REGULATORY FRAMEWORK

iGEM Toronto 2026 - PetaBite







Contents

Key Terms, Abbreviations and Acronyms 3
Key stakeholders 4
1. What is a framework 6
2. Open science 8
2.1 FAIR principles 9
2.2 Nagoya Protocol 10
2.3 Dual-use research of concern (DURC) 13
3. AI regulations 15
3.1 Canadian Frameworks 16
3.2 EU AI Act 16
3.3 NASEM AI Code of Conduct 17
4. Plastic Regulations 19
4.1 Canadian Environmental Protection Act 20
4.2 Single-use Plastics Prohibition Regulations 20
4.3 Environmental Safety and Degradation Byproducts 21
4.4 Cartagena Protocol on Biosafety 22
4.5 International Frameworks for Plastic Pollution 23
4.6 International Frameworks for Biosafety and Engineered Organisms 25
5. PETase Regulations 29
5.1 PETase and Environmental Deployment Regulations by Country 30
5.2 Why These Regions? 33
6. Ethics 36
6.1 Data Ethics 37
6.2 Equity in Deployment 37
6.3 Plastic Justice 38
6.4 Waste Colonialism 38
6.5 Transboundary Waste Governance 39
7. Responsible Development 41
7.1 Ethics & Global Justice 42
7.2 Regulatory Considerations by Region 43
7.3 Feedback Integration 45
7.4 Next Steps 46

Key Terms, Abbreviations and Acronyms

PetaBite	iGEM Toronto 2026 project name. Includes the entire optimized workflow(algorithm, assay, bioreactor, etc)
PETadex	Public database hosted at www.petadex.net. Derived from the Logan database by screening it for PETase homologs using the logan-diamond search.
PetaScale	The biotechnological startup translating Petadex enzymes into commercial biodegradation systems.
Logan	Planetary-scale genome assembly and search index of NCBI Sequence Read Archive (SRA). The SRA is a public repository housing every publicly deposited sequencing run, spanning 27.3 million datasets and approximately $5x10^{16}$ base pairs.
WWTP	Waste water treatment plant

Key stakeholders

Dr. Natasha Anwar	Molecular pathologist and bioethicist on Pakistan's National Bioethics Committee; stressed affordability, real-world implementability, and documented project changes as the test of genuine ethics.
Dr. Niti Sharma	Environmental scientist (India) studying river-sediment microbes; required ecological studies before open-water trials and a state No Objection Certificate.
Mr. Excel Amaefule	Policy and governance expert engaged with Nigeria's NESREA; flagged ethics dumping and urged early regulator engagement and deciding with communities.
Dr. T. Sogbanmu	Environmental toxicologist at the University of Lagos and EIA reviewer; emphasized community co-creation and peer-reviewed accounting of degradation byproducts.
Jenny Hutagaol	Representative of Seven Clean Seas, a Singapore-based ocean-impact social enterprise (est. 2018) running plastic cleanup and plastic-credit programs in Indonesia and Thailand; favored a post-treatment enzyme application and surveying consumer perception first.
Dr. Leroy Little Bear	Blackfoot scholar, architect of Section 35 Indigenous rights, and founder of Canada's first Native American Studies Department; framed transactional vs. transformative approaches and stressed deciding with communities.
Karen Wirsig	Environmental Defence Canada; warned enzyme degradation could excuse continued plastic production and should supplement, not replace, waste reduction.
Solace Anyanwu	Bioprocess and policy specialist at the University of Alabama; noted living engineered organisms face stricter, slower approval and recommended immobilized enzymes for wastewater.
Dr. Ryan Prosser	Researcher at the University of Guelph studying the environmental impact of agricultural and industrial chemicals (and freshwater mussel conservation); explained a working enzymatic removal method could let regulators set microplastic limits in biosolids.

Dr. Hubert Cabana	Professor of Environmental Engineering at the University of Sherbrooke and expert in fungal and enzymatic wastewater treatment; cautioned that incomplete PET degradation can yield more toxic fragments, so validation must prove complete breakdown to non-toxic products.
Dr. Grant Allen	Professor of Chemical Engineering at the University of Toronto (BioZone), former Department Chair, and Fellow of the Canadian Academy of Engineering; flagged dilution and competing organics in WWTPs and recommended enzyme immobilization.
Dr. Rasha Maal-Bared	Principal Environmental Scientist at CDM Smith working in water-treatment R&D; drove the shift to microcosm scale, mesophilic temperature filters, and a laundry-detergent application.
Shane Harker	Founder of Rethink Resource; advised positioning PetaBite to complement mechanical recycling, leading with biosolids microplastic reduction.
Arjun Krishnan	Plastics recycling infrastructure expert; recommended anaerobic digestion focus and a research question on the enzyme's environmental fate.
Dr. Maria Martin	Lead of the Protein Function Development team at EMBL-EBI and a key figure in the UniProt Consortium; recommended distinguishing predicted from experimentally confirmed enzyme entries.

1. WHAT IS A FRAMEWORK?

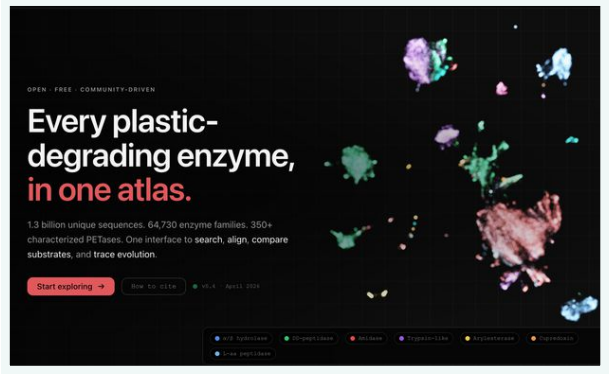


What is a framework?

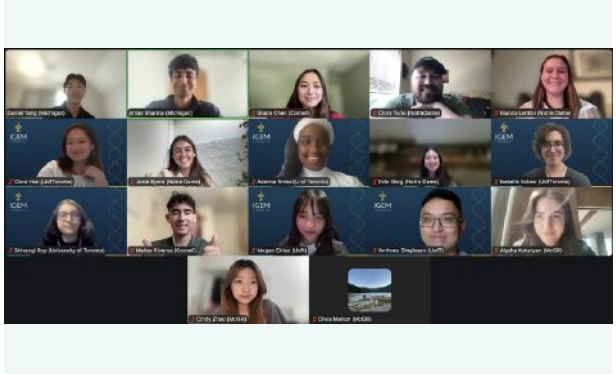
A regulatory framework is a set of guidelines and rules established by governments and organizations to ensure that scientific research and industrial operations prioritize public safety and well-being. These guidelines are designed to minimize the risks associated with developing and deploying new technologies.

However, existing regulatory standards may not adequately address the unique characteristics of emerging technologies. A dedicated framework provides a flexible, risk-based approach to addressing regulatory gaps and potential barriers to deployment. Our motivation for developing this framework was further reinforced at the University of Michigan Bioethics Symposium, where we exchanged ideas with other iGEM teams. Through discussions about the ethical challenges they encountered in their projects, we identified public and ecological safety as recurring concerns.

In the case of this year's PetaBite, we are engineering PET-degrading enzymes built for real-world deployment, such as municipal wastewater treatment facilities. This project involves using machine learning models guided by a database of over 1 billion plastic degrading enzymes identified through the planetary scale genomic data mining collaboration, the Logan index. Chosen enzymes are then processed with high-throughput wet-lab testing. Results of which will be hosted on our public database website, PETadex (petadex.net). Introducing AI-guided biological components into industrial environments raises regulatory concerns regarding ecological safety and AI transparency. Furthermore, PETadex's open-science approach introduces considerations surrounding responsible data sharing and accessibility. To support PetaBite's potential global deployment, we developed a regulatory framework informed by consultations with international stakeholders and professionals, particularly those from regions disproportionately affected by plastic pollution. This framework aims to ensure that our technologies can be deployed safely, transparently, and in alignment with emerging regulatory standards.



PETadex Homepage



UMich Bioethics Symposium

2. OPEN SCIENCE



2. Open Science

Open Science is the practice of making scientific inputs, outputs and processes freely available to all with minimal restrictions [1]. PetaBite applies this approach through PETadex, a public database hosting over 64,000 enzyme families. Launching a large-scale database requires robust oversight, introducing bioethical, safety, and equity challenges. Providing unrestricted access to massive genetic sequence datasets introduces dual-use risks, where information could be exploited for its unintended causing threats. Unrestricted access also raises the question of extractive research patterns, using biological assets sourced from the Global South without equitable returns. This Open Science section establishes clear guidelines to ensure that global access to biological information is managed responsibly and transparently.

2.1 FAIR principles

Following the Canadian federal Roadmap for Open Science, a core requirement of Open Science is that it should be Open by Design and by default, adhering to the FAIR principles [1].

Findable

Scientific data should be clearly labelled, regularly updated, and easy to locate. PETadex supports this principle by maintaining annotated enzyme records, ensuring that each sequence and its function are properly characterized. This allows users to search for PET-degrading enzymes relevant to their research or intended applications.

Accessible

Ensures that once data is found, it can be easily retrieved by anyone with minimal barriers. PETadex (petadex.net) serves as a centralized public platform for our characterized enzymes, making them readily available publicly.

Interoperable

Allowing data on PETadex to be capable of integration with other datasets and software. PETadex uses globally recognized biological data standards. The search function is easily usable supported my formats like ORF ID, GenBank accession, or SRA library. Genomic sequences are also stored in FASTA format, and enzyme properties such as BHET activity and geographic metadata and structured using standard open schemas (CSV and JSON) allowing easy download.

Reusable

Safeguards the reliability of data, and that it's well documented and clear enough that users can replicate the work and build upon it. PetaBite shall provide thorough documentation to ensure the reproducibility of results. This includes transparency regarding PetaBite's machine-learning models and the protocols for computational workflows. Moreover, there shall be clear documentation of the high-throughput Wet Lab validation. This data will be centralized and accessible from the PetaBite iGEM wiki.

PetaBite adopts the federal Roadmap for Open Science in tandem with Canada's goal of making science accessible to all. Analyzing PetaBite's alignment with the FAIR principles ensures that its data is not just public but purposely and responsibly designed as Open Science.

2.2 Nagoya Protocol

The Nagoya Protocol is an international treaty designed to govern the fair and equitable sharing of benefits from the utilization of genetic resources. Adhering to the Nagoya Protocol is critical to prevent extractive research practices, particularly in which PetaBite uses digital genomic resources sourced globally, but analyzed and synthesized in the Global North. To integrate the Nagoya Protocol, this regulatory framework targets the Protocol's mandates through targeted sections most relevant to PetaBite.

2.2.1 Data provenance

PETadex, our public database, hosts 1.3 billion unique biological sequences, utilizing public metagenomic data sources via the LOGAN index. Because these sequences are derived from various sources globally, clear documentation of their origin is an essential regulatory requirement. To do this, every sequence on Petadex is linked to its corresponding provenance data, ensuring that all sequences retain their public accessions (BioSample or SRA links), geographic origin, and sampling dates.

Tracking data provenance supports the mechanisms outlined in Article 17: Monitoring the Utilization of Genetic Resources in the Nagoya Protocol on Access and Benefit-sharing [2]. Article 17 requires parties to uphold transparency regarding the source and utilization of genetic resources through "checkpoints." PetaBite upholds transparency with data provenance in its database schema, ensuring compliance with these international standards.

2.2.2 Non-Monetary Benefits

Under Article 5 (Fair and Equitable Benefit-Sharing) of the Nagoya Protocol, users of genetic resources are obligated to share the benefits of their utilization fairly and equitably. Benefits can be non-monetary or monetary as outlined in the Protocol's Annex. Section 2 of the Annex outlines recognized forms of non-monetary benefit sharing. Those relevant to PetaBite include:

a) Sharing of research and development results;
e) Admittance to ex situ facilities of genetic resources and to databases;
k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;

Providing the community with unrestricted access to research data and Petadex is a formally recognized method of equitable benefit-sharing under the Nagoya Protocol.

2.2.3 Contribution to Environmental Conservation and Sustainable Use

Under Article 9 of the Nagoya Protocol, entities are encouraged to direct the benefits of using genetic resources towards the conservation of biological diversity. Canada's designation of plastic manufactured items as a toxic substance under the Canadian Environmental Protection Act (CEPA) concludes the threat plastic pollution poses to global biodiversity [3]. By centralizing the genetic resource of billions of unique PET-degrading enzyme sequences into a characterized, searchable database, PetaBite expands access to bioremediation tools to break down plastics threatening biological diversity.

2.2.3 Contribution to Environmental Conservation and Sustainable Use

Articles 22 and 23 of the Nagoya Protocol emphasize capacity building and the transfer of technology, particularly in developing countries. Whilst providing raw genetic data, PetaBite also provides the computational tools to analyze it. PETadex provides access to bioinformatics tools including DIAMOND search algorithms and computer-rendered Newick phylogenies. By centralizing this technology as an open-source toolkit licensed under MIT, PetaBite empowers researchers to leverage global genomic resources. Concurrently, PetaBite Venture translates these genomic resources into physical applications by actualising the deployment of engineered PET-degrading enzymes, such as in municipal wastewater treatment plants (WWTPs).

Consultations with international stakeholders were conducted to establish equitable technology transfer. This process identifies constraints that will shape the deployment of PetaBite in the Global South:

Digital Infrastructure Constraints	Open access does not inherently guarantee equitable technology transfer due to bandwidth limitations. This framework mandates tools provided via PETadex to be continuously optimized for low-bandwidth environments.
Physical Infrastructure Constraints	While PetaBite focus on deployment on centralized WWTPs, consultations revealed that highly centralized WWTPs can be absent in developing regions. Therefore, future optimizations for PET-degrading enzyme deployment cannot solely rely on this infrastructure.
Co-Creation	Both open science and deployment infrastructure risk “ethics dumping” where technologies are designed without local regulatory consideration. PetaBite continues to reach out to global stakeholders to ensure the utmost considerations of diverse regulations. This ensures technologies are guided by community needs allowing for its best transfer.

2.2.5 Awareness-Raising

Article 21 of the Nagoya Protocol mandates measures to raise public awareness regarding the importance of genetic resources. Foremost, this section pays heed to point (a) under article 21, promoting this protocol and its objective by including it in our regulatory framework, which will be accessible on the PetaBite iGEM wiki. PetaBite places strong emphasis on public education and stakeholder inclusivity.

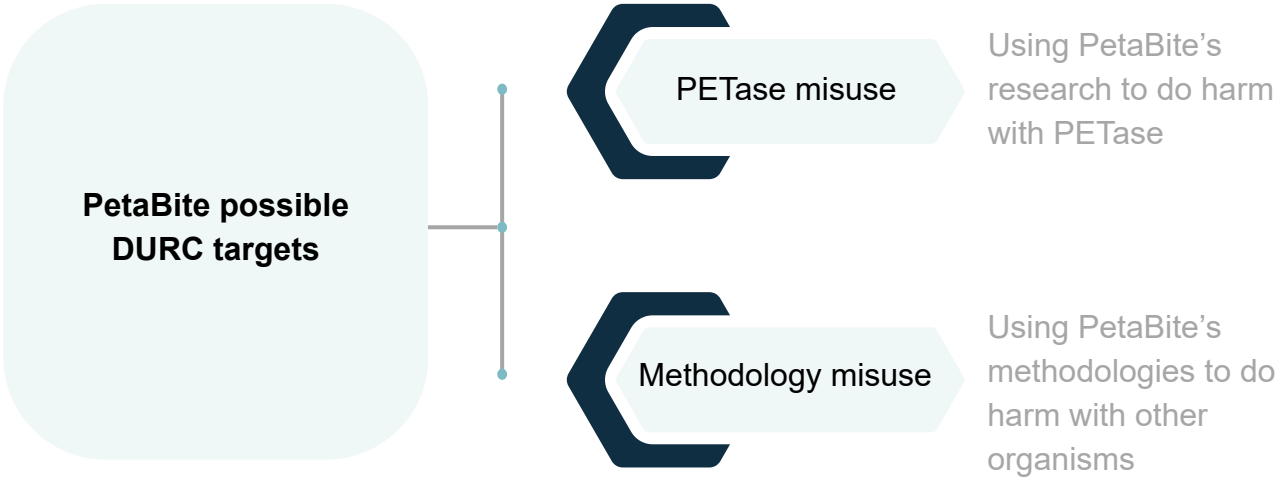
Point (b) emphasizes communication with indigenous, local communities, and relevant stakeholders. PetaBite conducts continuous stakeholder outreach globally, with an emphasis on stakeholders in locations at the highest risk and greatest vulnerability to plastic pollution. Stakeholders include, but are not limited to: Indigenous representatives in Canada, NGO representatives working with indigenous communities, researchers from and researching plastic pollution in Sub-Saharan Africa and Pakistan. Communications here are two-way, where PetaBite is both raising awareness of the issue of plastic pollution and how it could be solved by access to the genetic resources of PETase as well as learning how to better combat the issue at hand given its diverse stakeholders.

Furthermore, upon consulting Dr. Leroy Little Bear, the issue of communication with indigenous or vulnerable communities surfaced. Rather than using complex scientific terms to do with enzymes and their novelty, communication must center on a narrative to beat plastic pollution. This ensures communities fully understand the aims of this technology, overcoming communication barriers and allowing efficient exchange of ideas.

2.3 Dual use research of concern (DURC)

DURC refers to properties of life science research, including organisms or scientific methods, where with little to no modification, can be intentionally misused to cause harm [4].

2.3.1 Hazard identification



PETase misuse

At first glance, it makes sense to see how much of the world's critical infrastructure is made of plastic. Thus, petabite's open source information on PETase could theoritcially assist the attaining and spreading of petases to damage critical infrastructure. However, it must be considered that PET is a lightweight thermoplastic primarily used for single-use packaging, or synthetic clothing fibers. Most critical infrastructure make use of more durable polymers like Polypropulene (PP) or Polyvinyl chloride (PVC). Furthermore, PETases are deployed and tested to deal with microplastics, which are plastic that have been broken down and dissolved in liquid. Intact plastic structures are unlikely to be severely harmed by PETases.

There may also be uncharacterized harmful properties present in enzymes hosted on PETadex, in that PETadex would be aiding the dissemination of toxic substances. DURC in this case is based on the assumption that an uncharacterized harmful property exists in an enzyme on PETadex. Since the PETadex itself does nothing in helping find these uncharacterized properties, there is no aid to misuse. Moreover, there is hardly any motive for adversaries to be looking on a database for plastic degrading enzymes when looking to cause harm.

Methodology misuse

Machine learning models are subject to heavy DURC responsibilities. However, in the context of PetaBite, there is a low possibility of misuse. Models on PETadex are trained on wet-lab data relating to PET plastic degradation and possess no capabilities relating to pathogenicity of toxicity. Repurposing this computational pipeline for misuse would require building an entirely different model from scratch. Additionally, digital sequences remain harmless without physical synthesis, which is gated by commercial gene synthesis providers that screen orders against known harmful genetic strains.

There may also be concerns regarding bioreactor methodologies as there has been a history of misuse seeking to culture dangerous organisms. However, petabite's methodologies are engineered for low-volume, high-throughput enzymatic assays. The hardware lacks containment features required for cultivating pathogonetic or toxic substances. Adversaries seeking to culture dangerous organisms would lack motive, instead seeking common incubators or fermentors leaving no motive to exploit PETase testing hardware.

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[1] Roadmap for Open Science https://science.gc.ca/site/science/sites/default/files/attachments/2022/Roadmap-for-Open-Science.pdf

[2] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

[3] Order Adding a Toxic Substance to Schedule 1 to the Canadian Environmental Protection Act, 1999: SOR/2021-86 https://gazette.gc.ca/rp-pr/p2/2021/2021-05-12/html/sor-dors86-eng.html

[4] Global guidance framework for the responsible use of the life sciences https://www.who.int/publications/i/item/9789240056107

3. AI REGULATIONS



3. AI Regulations

3.1 Canadian Frameworks

3.1.1 PIPEDA

The Personal Information Protection and Electronic Documents Act (PIPEDA) is Canada's federal privacy law which governs how organizations in the private sector collect, use, and disclose personal information in the course of commercial activity [1]. The Act does not address AI directly. However, the Office of the Privacy Commissioner has confirmed through investigations of Clearview AI and OpenAI that PIPEDA applies to AI systems that collect or process data, with requirements for consent, transparency, and minimal retention [2], [3].

3.1.2 Directive on Automated Decision-Making

Canada's Treasury Board Directive on Automated Decision-Making, enacted in 2019 and updated in June 2025, establishes standards for AI systems that support or make administrative decisions [4]. The Directive applies formally to federal institutions. However, it represents the clearest articulation of responsible AI practice in a Canadian context and provides a useful benchmark for PetaBite.

A central requirement is explainability: the reasoning behind a system's outputs must be communicable to people affected by them [4]. For PetaBite, this means that when the ML model ranks one enzyme candidate above another based on predicted activity at a given pH or temperature, those criteria should be visible to users, rather than be presented as an unexplained score. Dr. Natasha Anwar raised this directly in our stakeholder interview, noting that AI generated predictions must be validated against human processes and that researchers cannot rely on model outputs without understanding how they were produced [5].

PetaBite aligns with the Directive by committing to full documentation of the ML model architecture, training data provenance, and known limitations, published on the iGEM wiki.

3.2 EU AI Act

The EU AI Act was created on August 1, 2024 as the world's first comprehensive AI regulation, introducing risk-based rules implemented in phases through 2027 [6]. Article 2.6 explicitly exempts AI models developed solely for scientific research from most of its provisions [6]. PetaBite's current pipeline therefore falls outside the Act's direct scope.

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However, as the EU AI Act represents the most comprehensive AI governance framework currently in force globally, and its transparency requirements for open-source AI tools show the direction international standards are moving. For open-source AI models made publicly accessible, the Act requires documentation of training data provenance and clear specification of intended use cases [7]. PetaBite voluntarily aligns with these principles by committing to documenting its ML model architecture and clearly communicating the output of enzyme rankings are model predictions, not validated activity measurements.

3.3 NASEM AI Code of Conduct

The National Academies of Sciences, Engineering, and Medicine (NASEM) has developed an AI Code of Conduct built around five principles: engagement of affected individuals, human advancement, monitoring, learning and innovation, and equity [8].

The equity principle raises a concern for PetaBite. The ML model was trained on sequence data mined from the Logan index, which draws on metagenomic samples collected globally. If that training data disproportionately represents sequences from well-resourced research environments, the model may underperform when applied to candidates from underrepresented ecosystems, including tropical or coastal environments more common in Global South contexts. This is a form of algorithmic bias that NASEM's equity principle directly addresses. PetaBite commits to investigating and disclosing this limitation.

NASEM's monitoring principle maps onto PetaBite's stakeholder outreach cycle. Continuous stakeholder engagement and iterative feedback integration ensure the AI pipeline is treated as an evolving tool, instead of a finished product, consistent with NASEM's monitoring principle that AI systems be regularly reassessed against real-world outcomes [8].

References

[1] Government of Canada, "Personal Information Protection and Electronic Documents Act (PIPEDA)," 2000. [Online]. Available: https://laws-lois.justice.gc.ca/eng/acts/P-8.6/

[2] Office of the Privacy Commissioner of Canada, "PIPEDA Findings 2021-001: Joint Investigation of Clearview AI," 2021. [Online]. Available: https://www.priv.gc.ca/en/opc-actions-and-decisions/investigations/investigations-into-businesses/2021/pipeda-2021-001/

[3] Office of the Privacy Commissioner of Canada, "PIPEDA Findings 2026-002: Joint Investigation of OpenAI," 2026. [Online]. Available: https://www.priv.gc.ca/en/opc-actions-and-decisions/investigations/investigations-into-businesses/2026/pipeda-2026-002/

[4] Treasury Board of Canada Secretariat, "Directive on Automated Decision-Making," updated June 24, 2025. [Online]. Available: https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=32592

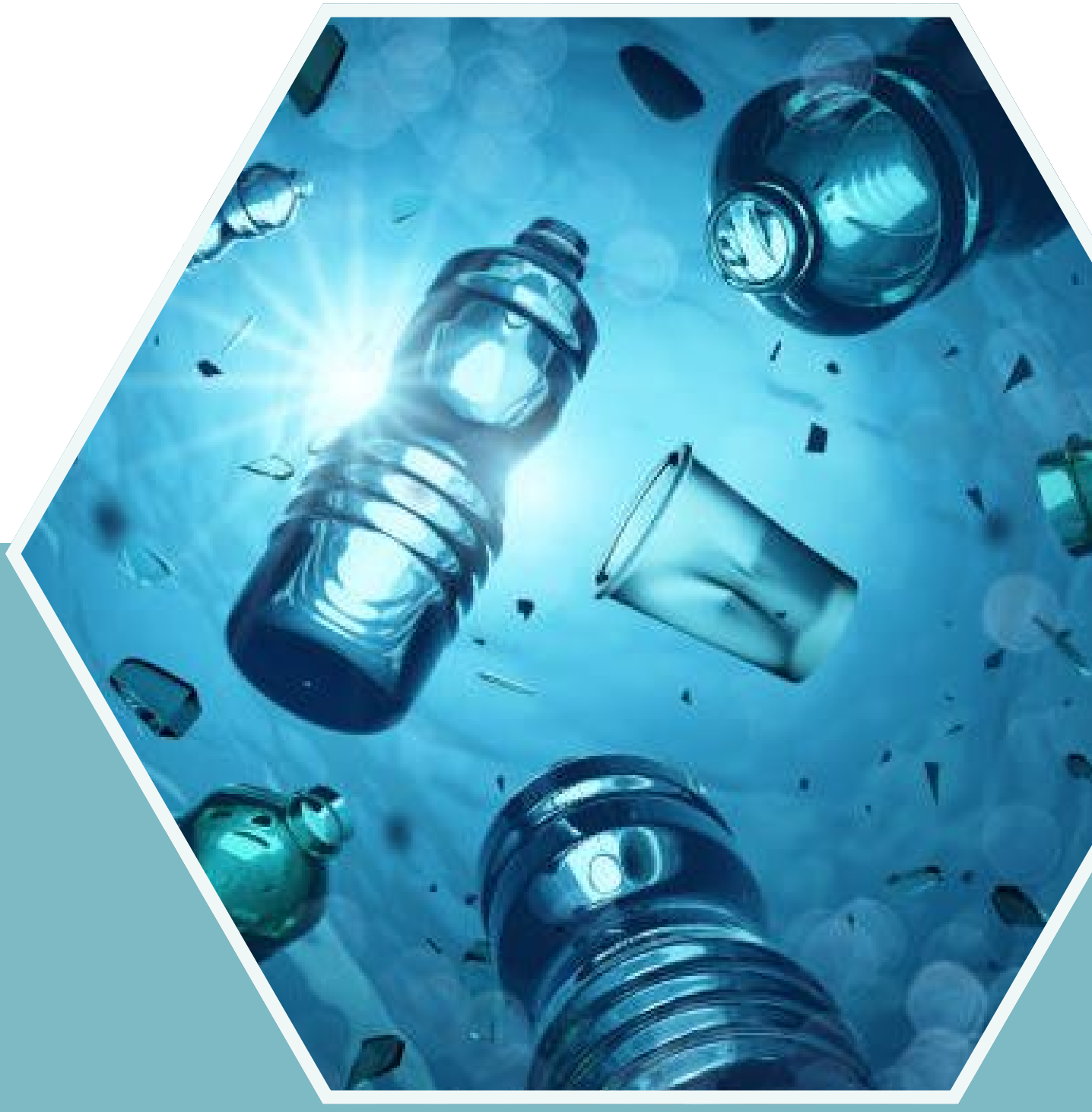
[5] N. Anwar, stakeholder interview conducted by iGEM Toronto Human Practices Team, 2025.

[6] European Parliament and Council of the European Union, "Regulation (EU) 2024/1689 (EU AI Act)," Official Journal of the European Union, August 2024. [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689

[7] A. Metzger et al., "Legal Matters in Research Software," arXiv, 2024. [Online]. Available: https://arxiv.org/pdf/2509.24646

[8] National Academies of Sciences, Engineering, and Medicine, "AI Code of Conduct," NASEM. [Online]. Available: https://www.nationalacademies.org

4. PLASTIC REGULATIONS

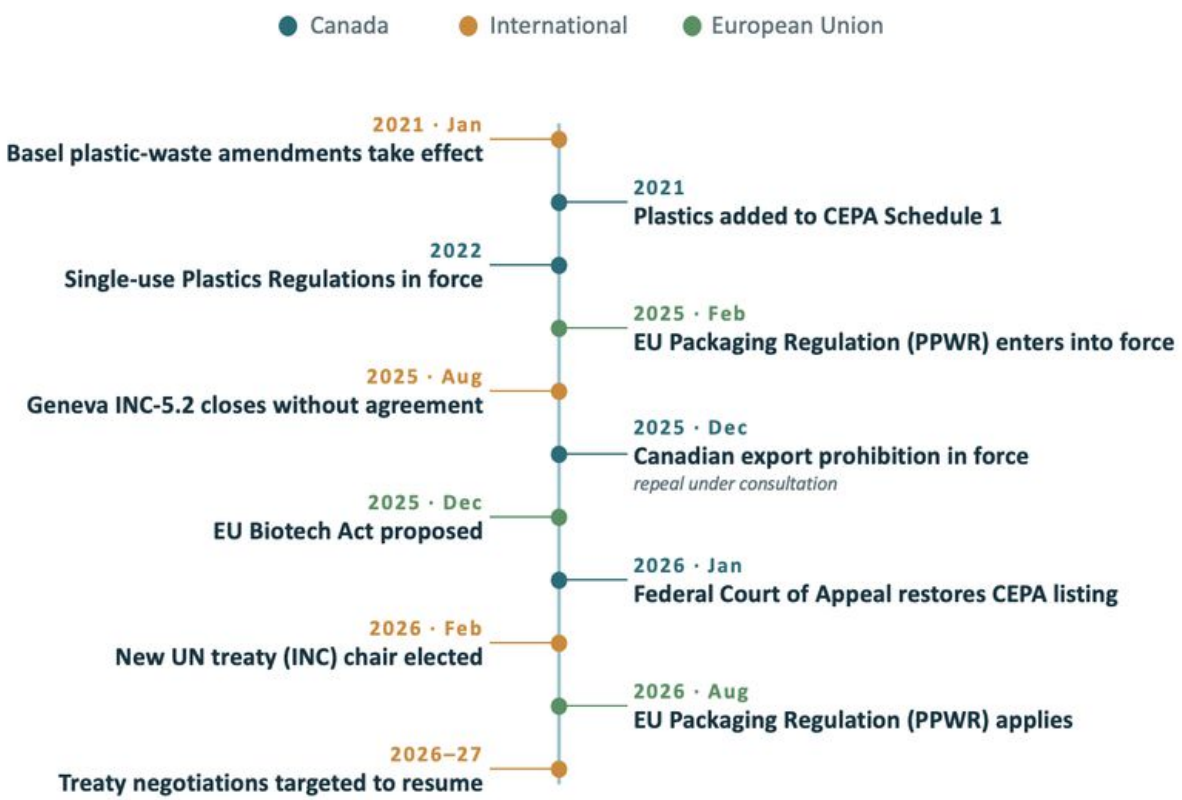


4. Plastic Regulations

PetaBite operates within a broader regulatory environment that treats plastic pollution as both an environmental and public health concern. Although PET-degrading enzymes may support plastic waste management, their use may also introduce new risks. Incomplete degradation, unintended byproducts, and the release of engineered biological systems must therefore be considered alongside enzyme performance.

Because the platform is meant to be used by others, this section reaches beyond Canadian law. Canada provides the anchoring framework, but anyone applying PetaBite elsewhere will meet different rules. The sections that follow set out the international instruments on plastic pollution and plastic-waste trade, the biosafety regimes governing engineered organisms in the major jurisdictions, and practical guidance for implementers.

Regulatory Timeline



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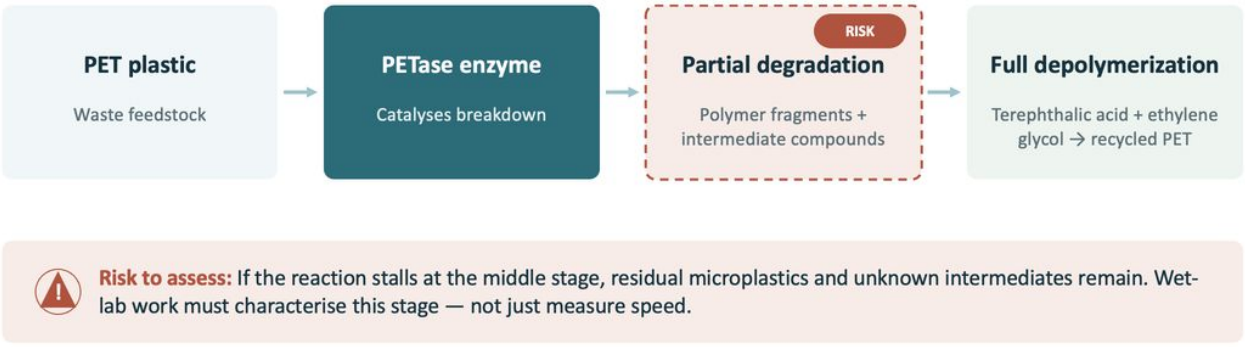
4.3 Environmental Safety and Degradation Byproducts

Breaking down PET does not automatically eliminate its environmental risks. Partial degradation may leave smaller polymer fragments or produce intermediate compounds before PET is fully converted into its monomers, and it is this middle stage that carries the greatest uncertainty (*see the PET Degradation Pathway*). PetaBite should therefore evaluate more than degradation speed. Wet Lab validation should identify the products formed, determine whether residual plastic remains, and assess how the process behaves under its intended conditions of use.

Where industrial or environmental application is being considered, the assessment should span several factors — from the toxicity and persistence of degradation products to the release and deactivation of the organisms involved (*see the Environmental Assessment Factors)*. Strong laboratory performance alone does not establish suitability for environmental release; PetaBite should distinguish candidates that merely warrant further research from those supported by sufficient evidence for controlled use.

PET Degradation Pathway



Environmental Assessment Factors



4.4 Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety governs the international movement and use of living modified organisms, particularly those intended for environmental release [6]. Engineered microorganisms that produce PET-degrading enzymes may fall within its scope. Canada is not a Party, and so is not bound by the Advanced Informed Agreement procedure that applies to certain exports of living modified organisms (*see the Jurisdiction Matrix*) [7]. This creates a regulatory asymmetry: if an engineered PETase-producing organism is exported from Canada to a country that has ratified the Protocol, the receiving country may still require notification, risk assessment, or authorization under its own biosafety framework. Canadian compliance alone would not be sufficient.

This becomes relevant if PetaBite supports the development or international distribution of engineered strains. The questions to resolve before any material is shared, whether it qualifies as a living modified organism, whether it is destined for contained use or release, and whether the receiving country requires prior authorization, are set out in the cross-border decision tree.

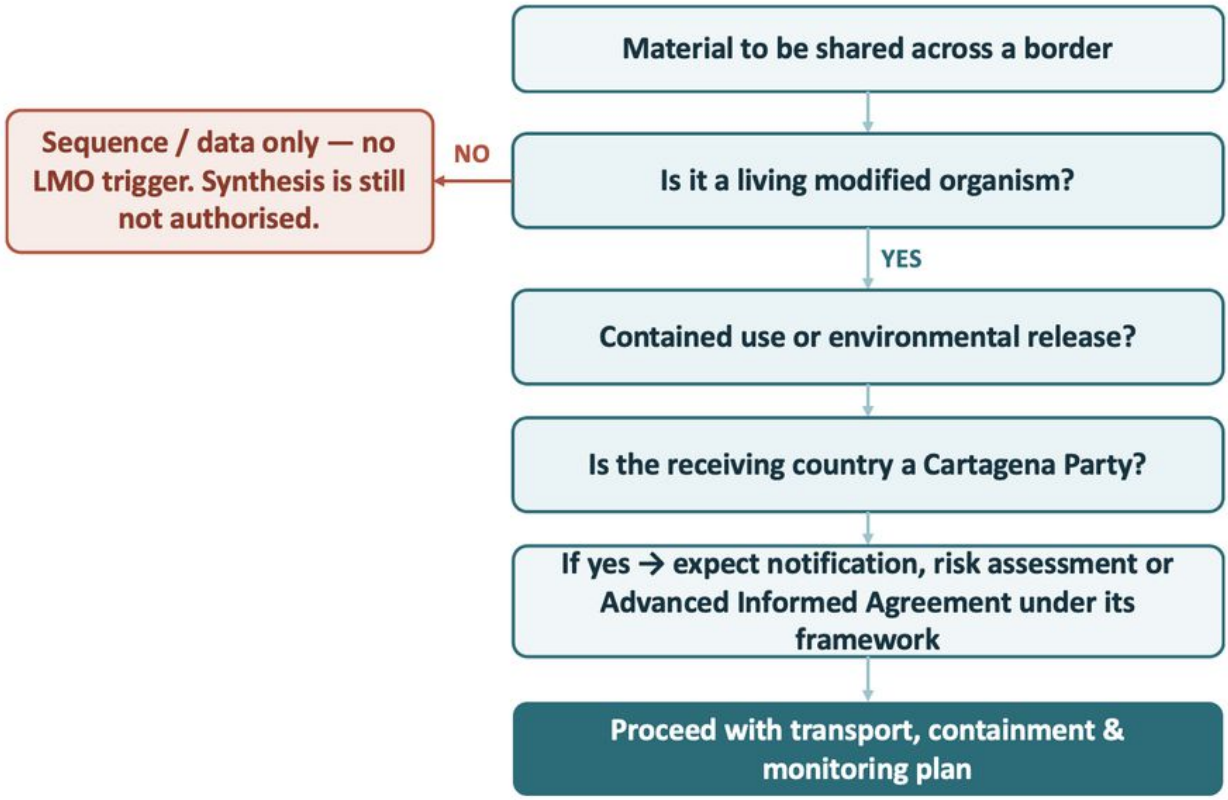
Petadex provides access to sequence information rather than living organisms. But users may build those sequences into engineered systems, so the platform should make clear that access to a sequence is not authorization to synthesize, transport, or release an organism. Where international applications are involved, PetaBite should follow Cartagena-aligned biosafety principles even though Canada is not legally bound, protecting the authority of receiving countries and supporting responsible use of the platform.

Jurisdiction Matrix

	Canada	United States	European Union
Cartagena Protocol Living modified organisms	Not a Party	Not a Party	Party
Basel Convention Plastic-waste trade	Party	Not a Party	Party
Global Plastics Treaty UN INC process	In negotiation	In negotiation	In negotiation

Key takeaway: Compliance at origin ≠ compliance at destination. A strain or shipment can meet requirements the exporting country never imposes.

Cross-border Decision Tree



4.5 International Frameworks for Plastic Pollution

Three instruments matter most to anyone implementing PetaBite outside Canada: the emerging global plastics treaty, the Basel Convention's controls on plastic-waste trade, and the European Union's packaging and single-use plastics rules. Their status and key dates appear in the regulatory timeline and the jurisdiction matrix; the EU regime, the most detailed of the three in force, is set out below.

4.5.1 The Global Plastics Treaty (UN INC process)

In 2022 the UN Environment Assembly created an Intergovernmental Negotiating Committee to develop a legally binding treaty covering the full life cycle of plastic [8]. Talks were meant to conclude by the end of 2024 but have stalled: the reconvened session in Geneva closed without agreement, and a later meeting elected a new chair after his predecessor resigned [9]. No treaty text has been adopted, and negotiations are targeted to resume around the end of 2026 or early 2027 [10] (*see the Timeline*).

4.5.2 Basel Convention: Transboundary Movement of Plastic Waste

The Basel Convention is the main treaty governing waste that crosses borders. Its 2019 Plastic Waste Amendments brought most plastic waste under the Convention's controls

through three new annex entries, ranging from cleaner single-polymer waste that can move as green-list material to mixed or presumed-hazardous waste that triggers the Prior Informed Consent (PIC) procedure [11] (*see the Basel Three-Tier Control*).

Two points affect PetaBite. Membership is uneven, as Canada is a Party, the United States is not, which limits plastic-waste movement between them (*see the Jurisdiction Matrix*) [12]. And if a PetaBite process yields plastic residues, partially degraded fragments, or waste-derived feedstocks that are shipped abroad, those materials may themselves trigger PIC. Anyone planning cross-border logistics should confirm how their material is classified before moving it.

Basel Three-Tier Control



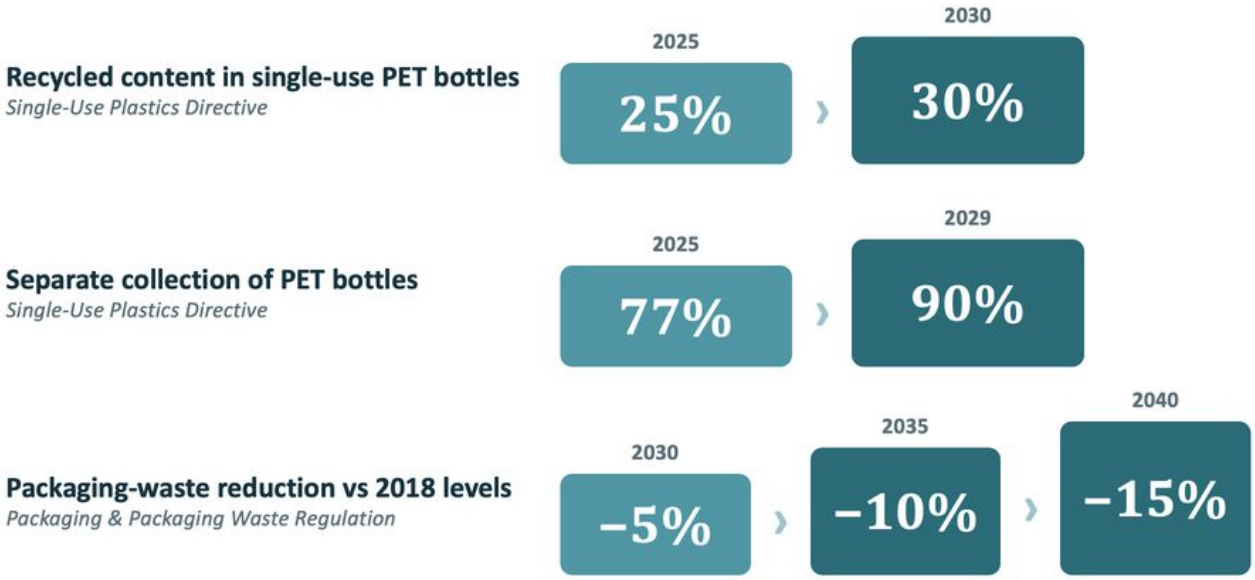
4.5.3 European Union: Single-Use Plastics and Packaging

The EU framework rests on two instruments. The Single-Use Plastics Directive (2019/904) bans certain single-use items where alternatives exist and sets recycled-content and separate-collection targets for PET bottles that rise over the coming years [13]. The Packaging and Packaging Waste Regulation (2025/40) complements it and, being a regulation, applies directly in every Member State without national transposition [14].

It requires all packaging to be recyclable by 2030, sets rising recycled-content thresholds and packaging-waste reduction targets, restricts some single-use formats, limits substances of concern such as PFAS in food-contact packaging, and mandates deposit-return systems for beverage bottles. The headline numerical targets appear in the EU targets visual, and the regulation's entry-into-force and application dates in the timeline. Non-EU businesses placing packaging on the EU market must appoint an authorized representative in the Union.

The recycled-content rules are the clearest opening for PetaBite. Enzymatic depolymerization breaks PET into monomers that can be repolymerized into near-virgin recycled PET, which can count toward these targets. Users operating in or exporting to the EU should confirm that the resulting material also meets EU food-contact and chemical-safety rules.

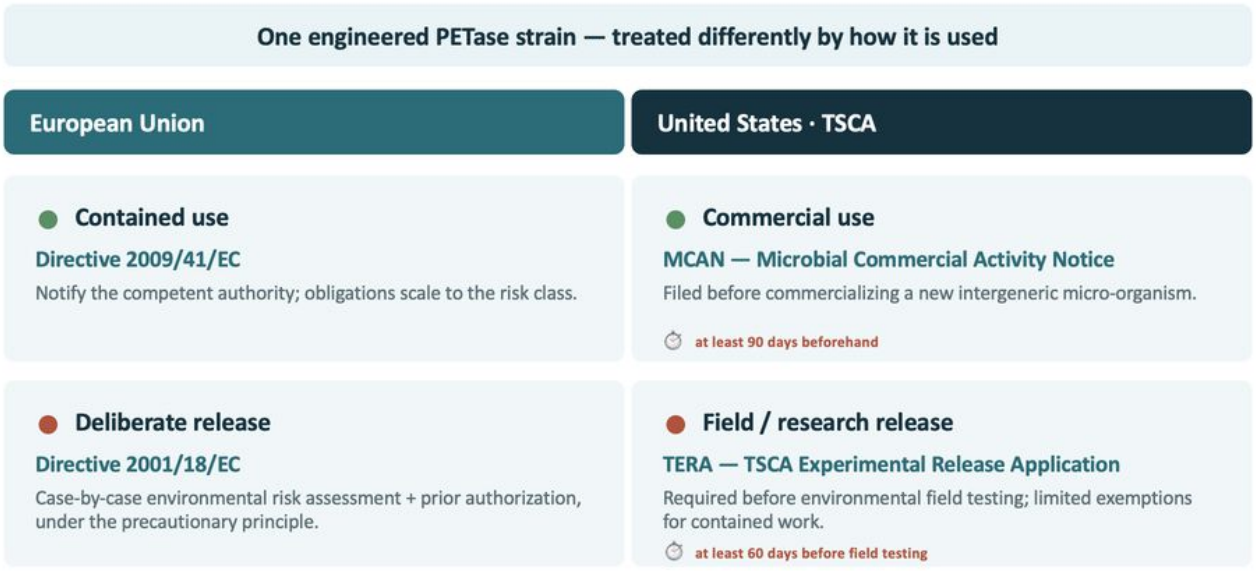
EU Targets



4.6 International Frameworks for Biosafety and Engineered Organisms

Petadex sequences may be built into engineered strains, which brings biosafety law into play. Section 4.4 covers the Cartagena Protocol, the international baseline for moving living modified organisms across borders. The EU and US regimes differ once that baseline is applied domestically, and the contrast is summarized in the Contained-Use vs Deliberate-Release Comparison.

Contained Use vs Deliberate Release



4.6.1 European Union: contained use and deliberate release

The EU regulates genetically modified organisms through several linked measures [15]. For a PET-degrading microbe, two directives matter most: one governs contained use in laboratories or closed facilities, the other deliberate release into the environment and placing on the market, with the release regime the stricter of the two (*see the Contained-Use vs Release Comparison*) [16]. Movement of GMOs out of the EU falls under Regulation 1946/2003, which implements the Cartagena Protocol.

The same strain is therefore treated very differently depending on use: contained inside a facility, it sits under the lighter regime; released, it enters the stricter one. The framework is also changing. The Commission has proposed a Biotech Act and amendments to the deliberate-release directive, including a possible low-risk category for micro-organisms and regulatory sandboxes (*see the Timeline*) [17]. This is a proposal, not law, and EU users should watch how it develops.

4.6.2 United States: the Coordinated Framework and TSCA

The United States relies on the Coordinated Framework for the Regulation of Biotechnology rather than a single biotechnology statute. It divides oversight among the EPA, FDA, and USDA under existing laws, focusing on the product and its intended use rather than the technique behind it [18].

For a PET-degrading microbe, the key authority is the EPA's control of new intergeneric micro-organisms under the Toxic Substances Control Act (TSCA). The EPA treats organisms formed through combinations of different genera as new and explicitly includes industrial enzyme production and the degradation of chemical pollutants among covered uses, a description that aligns with an engineered PETase strain [18]. The notice requirements for commercial use and for experimental environmental release, including their lead times, appear in the contained-use vs release comparison [19]. The United States is party to neither the Cartagena Protocol nor the Basel Convention (see the Jurisdiction Matrix), so a strain or waste shipment moving between the US and a party country can face requirements on the other side that US law does not impose.

4.7 Practical Guidance for Implementers

The frameworks above reduce to a short checklist for any PetaBite or PETadex user, set out in the implementer's checklist: separate the sequence from the organism; classify the activity as contained use or deliberate release; identify every jurisdiction involved, including any receiving country; assess degradation products early; and place the technology within waste policy rather than against it. Together these translate the legal detail of this section into a small number of decisions to settle before work begins.

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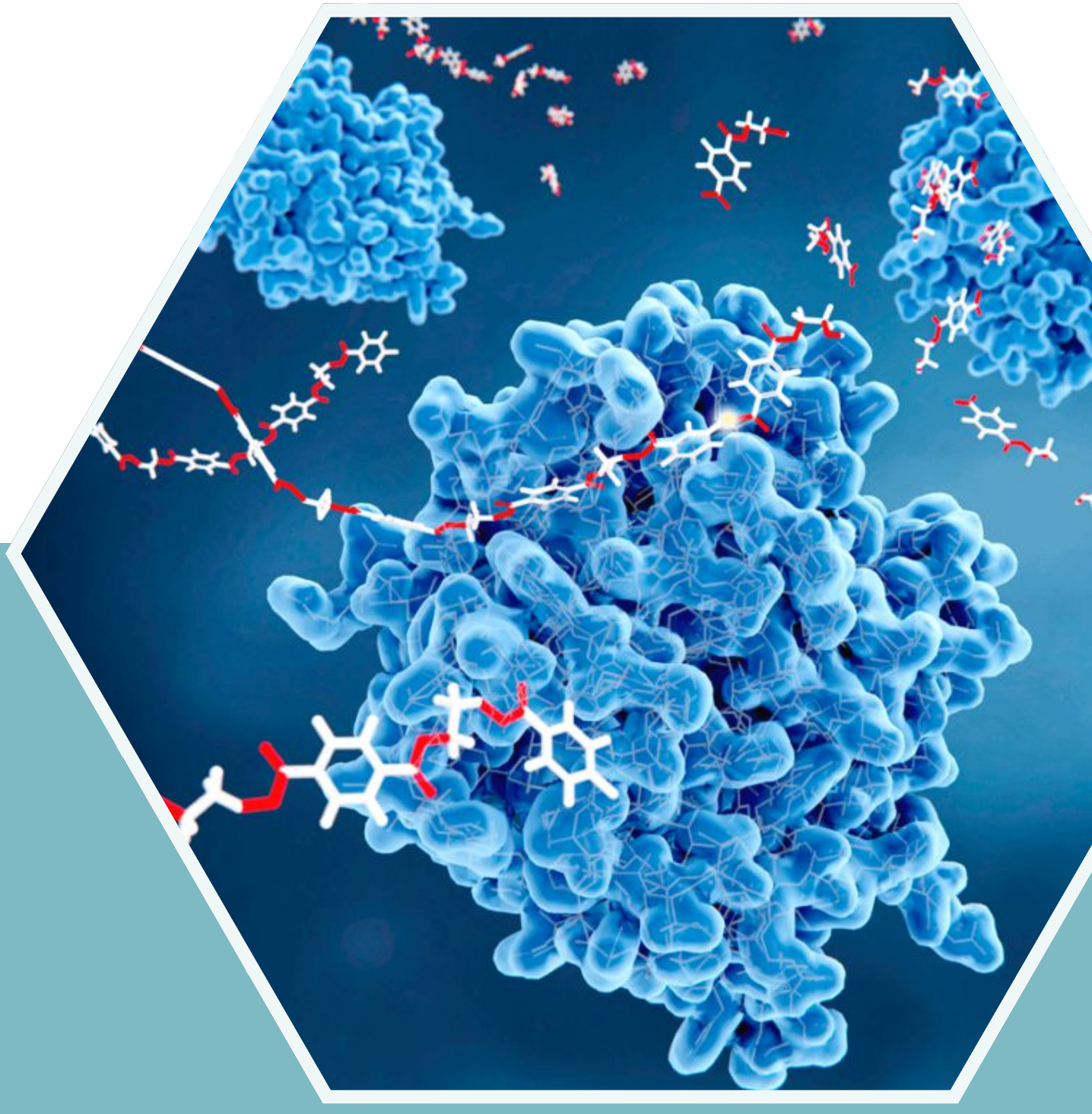
5. PETASE REGULATIONS



5. PETase Regulations

PetaBite relies on PETase enzymes to break down PET plastic. That capability could strengthen plastic waste management, but it also brings the enzymes under regulatory and biosafety oversight. How that oversight applies depends on the intended application and the place of deployment. Incomplete degradation, unintended byproducts, and the release of engineered biological systems all have to be weighed alongside enzyme performance. The frameworks that govern these risks vary widely by region, from well-developed to almost entirely absent.

5.1 PETase and Environmental Deployment Regulations by Country

The five profiles below span very different regulatory conditions. The table summarises how each compares on regulatory maturity, governing bodies and laws, infrastructure reality, deployment fit, and main risk; the profiles that follow add the interview-grounded detail behind each column.

Regulatory Landscape at A Glance

REGION	REGULATORY MATURITY	KEY BODIES / LAWS	INFRASTRUCTURE REALITY	DEPLOYMENT FIT	MAIN RISK
Pakistan	Absent — no national framework	IRBs (human-subject research only); National Bioethics Committee (advisory, non-binding); Environmental Protection Act 1997 (limited scope)	Many areas lack WWTPs; clean water and sewage mix within the network	• WWTP deployment assumption is directly undercut	• No binding oversight; affordability of real implementation
India	Layered — multi-authority, tied to specific water bodies	State No Objection Certificate; forest / fisheries departments; Ramsar Convention protections	Highly site-specific; PETase activity shifts with the seasons	• Navigable but per-site; ecological study required first	• Hard-to-control dose; heavy-metal and pollutant interference
Nigeria	Layered but weakly enforced	NESREA; Federal Ministry of Environment; NABDA; NBMA; Environmental Impact Assessment	WWTPs mainly in Lagos and Abuja, often below capacity; absent elsewhere	• Falls into a jurisdictional gray zone	• Weak enforcement; tick-box compliance; ethics dumping
Indonesia	Industry- and NGO-led; no formal state regime	Corporate and civil-society actors (e.g., Seven Clean Seas) act as gatekeepers	Infrastructure gaps filled by companies and community efforts	• Post-treatment step on already-treated water is acceptable	• Micro / nanoplastic fragments; erodes reduce-and-reuse habits
Indigenous / Canada	Rights-based; consent-driven	Section 35, Constitution Act 1982; the duty to consult	A governance framework, not infrastructure-bound	• Cannot be decided unilaterally on Indigenous lands or waters	• Technology becoming cover for continued overproduction

• Deployment fit • Main risk

5.1.1 Pakistan

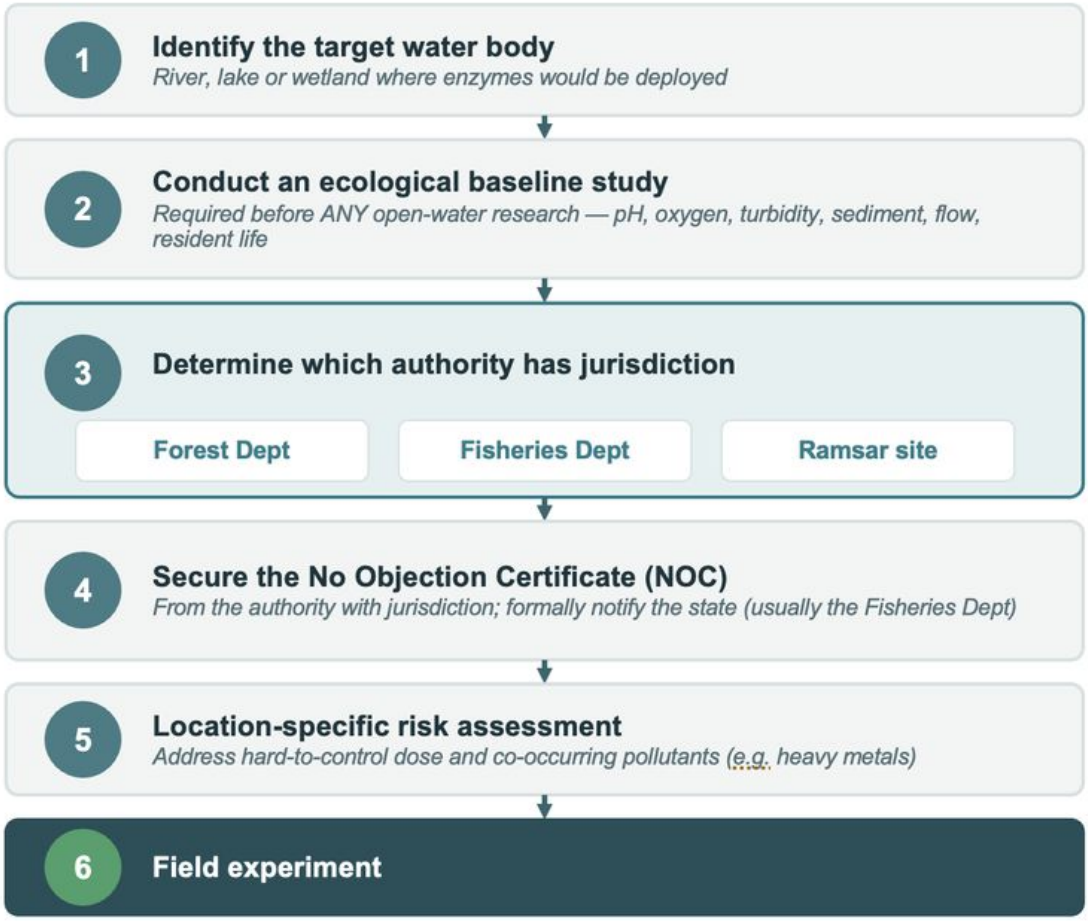
Pakistan has no national regulatory framework for synthetic-biology or environmental research. Governance is still forming, and most existing rules were written for clinical trials rather than environmental release. Dr. Natasha Anwar, who sits on the National Bioethics Committee, noted that no national document would cover a project like this [1].

Three structures define the oversight that does exist, two review bodies and one environmental law. Institutional Review Boards operate at the university level, but they review human-subject research only, so an environmental enzyme release falls outside their remit. The National Bioethics Committee reviews internationally funded projects through a mixed panel of scientists, physicians, and social scientists, yet it advises rather than enforces, aiming for best practice instead of binding approval. An Environmental Protection Act exists, in the form of the Pakistan Environmental Protection Act 1997, but its scope is limited and it does not clearly reach novel biotechnology [2]. The infrastructure gap matters as much as the regulatory one. Many parts of the country have no wastewater treatment plants at all, which undercuts the WWTP deployment assumption directly. Clean water and sewage also mix within the distribution system, and researchers are still mapping where that happens, a deployment context far removed from Canada's

5.1.2 India

India's permitting regime is organised around jurisdiction over specific water bodies rather than around biotechnology as a category.

India Permitting Pathway

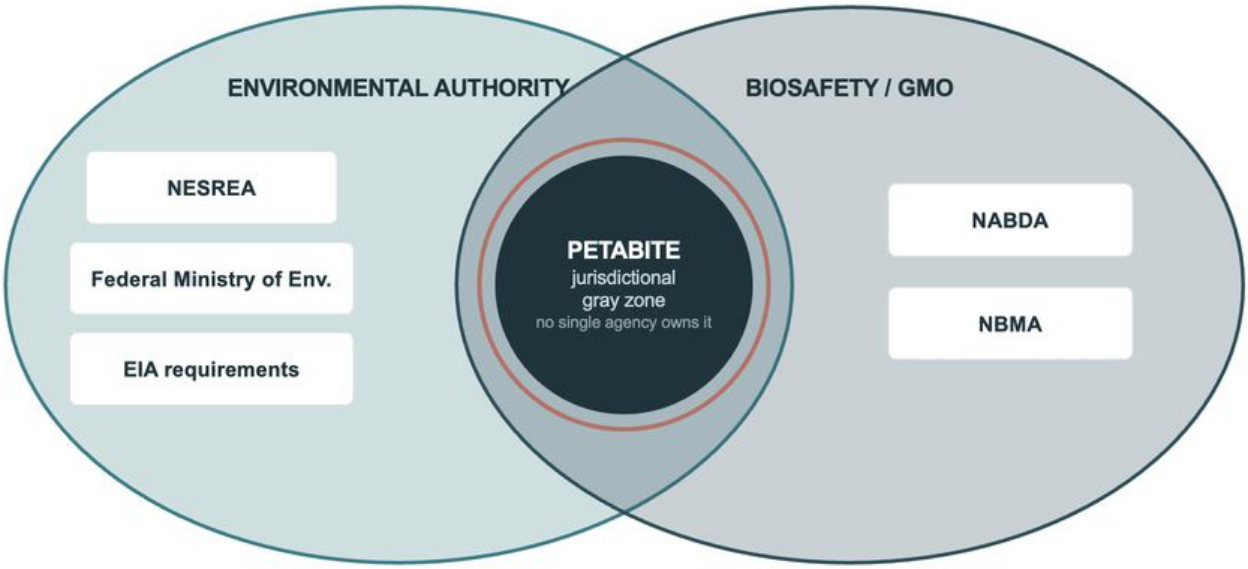


The pathway is navigable but multi-authority and site-specific: it means securing the right permissions from whichever authority holds jurisdiction over a given water body, then backing them with a location-specific risk assessment (the flowchart lays out the full sequence) [3][4]. Dr. Niti Sharma was firm on one requirement above the rest: an ecological study must precede any research in open water. These systems are shaped by temperature, pH, dissolved oxygen, turbidity, sediment and microbial composition, flow, and resident aquatic life, all interacting at once, and PETase activity itself shifts with the seasons, running higher in the dry season than the wet. Dr. Sharma also noted that open-water assays often fail or mislead when dose is hard to control and co-occurring pollutants such as heavy metals interfere, the kind of real-world evidence gap regulators would expect the team to have closed [4].

5.1.3 Nigeria

Nigeria's challenge is the reverse of Pakistan's. Frameworks are plentiful; enforcement is where they fall short. Mr. Excel Amaefule identified several agencies with overlapping authority (NESREA, the Federal Ministry of Environment, NABDA, and NBMA), plus the Environmental Impact Assessment requirements a project like this would also have to satisfy [5][8].

Nigeria overlapping authority / gray zone



The diagram maps how those bodies overlap and where PetaBite falls between them. The gaps behind them are structural. Enforcement architecture is weak, few people on the ground have the technical literacy to assess novel biotech, and frameworks can collapse into a tick-box exercise when nothing exists to implement them. Regulation also tends to react to problems rather than anticipate them. Because PetaBite fits no established category, it lands in a gray zone where no single agency clearly holds jurisdiction, a real risk for communities left without oversight.

The infrastructure picture compounds this: formal wastewater treatment is concentrated in Lagos and Abuja, often runs below capacity, and is largely absent elsewhere, where septic tanks and open drains take its place.

Mr. Amaefule's practical advice was to engage NABDA or NESREA early (not to seek approval, but to learn where the project sits and which frameworks they would flag), and to document that engagement as part of the team's human-practices work [5]. Dr. Sogbanmu, who has served on Environmental Impact Assessment review panels for the Federal and Lagos State Ministries of the Environment, added what reviewers look for: field-based evidence rather than lab results alone, and clear, peer-reviewed accounting of how degradation byproducts are managed, so the solution does not add to the toxicity it sets out to remove [9]. Both stakeholders returned to benefit-sharing under the Nagoya Protocol [10]. Open access, they warned, is not the same as equitable access, and ethics dumping, holding Global North standards for consent and oversight optional elsewhere, is a live risk the framework must guard against.

5.1.4 Indonesia

In Indonesia, plastic-waste governance runs more through industry and NGOs than through a formal state regime for enzyme deployment. Jenny Hutagaol of Seven Clean Seas, a Singapore-based social enterprise that runs ocean-plastic cleanup and prevention projects across Southeast Asia, described a landscape with no large-scale national solution, where responsibility tends to fall on individual companies and community efforts center on awareness and closing infrastructure gaps [11]. The practical gatekeepers, in other words, are as likely to be corporate and civil-society actors as government agencies. Her read on regulatory fit was that a post-treatment application would be acceptable, with enzymes added as a step to break down microplastics in already-treated water, augmenting existing treatment rather than releasing enzymes into open environments. Incomplete degradation that fragments plastic into micro- and nanoplastics would create a worse hazard than the original, one that cannot then be removed physically. Byproduct chemistry and the effect on surrounding soil or marine microbial life need to be understood before deployment. She also raised a governance concern with real weight: an easy end-of-pipe technology can erode the reduce-and-reuse habits that sit higher in the waste hierarchy, and a public unfamiliar with enzymes may read them as toxic. Her recommendation was to survey consumer perception before positioning PETase as a recycling solution [11].

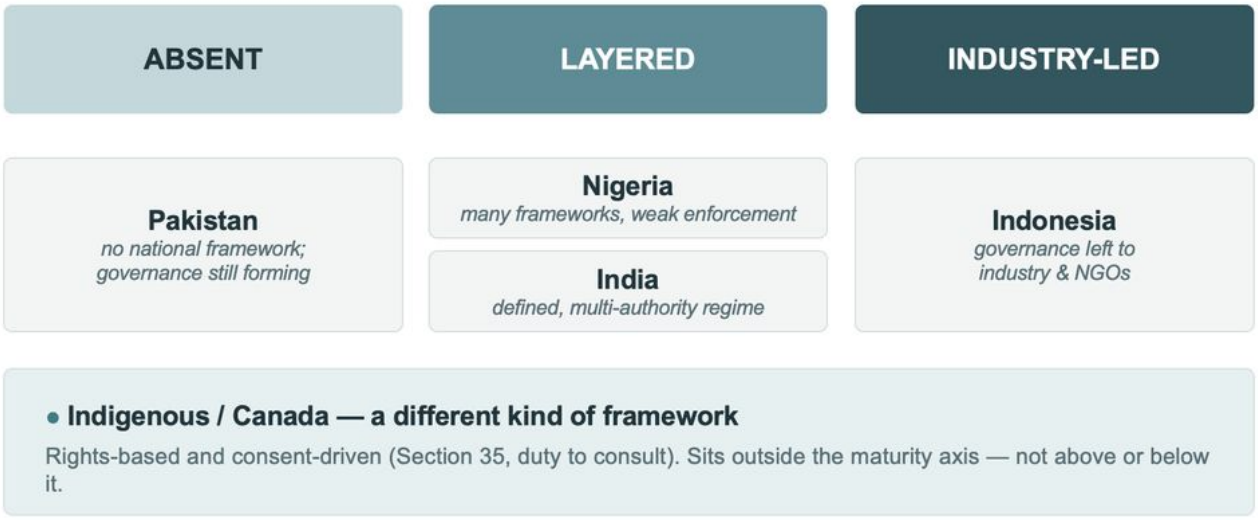
5.1.5 Indigenous Governance and Community Consent

This profile differs in kind from the others; it describes a governance framework grounded in relationality, consent, and self-determination, drawn from the team's interview with Dr. Leroy Little Bear, a Blackfoot scholar, an architect of Section 35 Indigenous constitutional rights, and founder of Canada's first Native American Studies Department.

It belongs here because PetaBite is built in Canada, where deployment touching Indigenous lands or waters carries genuine legal obligations [12]. Two elements are directly regulatory. Section 35 of the Constitution Act, 1982 constitutionally protects Indigenous and treaty rights, and together with the duty to consult it means deployment affecting Indigenous territory cannot be decided unilaterally [13]. Dr. Little Bear's work on the Indigenous Wisdom Advisory Panel, which folds Indigenous knowledge into the environmental monitoring of industrial impacts, offers a working model for safety and stewardship defined by the community rather than imposed from outside. He framed the underlying choice as transactional versus transformative. The transactional, convenience-driven logic is what normalised plastic in the first place; a transformative logic asks how a technology restores balance and treats the land as one would treat a relative. He supported the project on those terms, while cautioning that the technology should not become cover for continued overproduction. For the framework, this translates into deciding with communities rather than for them, weighing long-term and intergenerational impact over immediate gain, and staying humble about the "bigger, faster, more" mindset, a caution he aimed at AI-driven design in particular [13].

5.2 Why These Regions?

Regulatory Maturity Spectrum



The five profiles carry some of the heaviest plastic-pollution burdens in the world, and they are the contexts where PetaBite could be helpful. Anchoring the framework in the places most affected, rather than only in the Canadian setting where the tool is built, is central to the project's aim of not imposing a solution from elsewhere. As the spectrum above shows, the profiles also span the full range of regulatory maturity, and mapping that range is what makes the framework portable across absent, nascent, layered, and industry-led environments. Each profile rests on a primary interview rather than secondary literature alone. Speaking directly to experts surfaced grounded detail that published sources would miss, such as the clean-water and sewage mixing in Pakistan, the Ramsar-site permissions in India, and the jurisdictional gray zones in Nigeria.

The set also covers both a Global North-adjacent middle-income context in Indonesia and lower-income settings in Pakistan and Nigeria. That range matters for feasibility, because Dr. Anwar's warning about affordability and real implementation bites hardest in the lower-income profiles, while the Indonesian case tests whether an industry-routed deployment can work where the state is not the main actor. Moreover, several of these regions are plausible origins of the biodiversity and sequence data the database draws on, which makes them the communities to whom benefit-sharing is owed under the Nagoya Protocol principle raised by both Mr. Amaefule and Dr. Sogbanmu. Profiling them speaks to feasibility and to the project's commitment to equitable use of globally sourced data at the same time. Including an Indigenous governance profile grounds that commitment at home, keeping consent and co-design in view within Canada as well as abroad.

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6. ETHICS



6. Ethics

6.1 Data Ethics

PETadex draws enzyme sequences from public DNA repositories containing samples collected across many countries and ecosystems. Although the data may be publicly accessible, its biological origin still matters. Sequences originating from biodiversity-rich regions may be connected to national access and benefit-sharing requirements or expectations established by the communities and institutions that contributed the original samples. PETadex should preserve clear provenance records for every sequence. These records should identify the source database, accession number, sampling location, collection date, and any known access or reuse conditions. Users should be able to determine where a sequence came from before applying it to research or commercial development.

Public availability should not be treated as unrestricted ethical ownership. PETadex should also communicate any benefit-sharing conditions linked to the original genetic resource. Where a commercially valuable enzyme is identified, those who provided the samples or supported their collection should not disappear from the development pathway. Appropriate benefits may include research collaboration, acknowledgement, shared results, training, or access to technologies developed from the sequence. If PETadex later accepts user-submitted sequences, assay results, or other data, contributors must be told how their information will be stored and used. Consent should cover whether the data will be made public, used to train computational models, shared with third parties, or retained after submission. Users should also be informed of any process for correcting or withdrawing their contributions.

6.2 Equity in Deployment

The proposed applications of PET-degrading enzymes may depend on bioreactors, filtration systems, temperature control, monitoring equipment, and trained personnel. These requirements may be manageable in well-resourced facilities, but they cannot be assumed to exist in every intended region. Deployment plans should therefore begin with local infrastructure rather than a standardized technical model. A system that works in a Canadian wastewater treatment plant may not be practical in a community with unreliable electricity, limited laboratory access, or no capacity to monitor enzyme release. Where these barriers exist, PetaBite should consider simpler containment systems, local maintenance requirements, and partnerships that build technical capacity. Regulatory burdens are also uneven. Countries with established biotechnology frameworks may require extensive environmental and biosafety evidence before approving enzyme

deployment. Other jurisdictions may allow faster implementation because their rules or enforcement systems are less developed. Regulatory flexibility should not be used as an opportunity to test technologies where communities have fewer protections or less influence over environmental decisions.

6.3 Plastic Justice

Plastic pollution is not distributed evenly. High-income countries have historically consumed more materials and generated large volumes of plastic waste, while many lower-income countries experience greater exposure to unmanaged waste, dumping, flooding, and contaminated food or water systems. Plastic pollution can therefore affect health, food security, livelihoods, economic development, and the ability of communities to safely use their land and waterways. These inequalities are part of what is often described as plastic justice. The concept examines who produces and profits from plastic, who manages its waste, and who experiences the resulting harm.

More than half of all plastic produced since 1950 was manufactured after 2000. Single-use plastic production has also continued to rise; approximately six million more tonnes of single-use plastic waste were generated in 2021 than in 2019 [1]. At the same time, broader patterns of environmental inequality show that responsibility for ecological damage is concentrated among wealthier countries. For example, one analysis attributed approximately 40% of excess cumulative carbon dioxide emissions to the United States and 29% to the European Union, despite these regions representing a much smaller share of the global population [2]. Although this statistic concerns climate emissions rather than plastic alone, it illustrates the unequal production and distribution of environmental harm.

PetaBite should not frame enzyme-based degradation as a technological solution that removes responsibility from plastic producers or major consuming countries. Degradation may help manage existing waste, but it does not replace reductions in production, stronger producer responsibility, or investment in local waste systems.

6.4 Waste Colonialism

The export of waste from wealthier countries to countries with lower processing costs or weaker enforcement has been described as waste colonialism. This practice transfers the health and environmental consequences of consumption away from those who produced the waste and toward communities with fewer resources to manage it safely. China was historically the largest importer of plastic waste. After it introduced restrictions and largely ended these imports in 2018, global waste flows shifted toward other countries, including Malaysia, Indonesia, Thailand, Vietnam, and the Philippines. These countries are sometimes identified as major sources of ocean plastic because waste may be

mismanaged within their borders. Such labels can obscure the fact that part of this material was originally produced and discarded elsewhere.
Several countries have pushed back against this arrangement. In 2019, the Philippines returned 69 containers of waste to Canada after they had been incorrectly labelled as recyclable plastics, ending a dispute that had continued for several years. Malaysia also announced that it would return thousands of tonnes of plastic waste to exporting countries after imports rose sharply following China's restrictions. These cases demonstrate that waste transfer is not simply a logistical question. It involves national sovereignty, environmental protection, and the right of communities to refuse other countries' waste.

6.5 Transboundary Waste Governance

The Basel Convention regulates international movements of hazardous and other controlled wastes. Its plastic waste amendments, which took effect on January 1, 2021, brought most mixed, contaminated, and difficult-to-recycle plastic waste under prior notice and consent requirements. This means that many shipments cannot legally proceed without approval from the importing and transit countries. The Basel Ban Amendment is related but distinct. It prohibits covered hazardous-waste exports from Annex VII countries, including members of the European Union and the Organisation for Economic Co-operation and Development, to non-Annex VII countries. The amendment entered into force on December 5, 2019. International rules do not eliminate unethical or illegal trade. Plastic shipments may be incorrectly classified as clean recyclables, while limited inspection capacity can make violations difficult to identify. Differences between exporter and importer records also leave gaps in available trade data. PetaBite should therefore consider the full origin and destination of any plastic feedstock used in future pilots. Compliance should include documentation that the waste was legally obtained, accurately classified, and accepted by the receiving jurisdiction. Enzyme-based processing should not legitimize waste shipments that would otherwise be unsafe, exploitative, or inconsistent with international controls.

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7. RESPONSIBLE DEVELOPMENT



7. Responsible Development

7.1 Ethics & Global Justice

Ethics dumping is the practice of conducting research under standards that would not be accepted in the researcher's home country, by exploiting weaker regulatory oversight in low and middle income countries [1]. The term was formally introduced by the European Commission's Science with and for Society unit to describe research involving sensitive ethical questions conducted outside the EU in ways that would not be permitted within it. Nature Portfolio has since begun requiring disclosure statements on inclusion and ethics in international studies, acknowledging that exploitative research practices in the Global South are a documented historical pattern rather than an exceptional case [2], [3].

PetaBite works in conditions where such risks exist. PetaBite originates from Canada and relies on DNA data at the scale of the whole planet, which may involve DNA samples taken from biologically diverse countries from the Global South, such as Pakistan, Nigeria, and Indonesia. Some of the stakeholders' discussions brought up specific elements of this problem.

Dr. Natasha Anwar questioned us on the nature of stakeholder engagement. As she pointed out, ethics is frequently an afterthought, and one can tell the difference between meaningful ethics and performative ethics in whether a team can document specific changes made as a result of their conversations. She raised the question of why Pakistan should prioritize plastic pollution above other pressing environmental and social needs, and cautioned that a tool that cannot be afforded or practically implemented is not a meaningful intervention regardless of its technical performance [4].

Mr. Excel Amaefule noted that ethics dumping is a documented risk in North-South technology transfer, not just a hypothetical one. He mentioned the requirement for informed consent, benefit-sharing, accountability, and other processes that are mandatory in the Global North tend to slip into the optional category when in the Global South. The fundamental rule for him was to make decisions with the community, not for the community [5].

Dr. Sogbanmu made it clear that legitimate environmental biotechnology must be co-created and co-designed by the affected communities. Trust is not assumed, and public skepticism can prevent adoption even after regulatory approval is obtained [6].

Dr. Leroy Little Bear provided an extended ethical framework for our discussion. He distinguished between transactional thinking, which is based on extraction and efficiency, and transformative thinking, which is relational and focuses on ecology and its preservation. While he supported the creation of enzymes that degrade plastic in order to restore the balance in nature, he noted that the whole system, including business motives and consumerism, remained transactional. Ethical deployment of PetaBite requires ensuring it does not reinforce extractive patterns, and that the land and communities affected are treated with the same care one would extend to relatives [7].

The question of enzyme-based degradation technology was raised differently by Karen Wirsig of Environmental Defence Canada. She stated that the use of enzyme-based degradation technology could give plastics manufacturers a false sense of security, which could be used as an excuse for producing plastic waste instead of reducing its amount. The contribution of PetaBite should be presented as a supplement to the reduction of plastic waste [8].

These perspectives raise four questions that PetaBite must be able to answer.

1. Who benefits from enzyme discoveries derived from Global South biodiversity?
2. Are deployment decisions made with or for affected communities?
3. Does open access to PETadex translate to usability in low-infrastructure settings?
4. Are licensing and IP structures designed to prevent a situation where Global North institutions commercialize tools that Global South communities cannot afford?

The solutions need to take into consideration societal situations such as poverty and inequality, and also need to incorporate information learned through small-scale efforts and practices locally.

7.2 Regulatory Considerations by Region

Input from stakeholders has shaped how PetaBite views the regulatory environment for its proposed deployment across multiple jurisdictions.

Mr. Excel Amaefule clarified that Nigeria’s regulatory landscape for environmental biotechnology has a gap between policy and practice. The three agencies, NESREA, NABDA, and NBMA, all have jurisdiction concerning environmental biotechnology. However, their jurisdictions do not define a path through which one can get approval for use of a novel tool such as PETadex. It was suggested that PetaBite initiate contact with NESREA and NABDA to understand where the technology stands in their frameworks [5].

Dr. Niti Sharma, an environmental scientist specializing in the study of microbial populations in river sediments in India, pointed out that for field trials in water bodies of India, a No Objection Certificate is mandatory from the state department of fisheries and forests, along with ecological impact assessment prior to conducting any experiment in open water systems [9].

Solace Anyanwu, a bioprocess and policy specialist, noted that living engineered microorganisms face significantly stricter regulations than purified or immobilized enzymes, with unpredictable approval timelines that could stall deployment. She recommended prioritizing immobilized enzyme approaches for wastewater applications, a recommendation consistent with feedback from multiple engineering stakeholders [10].

One of the key experts on the regulatory path for microplastics in biosolids was Dr. Ryan Prosser from the University of Guelph. Currently, the regulatory push is directed toward nutrients, metals, and PFAS; however, microplastics might be the next step. Dr. Prosser noted that regulators are currently hesitant to set strict microplastic limits in biosolids because no effective removal methods exist. WWTPs would not be able to comply, which could force them to stop land application of biosolids entirely. A working enzymatic removal method could therefore give regulators the confidence to act, meaning PetaBite's development timeline and the regulatory timeline may move together rather than one waiting on the other [11].

Prof. Hubert Cabana raised an important issue regarding the environmental safety of PetaBite in terms of its regulatory stance. The incomplete degradation of PET may give rise to intermediate fragments that are more toxic and biologically active compared to the solid plastic itself. For proving any environmental advantage, one needs to prove the complete degradation of the material to nontoxic fragments, rather than just demonstrating the activity of the enzyme [12]. For wet lab, this means that showing an enzyme is active is not enough as validation needs to demonstrate complete breakdown to non-toxic end products.

As Prof. Grant Allen of the University of Toronto's BioZone confirmed, it is not easy to implement an enzymatic technology at the WWTP, because of the dilution effect and competing organics. However, Prof. Grant Allen suggested that it should be immobilized on some support, to avoid being washed out; the secondary clarifier, return activated sludge line or sidestream technology should be chosen as the most realistic place for implementation [13].

7.3 Feedback Integration

The point raised by Dr. Anwar was that genuine human practices work is whether the suggestions of stakeholders lead to tangible changes in the project, not just acknowledgement [4]. The changes that have been made to the PetaBite design based on discussions with the stakeholders have been listed below, and are documented by the team.

Based on feedback provided by Dr. Rasha, who is a principal scientist in environmental microbiology and water treatment R&D, the hardware prototype was shifted from a full scale bioreactor design to a microcosm scale. Mesophilic temperature range was included as one of the enzyme selection filters in PETadex. The Wet Lab assays have been modified to work in a temperature range between 15°C and 38°C. This takes into consideration that WWTP operations run at such temperatures. The PetaBite dosing system has also been redesigned for ease of use by the operator and remote monitoring. Dr. Rasha pointed out that adding PETase to laundry detergent would avoid the lengthy approval process required to introduce a new technology into a wastewater treatment plant. As a result, a laundry detergent application was added as a second avenue for PetaBite to pursue alongside the wastewater treatment use case.

After receiving comments on IP and database design from a TFC advisor, the database was redesigned to differentiate between predicted and experimentally confirmed enzyme entries, thus addressing the concern noted by Dr. Anwar with the communication of AI prediction limitations, and in line with the recommendation made by Dr. Maria Martin of UniProt [14].

After receiving feedback from Shane Harker, the founder of Rethink Resource and an expert on waste management, PetaBite's messaging was adjusted to complement rather than compete with mechanical recycling. The primary WWTP pitch now leads with microplastic reduction in biosolids. This addresses directly the concerns expressed by Karen Wirsig regarding enzymatic degradation becoming an excuse for making more plastic [14].

After receiving comments from Arjun Krishnan, a plastics recycling infrastructure expert, the deployment strategy was updated to focus on anaerobic digestion in WWTPs due to the high concentration of PET, longer retention times and stable conditions there. He mentioned that introducing a new biotechnological solution without studying its long-term environmental effects can backfire, pointing to PFAS as an example of a chemical that was widely used before its harmful persistence in the environment was understood. PetaBite added a formal research question about what happens to the enzyme after it has done its job: where does it go, does it persist in the environment, and is it safe [14].

7.4 Next Steps

PetaBite has conducted interviews with over 70 stakeholders across Pakistan, India, Nigeria, Indonesia, Canada, and Indigenous communities. Based on these consultations and the regulatory frameworks discussed above, several priorities have emerged.

PetaBite should proactively engage with NESREA and NABDA in Nigeria, as recommended by Mr. Amaefule, to better understand how PETadex fits within existing regulatory categories. These discussions would also be documented as part of the team's Human Practices work.

Any proposed field deployment, whether in Canada or internationally, must be preceded by ecological assessments, community engagement, and regulatory notifications, as emphasized by Dr. Niti Sharma and Dr. Sogbanmu. PetaBite should maintain consistent minimum safety standards across jurisdictions, regardless of differences in regulatory requirements.

Wet Lab validation must assess complete PET degradation into non-toxic end products rather than enzyme activity alone, as emphasized by Prof. Cabana and Dr. Prosser. Particular attention should be given to preventing the formation of nanoplastics through incomplete degradation. PetaBite should continue engaging with communities in regions most affected by plastic pollution to evaluate whether PETadex is accessible and practical in low-infrastructure settings.

Following Dr. Maria-Jesús Martin's recommendation to consult researchers directly about their needs, we also began conducting interviews specifically focused on PETadex. These interviews aim to gather feedback on the website's functionality, accessibility, and potential applications, ensuring that its development reflects how researchers would actually use the platform. By incorporating feedback from prospective users, we hope to develop a tool that is not only scientifically valuable but also practical and useful to the research community.

To support broader engagement, our Human Practices team hosted the inaugural University of Toronto Microplastics Conference, bringing together researchers, policymakers, and community stakeholders to discuss microplastic pollution and potential solutions. The conference addressed Dr. Sogbanmu's recommendation to encourage interdisciplinary collaboration and engage audiences beyond the scientific community. It also provided an opportunity to share PetaBite's work and gather feedback from a broader audience [6]. Learn more about the conference in our Education section.

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[5] E. Amaefule, stakeholder interview conducted by iGEM Toronto Human Practices Team, July 8, 2026.

[6] T. Sogbanmu, stakeholder interview conducted by iGEM Toronto Human Practices Team, 2026.

[7] L. Little Bear, stakeholder interview conducted by iGEM Toronto Human Practices Team, June 15, 2026.

[8] K. Wirsig, stakeholder interview conducted by iGEM Toronto Human Practices Team, 2026.

[9] N. Sharma, written feedback provided to iGEM Toronto Human Practices Team, 2026.

[10] S. Anyanwu, stakeholder interview conducted by iGEM Toronto Human Practices Team, 2026.

[11] R. Prosser, stakeholder interview conducted by iGEM Toronto Human Practices Team, July 10, 2026.

[12] H. Cabana, stakeholder interview conducted by iGEM Toronto Human Practices Team, 2026.

[13] G. Allen, stakeholder interview conducted by iGEM Toronto Human Practices Team, 2026.

[14] iGEM Toronto PetaBite, SynBioBeta, TFC, and WebSummit Advisory Session Records, 2026.