Ethics of Emerging Biotechnologies for Innovators and Entrepreneurs

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Introduction **3**
Each section follows a similar structure: 4
Section 1 — The Public **5**
Key question: How does the public decide whether to trust a new biotechnology, and how can innovators create that trust? **5**
General perception of emerging biotechnology 5
Informative market purchasing 6
Building familiarity through education 7
Framework Conclusions 8
Questions to ask your own project 8
Section 2 — The State **9**
Key question: What is the government's role in making a new technology trustworthy, and what should innovators do while the frameworks are still being built? **9**
Trust in Government Frameworks 9
The role of governments: Investors 9
The role of governments: Regulators 10
Establishing governmental frameworks for emerging biotechnology: 11
Framework conclusions 12
Questions to ask your own project 12
Section 3 — Research Institutions **13**
Key question: Who gets to use, share and build on scientific knowledge and tools, and how do you create a system that is widely accessible but safe? **13**
Monetising Scientific Knowledge 13
Open Access to Science and Science Tools 13
Exchange of materials 13
Maintaining materials sharing with commercialised products 14
Access to scientific information 14
Open access as a decentralised framework 15
The cost of openness: training and safeguarding 15
Framework conclusions 16
Questions to ask your own project 17
Section 4 - Applied to our project **18**
Key question: How has what we learned been applied to our own project? 18
The public applied: 18
The State applied: 18
Research institutions applied: 19
References: **20**

Introduction

The recent years have seen fast-paced changes in our everyday lives fueled by rapidly progressing technology and discovery, and shifting environmental and cultural changes. The feedback loop of technological development, and its adoption and response by the public are tinged by looming threats of a loss of autonomy and climate collapse, yet ultimately it seems as though the wheel continues to turn. There are many reasons that technological and scientific progress is good; human innovation has defined each passing millennium and has undoubtedly given subsequent generations more fruitful lives. We are now entering an age where our inventions are no longer so separate from humanity, and where what we create does not only impact human culture**,** but our living ecosystems. It is therefore important that when we push technology forward, we consider the humanitarian implications in our design.

Among the new wave of development is biotechnology. Biotechnology is broadly used to describe the use of living systems to create or modify biological processes for a specific use. For example, using yeast for the fermentation of beer. A modern form of biotechnology is synthetic biology, which is the use of gene editing tools to apply engineering principles to biological systems (Karataş & Ayaz, 2025) . Synthetic biology ultimately expands the scope and precision of how a biotechnology can be tuned to approach a problem. Biotechnology underpins the bioeconomy, which is the use of biological agents to produce a range of products including materials, chemicals, food and fuel.

The impacts of biotechnology are enormous and widespread due to the genetic conservation across all lifeforms, which enables scientists to apply discoveries from one organism to another. Mainstream uses of biotechnology already underpin its significance. For example, insulin is produced in high quantities via recombinant expression in *E. coli* to treat diabetes (Nilsson et al., 1996). This method enables scalability and decreases the reliance on animals to produce insulin. The success and widespread adoption of recombinant insulin production is an example which innovators and entrepreneurs envision to be utilised for a wider range of products, ultimately creating a circular economy away from degradative and harmful manufacturing processes.

However, achieving this vision depends on more than the scientific developments behind biotechnology. Progress towards a bioeconomy requires stakeholders to cooperate and communicate. Moreover, we need to establish a 'case' for the bioeconomy in society, and how it offers a safe and more sustainable alternative to manufacturing than current industries. iGEM highlights this in the human practices component of the competition, whereby teams aim to understand how their synthetic biology project affects the world and how the world shapes their project. The current handbook examines how emerging biotechnologies can be effectively integrated and translated into public use by taking into account the perspective of the public, the state and research institutions. Finally, we will assess how these ethical frameworks have been applied to our own project.

Each section follows a similar structure:

1. **Key question:** The question answered in each section.
2. **The argument:** What we learned from the literature and from the people we spoke to.
3. **Framework conclusions:** short statements, each pairing a principle with what it means for you.
4. **Questions to ask your own project:** prompts for future teams to consider regarding our conclusions.

Section 1 — The Public

Key question: How does the public decide whether to trust a new biotechnology, and how can innovators create that trust?

General perception of emerging biotechnology

To examine how emerging biotechnologies may exist within a complete bioeconomy we must look at what drives the economy in the first place: consumers.

The Imperial iGEM team 2026 conducted a series of public interviews to understand the general public's perspective on synthetic biology and their response to integrating it into everyday products. When asked, 'What is the first word or feeling that comes to mind when you hear the words synthetic biology?' Most respondents reacted with shocked confusion, answering, "What's that?" This majority response from the public reflects a lack of awareness for synthetic biology as a manufacturing technique and as a field of science. This suggests synthetic biology is not widely discussed or taught to mainstream audiences. Alongside confusion, some interviewees associated synthetic biology with words like bioweapons and injections, which are interpreted as negative and fearful connotations.

However, further discussion from team members responded by explaining what biotechnology and the bioeconomy is. Our explanation was as follows:

Synthetic biology is the use of genetically engineered organisms to manufacture valuable compounds in a less energy-intensive and wasteful way.

In response, people were excited to hear about an alternative method to produce things sustainably. We used the meat industry as a visceral example of biotechnology. Interviewees said they would consume alternative protein forms because 'natural' meat was no longer produced naturally. Overall, we concluded that these initial negative associations with biotechnology do not reflect the actual willingness, if not eagerness, to adopt biotechnology. What is missing is communication between innovators and the public as to what biotechnology actually is, and how it is applied in everyday products.

Informative market purchasing

We next asked our public interviewees about their experience buying products as a consumer; we used food and cosmetic products as examples. People were largely unaware of the product contents or how they were sourced. Price was the most important consideration of a product. Consumers generally did not do the due diligence of verifying what was in a product. In modern life, where packaged food contains up to 60 ingredients (Gaines et al., 2021) and commercial shampoo contains up to 30 (Trueb, 2007), most people do not have the time or expertise to verify a product's contents.

This behaviour can be compared to the well-documented failure of the “deficit model” in science communication (Sturgis & Allum, 2004). The deficit model assumes that public resistance to technologies like GM food and nuclear power stems from a lack of information, and that providing more data will sway public opinion. However, this has been proven to be largely untrue. In our case, if the public does not read and understand all the ingredients of products already on the market, they are unlikely to do the same for emerging biotech products.

We interviewed Dr Patrick Boyle, formerly Chief Scientific Officer at Ginkgo Bioworks and co-founder of American Wetware, who argued that trust is built through relationships, reputation, and “vibes and feelings,” rather than open-source datasets. When considering implementing new technologies, expecting the public to understand every underlying detail is not scalable, rather, a better method is to create trust between those who have the expertise to effectively develop these technologies. Dr Boyle concluded that developers have a responsibility to make products that customers can understand if they want to, but shouldn't need to in order to purchase them with security and confidence.

Our own UK/EU Mini Jamboree questionnaire suggests this misconception persists even among iGEMers building new technologies. Of 11 respondents, 82% named “lack of public understanding” as the biggest factor affecting public trust in synthetic biology. This corresponds to the very same deficit model. The sample is small, so we treat it as indicative rather than representative, but it suggests that the assumption Dr

Boyle rejects could be a default starting position for synthetic biologists entering the field.

Building familiarity through education

Dr. Boyle's perspective suggests that large amounts of technical transparency are unlikely to change how the public feels about emerging biotechnology, but that creating a trusted and open environment is how implementation can be scaled up. When we informed our public interviewees about synthetic biology and its possibilities we gathered a positive response. When asked “Do you feel that your previous education has taught you about biotechnology or even biology for you to understand these changes?” The answer was largely that the current education system did not accommodate for how biotechnology differs from industrial technology and its impacts on the environment and health. Raising awareness about what biotechnology is and how it can be used is important for its long-term sustainability as a consumer choice.

A good example of this is how genetic engineering itself is framed. Historically, there has been public resistance to products that are genetically engineered. One of the biggest challenges that we anticipate to be with the implementation of biotechnology is negative public perception towards genetic engineering. This resistance may be because genetic engineering feels like the antithesis to something natural. However, humans have been controlling the genetics of living things for thousands of years through the selective breeding of crops and animals, which has produced much of the food we eat today. Explaining genetic engineering not as something counter to nature but as an extension of it may therefore be a more convincing narrative than technical detail, and is the kind of information that helps people feel familiar with a technology rather than overwhelmed by it.

Additionally, the way people should be educated should accommodate the fact that not everyone wants to be a biologist. One insightful street interview alluded that art and theatre may be an effective way to communicate science by humanising it. There are already examples of plays being used to communicate the effects and symptoms of dementia which accommodate clinician and research backgrounds, as well as those affected by the disease. Something similar could be done with bioengineering.

Framework Conclusions

- **Perception is shaped by framing and familiarity more than by technical information.** Lead with what the technology is and does in everyday terms, not with technical detail.
- **People make trusting decisions to purchase a product with limited information.** Make clear, honest information easy to find where the decision reaches consumers.
- **Education works when it builds familiarity, not when it delivers data.** Design public engagement around reframing and conversation, and treat it as a two-way exchange.

Questions to ask your own project

- What words will people use for our project, and what associations do those words carry?
- Who is our project audience i.e. the end user, adjacent industries?
- Where would someone first encounter our technology, and what would they need to know in that setting?
- How would our design change if public concern became a problem?

Section 2 — The State

Key question: What is the government's role in making a new technology trustworthy, and what should innovators do while the frameworks are still being built?

Trust in Government Frameworks

We have previously established that on an individual basis, the general public does not validate how a product is manufactured. We followed up by asking, 'To what extent do you trust the government to produce safe and ethical products?' A majority response we received indicated trust in the safety of products already on the market. This trust in higher authority may explain the low levels of individual interrogation over what is bought because responsibility for a product's ethical and safety judgement has been delegated to institutions above the individual consumer. In order to understand how the bioeconomy might take shape, we next will examine the institution that responsibility has landed on: the government.

Governments hold a dual position in the market. First, governments have large purchasing power, and through both purchasing and research funding, they influence which research projects develop. Second, governments act as regulators, setting rules and standards that all other market participants must adhere to (Office Fair Trading, 2009).

Because the public has delegated its judgement to the government, these roles act as a kind of 'trust infrastructure', thus linking emerging biotechnology to consumer trends.

The role of governments: Investors

Government markets are not-for-profit markets, meaning that the main incentive is to serve people rather than generate profits (Mandal, 2021). Historically, periods of economic development have occurred alongside technological leaps. This is because new technology increases productivity, cuts costs and drives the growth of new industries. However, technological leaps are not an effect of sudden discovery but rather occur as an effect of cumulative scientific progress. This cumulative scientific progress can be seen as a long-term government investment.

A major factor contributing to the trust and adoption of novel technologies is long-term familiarity. A product that feels unfamiliar can trigger resistance, resulting in buyers sticking

to what they know instead of adopting something novel. One public interviewee described adopting a new marketing trend (the example given was solar panels) by explaining, “if it’s been on the market for a while and others are buying it, I would be more likely to buy it too.” A government that has invested in the science behind a product, and also regulates it, may therefore resolve some of this uncertainty, because the government's own long-term involvement may already signal familiarity.

The role of governments: Regulators

If investment builds familiarity over decades, regulation is assurance at the point of market entry. Therefore, the government's second role in building trust is to regulate the lab-to-market pipeline for emerging biotechnologies.

Regulation can be achieved by setting standards for biotech companies to adhere to. We spoke to Danielle Hamm, Director of the Nuffield Council on Bioethics, which advises governments, regulators and research funders on the ethical questions raised by emerging science. The risk she identified when standards are missing is what she described as a pacing problem, where science outpaces legal standards, and falls out of alignment with public values, provoking backlash. She said the best approach to this was anticipation, where potential futures and the implications of emerging technologies should be mapped to ethical analysis. The base of this ethical analysis comes from discourse with the public, allowing governance to mirror public values and create trust and transparency. As an example, she contrasted the scrutinized arrival of GM crops, which saw late public engagement coinciding with public resistance, and mitochondrial donation and the Precision Breeding Act, where early engagement allowed policy to reflect public values.

From Ms. Hamm’s own experience, she regarded Nuffield Council's recommendations to be quite permissive, but within strict boundaries; a balance facilitative of science rather than restrictive of it. An example of regulation as an enabling force was the early adoption of clear recombinant DNA and biosafety-level regulation (following the 1970s restriction-enzyme era) in Cambridge/Boston by Cambridge City Council in 1977. These standards gave biotech and pharma companies confidence in "the rules of the road" which has helped the region become a hotspot for developing biotechnologies.

Ultimately, when governmental regulation reflects public values, it encourages emerging technologies by creating a framework for innovation to operate within.

Establishing governmental frameworks for emerging biotechnology:

Given the government's role in regulating and influencing biotech research, building ethical scientific frameworks in advance and alongside technological development is crucial to advise how to safeguard and translate science into everyday use. In the case of biotechnology, such a structure may look like the National Academies of Sciences, Engineering, and Medicine *Safeguarding the Bioeconomy* in 2020. The outcome was a framework drafted by committee members for understanding, evaluating, and protecting the bioeconomy while sustaining innovation and growth. Dr. Patrick Boyle, who was a committee member of the Safeguarding the Bioeconomy framework outlined several practical lessons from his experience which are worth highlighting.

- Identification of the intended audience for the framework's use should be done prior to designing its structure. The language used should accommodate how that audience thinks and works.
- An interdisciplinary set of stakeholders and expertise should work together in order to provide a diverse set of perspectives and form a holistic framework when tackling complex problems.
- The technology's impact across the design-build-test-learn (DBTL) cycle should be deconstructed to identify what safeguards exist for each stage.
- Frameworks should be built by tracking technology trends and trajectories rather than specific predictions**.** Areas of high uncertainty should be characterised and highlighted as non-deterministic.

Taken together, the advice from Dr. Boyle suggests that frameworks should be designed around their audience, inclusive of diverse expertise, structured to show where safeguards sit in the DBTL cycle, and adaptable to uncertainty. Finally, in order to assess whether publicly funded research should come with ethical obligations when exposed to the public, our interview with Ms. Hamm indicated that the ethical requirements should remain independent from funding sources and that ethical frameworks must be constructed simultaneously with the science.

Framework conclusions

- **Frameworks help build public trust by connecting emerging technologies to existing bodies.** Show how your work sits within existing oversight rather than asking people to trust you directly.
- **Anticipatory frameworks serve better than reactive ones.** Break your project into design, build, test and learn steps and ask where risk sits at each.
- **Regulation is correlated to applications, not to techniques.** Define what your technology will be used for before approaching regulators.
- **The frameworks for emerging biotechnologies are still being written.** That gives innovators a window to contribute, and engaging early is part of the responsibility for developing a novel biotechnology.

Questions to ask your own project

- Which government bodies fund, buy or regulate the application we have in mind?
- Which steps in our DBTL cycle carry risk, and who would be in charge of risk management for each step?
- Which existing rules would apply to our project, and where are there gaps?
- How would we contribute to a framework being written for our technology, and what are we doing now to make that possible?

Section 3 — Research Institutions

Key question: Who gets to use, share and build on scientific knowledge and tools, and how do you create a system that is widely accessible but safe?

Monetising Scientific Knowledge

A major difference between discovery-based science and bioengineering science is that discovery-based science generates results that inform our fundamental understanding of life, whereas bioengineering science generates a physical output. This distinction is important because in bioengineering, this output is monetizable and introduces privately funded research.

Alongside public government-funded projects introduced in section 2, commercialisation of biotechnology now influences scientific research and distribution of biotechnology. One mechanism linking investment to scientific research is the commercial exploitation of intellectual property, where a patented platform belongs to a single entity. However, when patents and exclusivity exist, there is less opportunity for open collaboration and data-sharing that discovery-based science relies on to progress.

Open Access to Science and Science Tools

Commercialisation turns discoveries into products people can use, but open access to foundational tools and knowledge pushes science forward. The open access model can be broken down into two parts: the exchange of materials, and access to scientific information. A third consideration resulting from open access is how to train people who have access to biotechnology tools.

Exchange of materials

Research science is an inherently collaborative discipline because the problems it addresses are too complex for any one group to solve alone. An open exchange of ‘science’ (broadly) is common practice between labs without restriction. For example, sharing protocols, training for a new technique, or just getting a second opinion. The benefit of these exchanges is increased efficiency and depth in approaching complex problems.

We spoke to Professor Jim Haseloff, who launched the OpenPlant and Biomaker initiatives at Cambridge University to increase access to plant synthetic biology and co-authored the paper *Opening options for material transfer*. The OpenMTA is a standardised legal framework that relaxes restrictions on materials sharing in order to enable sharing and innovation (Kahl et al., 2018). Bioengineering networks (e.g. iGEM) use it, where restrictions prevent future teams from modifying and reusing biological building blocks.

In advocating for an open access model for emerging biotechnologies, Professor Haseloff compared the benefits from the exchange of experience between labs to the exchange of genetic engineering components. Genetic engineering requires parts i.e. a promotor, gene units, RBS, vector backbones etc., to heterologously express genes, these parts are referred to as wetware. In bioengineering, these standard components form the foundation of biotechnology. Professor Haseloff argued that as DNA synthesis becomes cheaper and more accessible, shipping these parts between research groups will accelerate innovation. By providing a shared physical foundation, scientists can more easily collaborate, and build upon each other's work.

Maintaining materials sharing with commercialised products

Professor Haseloff argued that keeping foundational tools openly accessible does not impede building novel, commercially viable products on top of them, and that gatekeeping the tools themselves makes equitable use of biotechnology more difficult.

One way to account for intellectual property within an open access model is by differentiating wetware parts from complete genetic engineering circuits. The genetic engineering circuits are what become IP-sensitive and commercially viable. The resulting model becomes one with open access foundations and commercially viable products that are built on top of them.

Access to scientific information

Open access also includes access to published and relevant scientific information. If materials are to be exchanged, there must also be a coupling to access of information about how something can be used, and previous investigation into it.

Information on novel science is primarily disseminated through scientific journals, which themselves remain exclusive to those who have access. First, published articles are validated through peer review, which can be biased based on institutional prestige and geography. Additionally, making an article immediately free to the public in a high-level journal like *Nature Biotechnology* typically costs an Article Processing Charge (APC) of $12,850, whereas a more specialised or mid-tier open-access journal costs closer to $2,500, and some society-backed journals cost nothing (Manusights editorial team, 2026) . Ultimately, while authors can publish via traditional subscription pathways for free, the option to make research globally accessible favours wealthy institutions. This limits who has access to current knowledge and whose research gets visibility.

Open access as a decentralised framework

An open exchange of materials and scientific information contributes to a more decentralised model of global biotechnology manufacturing by providing access to tools that groups with limited resources can adapt and use. Developed by Professor Haseloff at Cambridge, OpenPlant and Biomaker are examples of this in practice. OpenPlant developed an open-source, standardised toolkit for engineering the liverwort *Marchantia polymorpha*, a simple plant used in synthetic biology and used by research groups worldwide. Biomaker, is a short programme that gives interdisciplinary teams a toolkit and a small budget to build low-cost, open-source biological tools. Both lower the equipment and cost barriers to conducting biological research, which is what decentralisation depends on.

During our interview with Professor Haseloff, he argued that because biology is inherently globally distributed, it is easier and cheaper to maintain than other technologies (ie., continuous growth and replication of bacteria or plants). If the parts needed to program biology were accessible and cheap, then the ability to create biotechnology would become accessible to more people. In this way, sharing materials offers an opportunity to reduce global inequality in scientific research.

The cost of openness: training and safeguarding

Increased accessibility also brings increased risk; with wider access to bioengineering tools, there is a greater likelihood that people could misuse them. Open access initiatives should

therefore be paired with a framework for training bioengineers. Following section 1, General education can inform the public about biotechnology, but those who continue to work in the field need more specific training.

One way to approach this is by teaching ‘safeguarding science’. To discuss this, we interviewed Edward You, formerly of the FBI's Weapons of Mass Destruction Directorate, who argued that oversight and ‘top-down’ control from higher authority bodies is not the most effective way to prevent the creation of harmful biotechnologies. The danger stems from the same inherent open-source nature of biotechnology which can enable low-cost research among a wider group of people. Instead, he argued that the most effective approach is to educate and empower the community itself so that everyone shares responsibility. He described this as moving from "do no harm" to "not on my watch." By teaching students to maintain safeguarding and ethical boundaries on a community-oriented level (as opposed to individual), responsibility shifts away from a centralised model and becomes embedded within communities. Thus, the main takeaway should be that open-access science works only if the people using it understand their role as emerging biotechnologists and innovators.

Framework conclusions

- **Monetisation and openness can occur at the same time with clear differentiation over what is IP sensitive.** Decide early which parts of your work are foundations to share and which are applications to protect, and say so openly.
- **Sharing materials depends on infrastructure.** Use standard agreements and exchange systems, such as the OpenMTA, so sharing survives commercialisation.
- **Access to information is unequal.** Publication costs and credit practices shape who can contribute and whose research gains visibility.
- **Open access distributes capability and responsibility together.** Sharing tools also means training the people who use them.
- **Openness requires training and safeguarding.** Build a culture of "not on my watch" into your team's onboarding and what you decide to share.

Questions to ask your own project

- Which parts of our work are we willing to share freely, under what terms, and why?
- What would a researcher in a lower-resource setting need in order to reproduce or build on our work?
- If someone misused what we released, who would notice, and what training or screening could have helped?
- How do we prepare for future teams who want to build on our project?

Section 4 - Applied to our project

Key question: How has what we learned been applied to our own project?

Our project is an ordered, self-healing protein hydrogel built from engineered HET-s fibrils. Our design can be applied to enzyme immobilisation for industrial biocatalysis, reducing the need for continuous replenishment of enzymes used in industrial processes. We will use our project here as a worked example, taking each section's framework conclusions and applying it to our own decision making.

The public applied:

Section 1 argued that perception is shaped by framing and familiarity more than technical detail. HET-s is a fungal protein that forms prion-like fibrils, and the word "prion" is likely to carry the same fearful associations our interviewees initially showed toward synthetic biology. Following our own findings, the right response is not technical data to differentiate functional vs pathogenic prions, but a familiar framing. HET-s is a natural protein, and we are using its structure as a building material, similar to the use of natural materials such as silk or cellulose. Section 1 also advised us to clarify who our target 'public' is. Because our hydrogel is an industrial material, most people will never buy it, so public trust is delegated to the companies and communities that use it, such as those involved in wastewater treatment, more than with consumers directly. Finally, as our questionnaire found the deficit model to be the default assumption among iGEMers, and because Section 1 concluded that familiarity rather than information drives trust, we built our workshops around familiarity with synthetic biology and its applications rather than factual recall.

The State applied:

Section 2 concluded that regulation is directly correlated to a product's applications, and that we should define the application first. Our project's two use cases, the cellulosome-mimic for biomass conversion, and CotA laccase for wastewater and biofuels, require different regulators and concerns based on their downstream applications. For the first use, effluent and discharge should be considered, and in our second application product purity is the main

concern. Depending on the use of our products, our team should speak to experts in each field about how our product and its risk compares to others on the market.

Through our conversation with Dr Boyle, we learned that breaking the technology into design, build, test and learn stages is an effective way to implement safeguards at each stage. For example, the fibrils are expressed in *E. coli* but the final hydrogel is cell-free, and its assembly can be reversed with free biotin. These steps, including waste disposal, are relevant to a regulator, and we can describe them in the language our audience uses.

Research institutions applied:

Section 3 distinguished open foundations from commercial products built on top. For us, sharing the underlying parts, such as the constructs for engineered HET-s variants and the sortase tags, would be shared under agreements like the OpenMTA, while recognising that complete hydrogel applications are where commercial value would sit. Additionally, iGEM requires unrestricted access to our parts on the iGEM registry, therefore any IP decisions would have needed to be made before public disclosure of our project. The general reflection on openness and safeguarding made in Section 3 also applies to us. Sharing tools means sharing responsibility for how they are used, and this handbook is part of how we hand on that responsibility to the next team.

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