth creation, have largely been behind the momentum experienced by scientific research and technology development. War times have also historically led to advances in experimentation, though with radically different finalities.

While emerging biotechnologies have been both fostered and stifled under various governments, there does not appear to be a bias for or against biotechnology itself. For example, in the USA conservative

political traditions have prevented research into human embryonic stem cells whilst allowing research into genetically modified crops.

Disruptive political conditions such as war and revolution would stall almost all research, with the notable exception of that carried out in military facilities. With demonstrable necessity and accessible funding, research into military biotechnology could flourish. Examples of rapidly-developed biotechnologies include Agent Orange and weaponised strains of tularemia. Disruptive non-military political conditions such as pandemics and natural disasters can also lead to the rapid development and deployment of biotechnologies like tests and vaccines (e.g. the international reaction to the outbreak of H1N1 swine flu in 2009).

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?**

The concept of "playing God" – that altering biological systems is morally wrong and should be outside the sphere of human influence – is often encountered (along with the prefix "Franken-") in reports of emerging biotechnologies. Biotechnologies also often provoke strong public reactions, stalling policy decisions or favouring populist ones over evidence based ones.

The patenting of lifeforms is specific to emerging biotechnologies, and is an emerging ethical issue. Does a new strain of bacteria constitute novel piece of intellectual property, or simply a reworking of what already exists? Do we even have the right to own and commercialise life itself?

No other ethical or policy issues that are specific to emerging biotechnologies spring to mind – the accusation of "playing God" can be (and is) equally applied to older biotechnologies such as vaccination and IVF. Issues surrounding health hazards and environmental release also apply to existing and non-biological technologies such as pesticides.

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

Treating life (human, animal, plant) as commodity is one of the potential risks – the line separating the benefits of any given new biotech from the manipulation of life forms that could lead to alteration/disruption of natural cycles is often blurred.

The social/ethical issue of access to an emerging biotechnology is often overlooked, as it is typically trumped by commercial interests. One example is the availability of advanced drugs (which are expensive to develop but cheap to manufacture) to those who can't afford them, either in developed (current IP issues in Canada where the generic companies are infringing on the patents of industry doing the R&D in order to offer cheaper alternatives to an overtaxed public health care system) or in poor/developing countries – IP law has been used to prevent the sale of more affordable generics. Is it ethical to regulate access to lifesaving medicine on the basis of wealth?

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?

The public/cultural perception of stem cell research in the US has led to several high profile policy decisions and changes in recent history, resulting in funding to research in these areas being severely disrupted.

The ethical, social and policy issues surrounding the GMO debate has resulted in varying deployment strategies in funding priorities for research into these areas, as well as the deployment of GMOs in various countries.

Priorities or "Grand Challenges" identified in developing countries have led to setting certain research priorities in health related research (most recently maternal and child health) and climate mitigation in the developing world by leaders in the G8 and G20 countries.

The (relatively) recent boost in malaria research, partly driven by philanthropists such as Bill and Melinda Gates, appears to be ethically driven. There is little direct profit in eradicating malaria, but it causes many needless deaths.

Many non-profit organisations that deploy biotechnology are motivated to do so by social and ethical drivers (examples include liquid-lens glasses and rapid HIV/AIDS testing).

The introduction of myxomatosis and calicivirus in Australia (and, to a lesser extent, New Zealand) was driven by social pressure from landowners and government pest control policies. Without this pressure/policy, rabbits may have been controlled by other means (conversely, it is on ethical grounds that opponents of biowarfare campaign).

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?

The concept of the manipulation of life is not only a matter of causing harm (some of the implications are philosophical in nature), but is difficult to treat and articulate in a context that sees technological advancement as a continuous extension for human agency that is often not immune from a degree of hubris.

The precautionary principle, that new technologies should not be introduced until there is near-certainty that they are not dangerous, should always be taken into account. With many biotechnologies having the ability to escape control and/or cause great harm, not taking appropriate precautions is irresponsibly cavalier. For example, the liberal use of pesticides such as DDT and BHC to control blue ticks in South Africa in the 1950s was both a colossal waste of money (as the ticks evolved resistance in a matter of months) and hazardous to health (as the chemicals contaminated water supplies).

The principle that science should serve to advance human knowledge and serve the public good should also not be forgotten. This is particularly apt in view of the emergence of "designer" animals that, for reasons of aesthetics, have a particular colour or shape. Not only is this a huge trivialisation of genetic engineering, it diverts resources from more useful endeavours and reduces the role of a living animal to a fashion accessory. It should be noted that this practice has been going on for centuries in the form of selective breeding for aesthetic traits, which is similarly deplorable.

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?

The current "owner" (lead investigator, inventor, financial backer, patent holder etc.) of an emerging biotechnology should bear the responsibility for decision-making, with appropriate referral to independent regulatory or oversight bodies. It is a hard balance to keep: regulation should not stifle research and development, yet some risks are not worth taking. Strong ethical frameworks, such as those which exist for human subject research, should be put in place for all potentially harmful technologies. The technology developer should be operating within a regulatory framework clearly delimiting responsibilities and scope for action. Flaws in the regulatory framework would shift responsibility to the regulatory body itself. Moral hazard is preciously human, and incurred in all endeavours (see financial crisis 2008).

There should be a chain of accountability for all technologies, which ends at the data (i.e. the studies that showed that the technology was safe). It may be that nobody is at fault, if the risk could not have been anticipated (though establishing that would be a job for an independent inquiry), or it may be that somebody was negligent (for example, through suppression of results, rushing to commercialise or ignoring regulatory requirements).

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

Risk and precaution have played great roles in policy decisions concerning emerging biotechnology. The current regulatory frameworks in place for the commercialisation of pharmaceuticals and health-related products are one examples of this. While potentially regarded as severe and cost prohibitive, the framework was designed in a reactionary fashion as it became evident that the capitalist system was biased for wealth creation over ethical considerations.

Both risk and precaution have been cited as reasons for restricting the cultivation of genetically modified crops. For example, France banned MON810 in 2008 in order to assess potential effects on human health, and Japan banned Canadian canola imports in order to prevent cross-pollination with non-GMO native plants. Similar restrictions exist on the use of live GMOs in medicines such as vaccines.

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?

While a single framework would be simpler in administrative terms, a one-size-fits-all approach may not work as envisaged in such a diverse and "hackable" field. For example, the recent interest in 3D- and bioprinting will soon allow for almost anybody to construct biological materials in their own home (home-brew molecular biology is already possible with off-the-shelf technology and Internet guides). Regulation based on restriction of materials and technological lock-in (such as is currently used in the chemical and recording industries) has some place, but the vast markets in illegal drugs and pirated media amply exemplify the insufficiencies of those approaches. With some biotechnologies having enormous potential for harm, there is little room for error. Rapid technological change may render larger framework legislation/regulation obsolete too quickly, so an individual or small cluster approach to regulation of biotech subsectors may provide for a more agile approach and one capable of responding (i.e. be amended/integrated) more readily to changes and advancements in R&D.

In the computer and software industries, open source approaches have proven to be more secure than restricted ones, principally due to the larger pool of error-checkers and the rapid deployment of fixes. Whether this approach would work for potentially dangerous biotechnologies – and biosafety must be given highest priority – remains to be seen.

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

The electorate has a right to direct the elected, which means that the public should have a say in the setting of policy. However, the public (and those making the decisions) can also be remarkably misinformed about scientific matters (the widespread belief that vaccines cause autism being a higher-profile example, or the effectiveness of homeopathy), and easily swayed by media hype. When emerging biotechnologies are believed to have potential for harm (for example, GMOs) or are felt to risk crossing moral lines (for example, embryonic stem cells), there should be a survey of public opinion to establish what opposition exists, and under what circumstances the technologies are acceptable. Decisions should be weighted by public opinion, but should not disregard scientific evidence outright in favour of a misinformed public. It is also important to foster a cultural understanding of evidence based decision making as well as ascribing a cultural value to science itself.

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

Approaches that tend to work for scientific audiences, such as referral to well-established works and peer review, do not enjoy as much credibility in the public sphere. The public has to be "sold" on the benefits (or potential benefits) of emerging biotechnologies, and reassured that they will not be put at risk nor have their views summarily ignored. This stems from a public distrust of science itself, and is by no means easy to address. Engagement with lobby groups and the general public through venues such as Café Scientifique goes some way towards demystifying and humanising emerging biotechnologies, but is not a complete solution (other venues include public consultations, educational debates, discussion fora with experts and representation from different viewpoints and referenda). Better science education and outreach in general would be highly beneficial, as would a shifting of education

policy to give more emphasis on statistics and risk, though those are longer-term strategies. More openness in how science is done (for example, by making more journals open-access and having more places like the Darwin Centre where the public can see actual science at work) would also be desirable, though it would have to be offset against the effect on the scientists.

Large-scale public engagement activities may be evaluated by considering the numbers of people applying to study sciences in schools or universities. Smaller ones may be evaluated informally with polls or surveys, or by the reduction in hate mail volume that scientists in contentious fields get.

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?

Biotechnologies are a more sensitive issue than many other technologies and do require special kinds of public engagement. Biotechnology is seen as more frightening and akin to playing god, and this is in part (I believe) because of a lack of understanding of the greater community. To gain a greater acceptance of biotechnologies more effort must be made to engage the general public, and demystify biotechnology. In each era of technological advancement, there was a period required for the general public to gain trust in the technology used.

With little public interest in politics and engagement with policy, there should be more democratic channels for input anyway. Biotechnologies tend to push more buttons than other technologies, which means that policy and engagement have to be handled with a bit more care and may necessitate additional channels for debate (but this would not necessarily warrant an entirely different approach to public engagement).