

Synthetic Biology: Major issues of concern to Quakers

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Overview

This paper will first touch on how Canadian Quakers have been involved with biotechnology and one particular subcategory — synthetic biology. We then consider four issues regarding synthetic biology:

- 1. The approach to regulation: precautionary versus proactive;
- 2. Technology's uncertainties and range of potential impacts;
- 3. The relevance of spiritual factors;
- 4. Regulating synthetic biology: the public's essential role.

We close by considering how Quaker values offer relevant wisdom.

What is synthetic biology and why are Quakers interested?

All living organisms, from bacteria to humans, have a common means of transmitting genetic information from one generation to the next — DNA. DNA is a complex, self-replicating molecule. It has been the focus of synthetic biology, which combines biology, computer science, and engineering to create novel life forms, with the expectation of using them for foods, fuels, manufacturing, military technologies, repair of human organs, research, and many other applications. We've written about many examples of the current and hypothetical uses of synthetic biology at http://quakerservice.ca/SyntheticBiology. During recent decades, synthetic biology has grown rapidly, so that made-to-order DNA and related biologicals are readily available at low cost.

In Canada, the Religious Society of Friends (Quakers), have long had an active interest in biotechnology. In 2000, after Harvard University applied for a Canadian patent for the oncomouse, an animal Harvard had created for the purpose of laboratory research, Quakers joined the Canadian Council of Churches as interveners in a case before the Supreme Court. In 2002 the patent was rejected on the basis that exclusive property rights to higher forms of life was inconsistent with Canadian patent laws.¹

In 2012, Quakers were asked to endorse *The Principles for the Oversight of Synthetic Biology*,² supported internationally by more than 100 environmental and social-justice groups.

Also in 2012, the World Conference of Friends (Quakers) issued a statement with strong imperatives, *The Kabarak Call for Peace and Ecojustice*. It stated, "...we must become careful stewards of all life," and, "We are called to teach our children right relationship, to live in harmony with each other and all

living beings in the earth, waters and sky..."³ This encouraged Quakers to be as committed to ecological justice as they have been to social justice. The Yearly Meeting (national gathering) of Quakers invited Quaker meetings across Canada to build a Quaker perspective on synthetic biology.

Since 2013, the Canadian Friends Service Committee (CFSC), the peace and social justice agency of Canadian Quakers, has explored synthetic biology by hosting educational talks, publishing updates about developments in this field and by discussing the subject within the Canadian Council of Churches as a matter of interest to other faith groups.

Since 2015, Quakers have participated in the UN's Convention on Biological Diversity's (CBD) formal process for appraising and responding to synthetic biology.

CFSC has sought to educate and discuss synthetic biology so citizens can play an active role in ethical regulatory decision-making.



Synthetic biologists in the lab. Photo CC-BY Steve Jurvetson https://www.flickr.com/photos/jurvetson/

1. The approach to regulation: precautionary versus proactive

A central issue for all emerging technologies, particularly synthetic biology, is by what means, and how much, to regulate the potential benefits and potential harms. Let's examine the words "precautionary" and "proactive"^{*} as they have been used in regard to development of technology.

^{*}Note: We're using the words "proactive" and "pro-action" so there will be simple terms to describe a certain approach. We hope there will be no confusion with the dictionary definition of proactive: "serving to prepare for, intervene in, or control an expected occurrence or situation, especially a negative or difficult one; anticipatory."

In 1998, a conference of scientists, environmentalists, philosophers and lawyers reached consensus on defining the precautionary principle/approach:

"When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action."⁴

In contrast to precaution, the proactive principle/approach places the burden of proof of safety on those who are concerned about harm, rather than on those who seek to use and/or profit from the technology. Proactive regulation would make intervention await scientific certainty that harm exists. A new technology would continue in use until there is convincing evidence of harm. Harms anticipated by some but that have not yet occurred would be much less likely to be recognized as dangerous, compared to using the precautionary approach. The central motivation for the proactive perspective is to not "stall innovation".⁵

Both precautionary and proactive approaches have their potential drawbacks: ...with precaution:

- Ambiguity in the definition of potential harms when synthetic biology is used in creating: viruses, bacteria, chemicals, manufactured products, weapons, plants, animals, human tissues, and more;
- Unduly limiting or rejecting potential benefits of synthetic biology;
- Delay or failure to launch a project in synthetic biology;
- A nation, industry, or organization losing competitive advantage in developing a product of synthetic biology.

...with pro-action:

- Bringing new products to market prematurely, before their hazards are recognized;
- Harms becoming recognized when it is too late to prevent them;
- Organisms created via synthetic biology changing unpredictably over time in more complex environments outside the lab environment;
- Bias against precaution, when those who would profit from a technology are involved in framing the approach to its regulation.

2. Technology's uncertainties and range of potential impacts

In considering a technological project, two issues lie beneath the precaution/pro-action divide:

- 1. managing uncertainty, and
- 2. defining the range of its potential impacts.

We commonly use the words like "uncertainty" and "risk" to refer to multiple aspects of a potentially harmful event, for example:

- its plausibility the chances of an event that has never happened;
- its impact the range of damage, from catastrophic to trivial;
- its recurrence the chances that it will reoccur, and under what circumstances; and
- the knowledge we have about it, both scientific and cultural.

Actually most things we call "risks" may not be known or quantifiable enough for that word to be technically accurate. With synthetic biology, we're more frequently dealing with situations of uncertainty, ambiguity, and ignorance, where probabilities of outcomes can't be clearly known.⁶



The CBD exists to conserve biological diversity, sustainably use its components, and equitably share benefits from genetic resources.

The UN's Convention on Biological Diversity (CBD) is an international treaty. During four years, Deborah Scott studied the CBD and how it came to define and respond to risk and uncertainty, specifically in the cases of biofuels and synthetic biology.

Officially, the CBD professes precaution. It states, "where there is a threat of significant biodiversity reduction or loss, a lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize this threat." However, in practice, Scott finds, "Several decades in, the meaning of precaution is still under debate."⁷

Scott finds that precaution is interpreted *broadly* by civil society groups and countries concerned with uncertainty and ambiguity in synthetic biology and *narrowly* by countries, researchers, and corporations trying to advance synthetic biology. Scott notes that, in considering whether to examine synthetic biology as a new and emerging technology, "when Parties [i.e. signatories to the CBD] were confronted

with a lack of scientific evidence — a situation that might call for actually applying precaution and not merely invoking it — Parties chose to delay decision making..."⁸

The range of harmful impacts perceived by a person or organization varies with their perspective and values. The scientist whose work focuses on changing molecular structures in controlled laboratory conditions usually has a narrower (*reductionistic*) perspective than the ecologist whose field work concerns open, and less predictable, larger systems (a more *holistic* perspective). Such perspectives frame the way risks and benefits are assessed. Considering component parts of an organism in isolation, using engineering metaphors, may be helpful in designing specific, synthetic organisms, but not in understanding their social and ecological significance in the world outside the lab.

An example of reductionistic thinking comes from a project to make "vegan cheese," using milk made through synthetic biology. Patrik D'haeseleer proposed to call the synthetic product "milk." If successful, it would contain just 11 synthetic proteins, many fewer than in the contents of natural milk.⁹ Are the missing proteins of natural milk irrelevant to the value of milk for humans? How does the digestion and benefits of natural milk by humans compare to that of the milk produced by synthetic methods? How will the long-terms effects of producing synthetic milk be assessed - effects on those who consume the product, as well as environmental and social effects (e.g. effects on employment, land use, and so on)?



In contrast, Craig Holdrege argues that the metaphors and resulting strategies of engineering, treating cells as a chassis to which different synthetic parts can be added or subtracted, are fundamentally flawed when applying them to living organisms.

"One reason we cannot explain the organism through the relations between parts, is that those parts tend not to remain the same parts from moment to moment. For example, as most molecular biologists now acknowledge, there is no fixed, easily definable thing we can call a *gene*. Whatever we do designate as a gene is so thoroughly bound up with cellular processes as a whole that its identity and function depend on whatever else is happening. The larger context determines what constitutes a significant part, and in what sense, at any particular moment. Where, then, is any sort of definable mechanism?"¹⁰

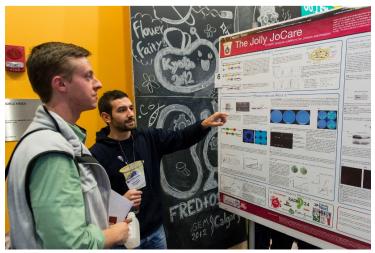
3. The relevance of spiritual factors

In recent centuries, apart from 20th Century physics,¹¹ a rationalistic materialism has been the philosophical underpinning of science and innovation. The last thing most adherents of the proactive approach want to consider is a concept like the "sacredness of life." Many persons, not just scientists, believe spirituality, theistic or non-theistic, has no place in the world of science.

A faith in tools, human ingenuity, and innovation has been necessary for technological achievement throughout history. Ironically, in part due to the successes generated by faith in technology, we are in the midst of multiple planetary crises of immense scale: chaotic climate change, the sixth mass extinction, a human population explosion, and others. The faith in technology has failed to direct human energies to confront these crises, though science has clearly defined them. Thus, paradoxically, a faith — the materialistic, non-spiritual worldview which many call "progress" — has directed humans to incautiously place life as we know it at severe risk. Given the failure of this prevalent faith, might other faiths better guide us?

Crudely speaking, two value systems compete in our approach to synthetic biology: one looks at life as a set of resources to be exploited; the other sees life as a web of sacred relationships to be treated with utmost care and respect.

A major problems we face is that decisions that make great sense to specialists looking at problems narrowly can add up to catastrophic outcomes in the big picture. Specialization and faith in progress can be helpfully counterbalanced by other forms of principled faith. The worth of an individual life, the importance of preserving a species from extinction, and the suffering of a sentient creature, are spiritual matters. They are matters of human valuation. From a materialist perspective, science should be free of subjective values. But in reality values (along with uncertainty, ambiguity, and ignorance) will be the principal determinants of decisions made. Thus, from a holistic perspective, faith in the proactive approach that now drives the rapid uptake of new technologies should be balanced with faith that supports precaution.



A student explains his project at the International Genetically Engineered Machines competition. Photo CC-BY iGEM Foundation/Justin Knight <u>https://www.flickr.com/photos/igemhq/</u>

Synthetic biology is still in its infancy. Yet soon, we may decide the rights of new species that are capable of feeling pain and joy, perhaps even capable of thinking. The sooner synthetic biology formally addresses the complex, spiritual issues of values, including the sanctity of life, the better.

As noted above, in Canada, local study groups of the Religious Society of Friends (Quakers) have studied issues raised by synthetic biology. Here are several formulations of Friends' values:

- "Science and mind are expressions of spirit. They could be used to create a more equitable world."
- "If, as a culture, you had a basic notion of the sacredness of community not just the human community you would automatically put safeguards in place."
- "When we change the biology of life, we can't know the consequences."
- "We advocate that the potential benefits of synthetic biology be pursued with reverence for life and social values, consistent with Quaker and other groups' spiritual values."
- "It may be helpful to avoid taking a fixed position, since our continuing lives and experience will contribute to our spiritual insight."

We must ask, again and again, "How will the moral and spiritual issues raised by synthetic biology be systematically addressed?"

4. Regulating synthetic biology: the public's essential role

The terms *science*, the acquisition of knowledge, and *technology*, the application of knowledge, are closely linked. These two endeavours offer invaluable services to humanity but become problematic when their aims get muddled. Theoretically, the use of science to evaluate a new technology should be unbiased. The approach would entail continual scepticism and openness to whether or not to use the technology. In practice, unbiased scientists and unbiased scientific research can be hard to find. This is certainly true in the highly contentious field of synthetic biology.



A contemporary example illustrates the issue. Thanks to recently-developed powerful methods of modifying DNA, *gene drives* may be possible in the near future. They are designed to increase the prevalence of a specific genetic trait or set of traits within a population of a species. In theory, this could lead to the synthetic organisms becoming more capable of delivering a useful biological or chemical product. Deliberately or accidentally released outside of a laboratory, organisms with a gene drive might one day be capable of changing the genetics of an entire species. For example, a mosquito population carrying a dangerous human parasite might be controlled by making its male mosquitoes sterile during the time required for several reproductive cycles. However, there are many unknowns regarding gene drives, including their off-target (unintended) genetic effects, their disruptive effects on species and ecosystems, and even their potential use as bio-weapons to eliminate crops or spread diseases.



Gene drives are being studied for uses from eradicating pests to editing living crops

Because of their potential biological power and the total lack of regulation at present, gene drives are now a focus of significant attention within the scientific community. Here is one precautionary example of thinking about how gene drive regulations could be developed,

"It is crucial that this rapidly developing technology continue to be evaluated before its use outside the laboratory becomes a reality... For emerging technologies that affect the global commons, concepts and applications should be published in advance of construction, testing, and release. This lead time enables public discussion of environmental and security concerns, research into areas of uncertainty, and development and testing of safety features... Most important, lead time will allow for broadly inclusive and well-informed public discussion to determine if, when, and how gene drives should be used."¹²

In contrast, a proactive approach sets out with the idea that new technologies like gene drives should be used, and then seeks to implement their use as quickly and efficiently as possible. For example, a summary article about the 2016 US National Academies of Science, Engineering, and Medicine's (NASEM) report on gene drives states that while the NASEM report proposes some constraints their "purpose is not to halt research but to establish conditions under which it can be successful." The article does not define "successful," but seems to imply that success means safely using gene drives outside of controlled, laboratory conditions. The article describes "a path toward possible release of gene drives."

On the article's first page, in the section entitled *Interpreting Precaution*, the authors state, "The potential benefits of research on gene drives make prohibiting the research unjustifiable."¹³ This is a premise based on values, not a scientific statement. The rest of the approach to precaution and regulation flows from this celebration of possible benefits before fully assessing possible risks, uncertainties, and unknowns.

The NASEM report itself is a very substantial 230 page review of issues surrounding gene drives and their development. Chapter 6, *Assessing Risks of Gene-Drive Modified Organisms*, ends with several recommendations like:

"Recommendation 6-1: Researchers, regulators and other decision makers should use ecological risk assessment to estimate the probability of immediate and long-term environmental and public health effects of gene-drive modified organisms and to inform decisions about gene drive research, policy, and applications."¹⁴

Yet, in the same chapter, the report highlights that this very information it recommends as necessary to inform decisions has not been published.¹⁵ The path is being prepared for using gene drives, while calling for important information to help influence decisions about the safety of using gene drives, while also stating that that information is not presently available. If key information is lacking, how can there be proactive confidence that the use of gene drives will be beneficial and not harmful?

How society embraces any new and powerful technology merits wide attention and discussion. Quick, high-tech fixes for complex problems can be extremely alluring. Evgeny Morozov has written about the "unhealthy preoccupation with sexy, monumental and narrow-minded solutions... to problems that are extremely complex, fluid and contentious. [This approach] presumes rather than investigates the problem it is trying to solve, reaching for the answer before the questions have been fully asked."¹⁶

Sometimes new technologies are presented as solutions when other low- or no-tech solutions that involve fewer risks, uncertainties, and unknowns already exist. But commonplace solutions may not appeal to desire and imagination; they aren't as new, exciting, or attention-grabbing.



Knowledge is not the same as wisdom. Sometimes we have "dangerous knowledge" — "knowledge that accumulates more rapidly than the wisdom required to use it."¹⁷ Governments and other organizations, when excited by a new technology, may take action before they have the necessary wisdom, and so be vulnerable to dangerous knowledge.

Regulators have the challenge to ensure that all potential risks are thoroughly considered and that dangerous knowledge is identified and treated accordingly. This would seem to require a precautionary approach and discussion of a range of viewpoints beyond the experts usually consulted.

If the public plays a passive role in society's processing of new technology, the interests of those who assume a proactive stance would be more likely to prevail. John Naughton writes:

"Most writers on the implications of new technology focus too much on the technology and too little on society's role in shaping it. That's partly because those who are interested in these things are (like the engineers who create the stuff) determinists: they believe that technology drives history."¹⁸

What must happen so that our societies no longer play a passive role in accepting technologies? There are a few examples where even established technologies have been abandoned for good reasons: chemical weapons and landmines were used extensively in war and with horrible consequences. They are now condemned by the international community and sanctions have greatly curtailed their use.¹⁹

An exemplary global action concerns a destructive, peacetime technology — the products that created a hole in the ozone layer. Cessation of the manufacture and distribution of chlorofluorocarbons was accomplished by the 1987 Montreal protocol, the first international environmental agreement to embrace the precautionary principle.²⁰



Today, we see that widely-adopted, useful technologies, like those dependent on fossil fuels, have driven the planet to an increasingly precarious position. Fossil fuels have affected most of the planet's

ecosystems and many of its species. Thus, the risks of technologies must be evaluated, initially and as long as they are in use.

In evaluating technologies, we must distinguish what may be hypothetically possible from what exists today. Many media stories present applications of synthetic biology as if they are certain to happen in the immediate future;²¹ this contributes to an unrealistic, proactive confidence.



The woolly mammoth is nowhere near being "de-extincted," but inaccurate reporting may give us the confidence that it is.

To maximize the potential benefits and mitigate against the potential harms of synthetic biology, its evaluators must include means of addressing all types of scientific uncertainty, using approaches that tend toward precaution. This includes not allowing the use of synthetic biology in cases were unacceptably severe or irreducible unknowns and uncertainties remain. Many advocates of pro-action stand to profit financially from it, so it's important that viewpoints of anyone with a direct or indirect conflict of interest be recognized and treated as such.

Independent, scientific assessment must precede the decisions that regulate synthetic biology. Well prior to decision-making, an independent, scientific assessment should be thoroughly communicated and discussed by the public. Decisions about risk and regulation should not be limited just to experts. Strong representation from a public that is scientifically-informed is essential.

Former President of the Royal Society, astronomer Martin Rees wrote in 2003, "The views of scientists should not have special weight in deciding questions that involve ethics or risks: indeed, such judgements are best left to broader and more dispassionate groups."²² Rees trusts that the public has a dispassionate and clear perspective. The view of many scientists is the opposite, that the public is driven by passionate and irrational fears of new technologies.²³ Both may be true, depending on how issues are framed and what is done to educate non-scientists.

Professor of science and society Daniel Sarewitz, writes in his article CRISPR: Science can't solve it:

"Democratically weighing up the benefits and risks of gene editing and artificial intelligence is a political endeavour, not an academic one.... There is no way to capture the full complexity of these issues from a scientific perspective.... Scientists are not elected. They cannot represent the cultural values, politics and interests of citizens.... Opening up questions of risk to democratic debate is on the whole good for science and innovation."²⁴

Sarewitz identifies projects that have successfully informed and engaged the public in meaningful discussions about new technologies.



Discussions of precaution vs. pro-action will always involve contested ideas and assumptions, and will never be purely scientific. Scott, in her study of the CBD noted that,

"Identification of risks is considered a purely technical stage, leaving political and cultural considerations to the risk management stage.... A significant body of social science research, however, has shown how richly variable situations of uncertainty are, and how their identification inevitably incorporates values, politics, and assumptions."²⁵

The issue of how big to make the circle – how many and which people to invite into the discussion and decision-making and what mechanisms to use – is critical. Not surprisingly, many who follow a proactive approach call for decisions to be narrow and focused. However, relevant types of expertise might then be overlooked. While a geneticist has certain expertise to contribute regarding a possible gene drive to eradicate malaria, the viewpoints of others are also important – ecologists, evolutionary biologists, anthropologists, local government officials, malaria patients, health workers... Narrow discussion may facilitate *groupthink*, wherein a number of experts with a similar worldview get together and make decisions without benefitting from a full range of perspectives.

Key Quaker values and synthetic biology

Six Quaker "testimonies" reflect values relevant to biotechnology:

- *Equality* leads to fair sharing of opportunity, and so to fair sharing across peoples and nations of synthetic biology's direct and indirect benefits, costs, and risks.
- *Peace* implies preventing military and violent uses of synthetic biology whether by nations, groups, or individuals.
- *Simplicity* means keeping to basics, not drawing down resources ecological, human, or financial when simpler ways are available.
- *Community* implies that peoples of all kinds collaborate in planning, managing, and benefitting from synthetic biology; it also implies deep consideration of the ecological communities to which we belong.
- Integrity implies full, informative communication and consistency between words and action. Integrity also calls on synthetic biology to respect the complexity of life, to consider all its levels, from the molecular to the ecosystem, to the societal, to the planetary.
- *Stewardship* means prudent care: of ecosystems, of people, of valued objects and cultural traditions.



Conclusion

We have explored these issues in relation to synthetic biology:

- 1. The approach to regulation: precautionary versus proactive;
- 2. Technology's uncertainties and range of potential impacts;
- 3. The relevance of spiritual factors;
- 4. Regulating synthetic biology: the public's essential role.

And we have noted Quaker interests and values relevant to biotechnology.

We thank you for your interest in this challenging subject and welcome your feedback.

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