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PetaBite

Entrepreneurship Regulatory Landscape



iGEM Toronto 2026 - PetaBite

1. Overview and Scope

Deploying an enzyme-based microplastic degradation technology in Canada requires navigating a two-tier regulatory system. Federal review determines whether the enzyme itself is legal to manufacture and use nationwide, while provincial review governs its deployment at specific provincial facilities.

This review will focus primarily on the regulatory landscape within Canada, where PetaScale plans to scale following iGEM. The regulatory report is most closely aligned with the wastewater treatment plant (WWTP) vertical, reflecting its comparatively greater feasibility for near-term deployment. Within Canada, operations within this vertical will focus on provincial regulations in British Columbia, Ontario, Alberta, and Newfoundland. These are the provinces where we have held promising initial feasibility discussions or identified the highest concentration of WWTPs.

For additional insights into the bioethical considerations surrounding the industrial implementation of biological solutions, please refer to the Regulatory Report on the Human Practices page.

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2. Federal Regulatory Pathway: Canadian Environmental Protection Act (CEPA)

Before PetaScale's PETase enzyme can be manufactured or used in Canada, it must be assessed under CEPA's New Substances provisions, the federal framework governing whether any new chemical or biological substance is safe to introduce into Canadian commerce. This assessment is carried out jointly by Environment and Climate Change Canada (ECCC), the federal department responsible for environmental protection, and Health Canada, which evaluates potential human health impacts (Environment and Climate Change Canada n.d.). Together, these two departments determine whether a substance can legally be manufactured, imported, or used in Canada, and under what conditions they can be implemented.

PETase is classified for this purpose as a biochemical substance, which is the regulatory category applied to enzymes and other biologically-derived products where the substance itself (rather than the organism used to produce it) is what is being manufactured and deployed. This places PETases under the New Substances Notification Regulations (Chemicals and Polymers),

commonly abbreviated NSNR, rather than the separate stream governing living organisms (New Substances Notification Regulations 2005). This distinction matters as it determines which specific dataset PetaScale must assemble and submit.

Two federal reference lists play a central role in scoping this dataset: the Domestic Substances List (DSL), which catalogues substances already recognized as manufactured or used in Canada, and the Non-Domestic Substances List (NDSL), its counterpart for substances already recognized in the United States (Canada Gazette 2025). A substance appearing on either list is treated as "existing" and is exempt from full notification; a substance appearing on neither is treated as new, triggering the complete notification process. As a computationally-designed enzyme sequence with no prior commercial precedent, PETase likely does not appear on either list and will accordingly be treated as a new substance requiring full notification.

The NSNR further distinguishes substances by manufacturing or import volume, assigning notification requirements under Schedule 10 for quantities between 1,000 and 10,000 kilograms per year, and Schedule 11 for quantities exceeding that threshold (New Substances Notification Regulations 2005, ss. 6–7). PETase does not qualify for the regulation's reduced-data pathway, which is reserved for polymers already listed or built entirely from already-listed components. Since neither condition applies to a novel enzyme sequence, PetaScale's notification is expected to proceed under Schedule 10 during pilot-scale deployment, transitioning to Schedule 11 as production scales toward commercial volumes.

The regulation imposes an additional, enzyme-specific requirement on top of this base schedule: where a biochemical substance possesses enzymatic activity, the notifier must also supply the information set out in Schedule 2, items 7 through 13: a dataset covering the enzyme's substrate specificity, optimal operating conditions, catalytic kinetics, cofactor requirements, and activity levels (New Substances Notification Regulations 2005, sch. 2). Since this data characterizes properties intrinsic to the enzyme itself, it will be generated through laboratory assays rather than compiled from existing literature that will constitute the most resource-intensive component of PetaScale's federal filing.

3. Provincial Regulatory Pathway: Ontario

Once federal legality is established, deployment of PetaScale's enzyme technology within Ontario falls under the authority of the province's environmental ministry, the Ministry of the Environment, Conservation and Parks (MECP), the body responsible for approving environmental activities and enforcing compliance across Ontario. MECP's authority to regulate wastewater treatment specifically flows from two statutes: the Environmental Protection Act (EPA), Ontario's broad environmental law governing discharges and contaminants generally, and the Ontario Water Resources Act (OWRA), a companion statute focused specifically on the protection and use of water resources, including sewage works (Environmental Protection Act 1990; Ontario Water Resources Act 1990). Together, these two statutes give MECP the legal authority to require, review, and approve the specific kind of change PetaScale's technology represents.

Because PetaScale's enzyme is introduced as an additive into an existing, already-approved wastewater treatment facility, the relevant regulatory step is not a new application, but an amendment to that facility's existing Environmental Compliance Approval (ECA). An ECA is the core operating permit that MECP issues for a wastewater treatment plant, in which any facility introducing a new industrial process, which enzyme dosing constitutes, is required to amend its existing ECA to reflect that change (Government of Ontario n.d.-a).

An ECA amendment application of this kind requires a defined package of supporting technical documentation. At its core, this includes a process description explaining exactly how and where the enzyme is introduced: its dosing method, its point of entry within the treatment train, and how long it remains in the system before discharge, along with effluent discharge criteria showing what effect, if any, the enzyme has on the quality of the water leaving the plant.

This effluent data must be developed following MECP's own methodology for setting discharge limits, known as Procedure B-1-5, and must be paired with an assimilative capacity study confirming that the specific river, lake, or water body receiving the plant's discharge can absorb any resulting change in effluent characteristics without harm (Government of Ontario n.d.-b). Finally, because a change of this nature can shift how a facility is categorized under MECP's own licensing system, the application must also include a facility reclassification assessment, confirming whether the plant's classification tier changes as a result of the new process.

Given the novelty of introducing a biological process additive that is opposed to the conventional chemical dosing MECP more routinely reviews, a pre-submission consultation with the ministry,

held roughly nine months ahead of filing, is a reasonable step to take before formal submission (OASIS Ontario 2026). Once filed, an ECA amendment of this kind can reasonably be expected to take over a year to review, though the actual timeline will depend on how the ministry scopes the assessment. Accordingly, PetaScale should reasonably adopt the full ECA pathway as its working planning assumption, subject to formal confirmation by MECP.

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4. Provincial Regulatory Pathway: British Columbia

Deployment of PetaScale's enzyme technology within British Columbia is regulated by the province's environmental ministry, the Ministry of Environment and Climate Change Strategy (ENV), the body responsible for issuing and enforcing environmental discharge approvals across BC. Within this ministry, oversight of wastewater and effluent discharge specifically falls to its Environmental Protection Division, the branch tasked with reviewing and administering discharge authorizations. This authority is established under BC's core environmental statute, the Environmental Management Act (EMA), and given further effect through two supporting regulations: the Waste Discharge Regulation, which sets out which activities and quantities of waste require formal authorization, and, specifically for municipal wastewater systems, the Municipal Wastewater Regulation, which establishes additional standards for municipally-operated treatment facilities (Government of British Columbia n.d.-a; Municipal Wastewater Regulation 2012). Provincial approval in British Columbia determines whether and how PETase may be deployed at a specific wastewater treatment facility, independent of federal notification requirements under the Canadian Environmental Protection Act.

Under the EMA, discharging effluent requires an approved waste discharge authorization (Government of British Columbia n.d.-a). Since PetaScale's enzyme is introduced into a facility already operating under an existing authorization, the applicable mechanism is an amendment to that facility's permit, submitted to the ministry's Permit Administration office (Government of British Columbia n.d.-b). The EMA distinguishes minor amendments, covering modifications with an equal or lesser environmental impact, from major amendments, which involve a new contaminant type or altered discharge characteristics and require fuller technical review (Environmental Management Act 2003, s. 16(4)). Because enzyme dosing introduces a biologically active substance not previously assessed under the facility's authorization, PetaScale's amendment is anticipated to be classified as major, subject to full technical review.

A major amendment of this kind must be supported by a defined set of technical documentation, structured by ENV around what it terms an Information Requirements Table (IRT) (British Columbia Ministry of Environment n.d.-a). At its core, the submission must include a process flow diagram illustrating all waste streams and identifying the specific point at which the enzyme is introduced into the treatment process, alongside a full characterization of the resulting effluent: its source, quality, quantity, and frequency, along with the methodology used to generate that data. This must be accompanied by an environmental setting assessment of the receiving water body as it exists prior to the proposed change, conducted in accordance with the British Columbia Field Sampling Manual for Continuous Monitoring and the Collection of Air, Air-Emission, Water, Wastewater, Soil, Sediment, and Biological Samples (British Columbia Ministry of Environment n.d.-a). Beyond this baseline characterization, ENV requires a Conceptual Site Model (CSM) mapping the contaminant's source, its transport pathways, and any potential receptors, distinguishing exposure pathways considered "complete" from those considered "incomplete" (British Columbia Ministry of Environment 2018), as well as an assessment of the receiving water body's assimilative capacity, evaluating whether it can absorb the resulting change in discharge. Since PetaScale's effluent is discharged directly to surface water rather than through a subsurface system, this assessment is expected to also include an Initial Dilution Zone analysis, which quantifies the area around the discharge point within which the effluent is expected to dilute to ambient water quality standards (British Columbia Ministry of Environment n.d.-b).

Because enzyme-based treatment characterization falls outside the sampling protocols ENV has developed for conventional chemical effluent, direct consultation with ministry staff at the pre-application stage is expected to be necessary (British Columbia Ministry of Environment n.d.-a). Unlike Ontario, where a nine-month pre-submission consultation window is formally recommended, British Columbia imposes no fixed scheduling requirement for this consultation.

British Columbia's pathway centers on amending the host facility's existing waste discharge authorization rather than pursuing a standalone application, with the amendment expected to be classified as major given the novelty of a biologically active additive. This classification triggers ENV's full Information Requirements Table, requiring PetaScale to generate effluent characterization, environmental setting, Conceptual Site Model, and assimilative capacity data, including an Initial Dilution Zone analysis given the facility's surface water discharge. As this data must be produced through laboratory and field assessment rather than compiled from existing sources, it represents the primary driver of both cost and timeline for PetaScale's British

Columbia submission, and should be scoped directly with ENV once a specific host facility is confirmed.

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5. Provincial Regulatory Pathway: Alberta

Deployment of PetaScale's enzyme technology within Alberta falls under the authority of Alberta Environment and Protected Areas (AEPA), the provincial ministry responsible for environmental approvals across the province (Government of Alberta n.d.-a). AEPA's authority to regulate wastewater treatment specifically derives from the Environmental Protection and Enhancement Act (EPEA), Alberta's core environmental statute, together with two supporting regulations that govern how the approval process actually works in practice: the Approvals and Registrations Procedure Regulation, which sets out the review process AEPA follows, and the Activities Designation Regulation, which specifies what level of authorization, registration or approval, a given activity requires (Government of Alberta n.d.-b).

This distinction matters directly to PetaScale's pathway: a registration applies to standardized, low-complexity activities governed by a pre-written Code of Practice, such as Alberta's codes for lagoon-based or collection-only systems, while an approval carries facility-specific terms for more complex operations like mechanical or activated-sludge treatment plants (Government of Alberta n.d.-a, n.d.-c). Since PetaScale's target host facilities are expected to be conventional municipal plants of this more complex kind, they would already operate under an individualized approval, meaning the relevant regulatory step is an amendment to that existing approval.

Alberta does not appear to organize its technical submission requirements around a single, standardized checklist. Instead, AEPA's review draws on its published Standards and Guidelines for Municipal Waterworks, Wastewater and Storm Drainage Systems, which sets baseline technical and effluent quality expectations for municipal systems (Alberta Environment and Parks 2021), combined with the director's discretion to request any additional site-specific information considered relevant to the particular amendment under review (Environmental Law Centre n.d.). In practice, this means the precise dataset AEPA will expect for an enzyme-dosing amendment is less fixed in advance than in Ontario or BC, and is more likely to be shaped directly through dialogue with the assigned application coordinator once a submission is underway.

Alberta's regulatory framework centres on director discretion rather than the published technical checklists used in Ontario and British Columbia, meaning PetaScale's submission requirements and review timeline cannot be finalized to the same degree of precision at this stage. PetaScale's planning therefore proceeds on two working assumptions: that its target host facility holds an individualized approval rather than a standardized lagoon registration, and that the proposed amendment will be treated as substantive given the biological nature of the additive. Early, direct engagement with AEPA's Regulatory Approvals Centre, once a specific Alberta host facility has been identified, will be essential to confirming these assumptions and establishing a defined submission pathway.

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6. Provincial Regulatory Pathway: Newfoundland and Labrador

Deployment of PetaScale's enzyme technology within Newfoundland and Labrador falls under the authority of the province's Department of Environment and Climate Change (ECC), and specifically its Water Resources Management Division, the branch responsible for regulating water and sewage systems across the province (Government of Newfoundland and Labrador n.d.). This authority derives from the Water Resources Act, the province's core statute governing the construction, operation, and modification of water and sewage works, which gives the department the power to issue and amend the permits these systems require (Government of Newfoundland and Labrador 2026).

Under the Water Resources Act, an existing sewage works, such as a municipal wastewater treatment plant, operates under a permit issued by the department, and any significant change to the design or operation of that works requires an amendment to the existing permit before the change can take effect, obtained specifically under Section 49 of the Act (Government of Newfoundland and Labrador 2026). Because PetaScale's model introduces its enzyme into a facility already operating under such a permit, rather than establishing new treatment infrastructure, the applicable step is a permit amendment submitted on behalf of the host facility. Given that enzyme dosing constitutes a substantive change to how the works is designed and operated, introducing a biologically active additive not contemplated in the facility's original permit, this would be expected to qualify as a "significant change" triggering the Section 49 amendment requirement, rather than a change the department would treat as administrative.

Newfoundland and Labrador does not appear to organize its technical review around a standalone effluent-criteria procedure in the way Ontario's Procedure B-1-5 does or a structured information table in the way British Columbia's IRT does. Instead, effluent discharged from a permitted sewage works must comply with the province's Environmental Control Water and Sewage Regulations, made under the Water Resources Act, which set the baseline quality standards any discharge must meet (Government of Newfoundland and Labrador 2023). Design and operational expectations more broadly are further shaped by the department's own published technical reference, the Guidelines for the Design, Construction and Operation of Water and Sewerage Systems, which sets expected engineering and performance benchmarks for these systems (Government of Newfoundland and Labrador n.d.). As with Alberta, the specific dataset the department will require to support an enzyme-dosing amendment is not laid out in a fixed public checklist, and would likely need to be scoped directly with the Water Resources Management Division once a specific host facility and process design are identified.

Since the province does not publish a standardized technical checklist or a stated review timeline to plan against in advance, PetaScale's working assumption is that enzyme dosing will be treated as a significant change requiring a Section 49 amendment, supported by effluent data demonstrating compliance with the Environmental Control Water and Sewage Regulations. This is a reasonable default given the biological nature of the additive, but as in Alberta, it should be confirmed through early direct engagement with the Water Resources Management Division once a specific Newfoundland host facility is identified.

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7. Executive Summary

7.1 Federal

Table 7.1. Federal notification requirements under CEPA

#	Requirement / Notification	Responsible Body	Submission Details	Estimated Duration
1	New Substances Notification	ECCC; Health Canada	Substance identity; DSL/NDSL confirmation; intended use; production volume	1 to 2 months

	(Chemicals and Polymers)			
2	Applicable notification schedule	ECCC	Schedule 10 (pilot), transitioning to Schedule 11 (commercial)	Determined by volume
3	Laboratory enzyme-specific characterization data	ECCC; Health Canada	Schedule 2, items 7 to 13: substrate specificity; optimal pH and temperature; catalytic constants (Km, kcat); cofactor requirements; activity per unit weight	3 to 6 months
4	Statutory minimum review notice	ECCC	60-day legal floor before manufacture or import	60 days minimum

7.2 Ontario

Table 7.2. Ontario ECA amendment requirements

#	Requirement / Notification	Responsible Body	Submission Details	Estimated Duration
1	ECA amendment application	MECP	Amendment to existing Environmental Compliance Approval (ECA) submission; not EASR-eligible	2 to 4 weeks (compiling and finalizing the package for submission)
2	Process description	MECP	Dosing method; entry point; residence time	2 to 4 weeks (drafting, based on finalized process design)

3	Effluent discharge criteria	MECP	Laboratory and pilot data generation, per Procedure B-1-5	4 to 8 months (laboratory and field data generation)
4	Assimilative capacity study	MECP	Confirms receiving water body can absorb the change	4 to 8 months (concurrent with above)
5	Facility reclassification assessment	MECP	Confirms classification tier impact	Assessed by MECP during review
6	Pre-submission consultation	MECP	Recommended given novelty of biological additive	9 months (lead time before meeting)
7	Ministry review	MECP	Formal review of complete application	12+ months

7.3 British Columbia

Table 7.3. British Columbia permit amendment requirements

#	Requirement / Notification	Responsible Body	Submission Details	Estimated Duration
1	Permit amendment application	ENV	Major amendment to existing Waste Discharge Authorization	2 to 4 weeks (compiling and finalizing the package for submission)
2	Process flow diagram	ENV	All waste streams; enzyme dosing point	2 to 4 weeks (drafting, based on finalized process design)
3	Effluent characterization	ENV	Source; quantity; quality; frequency; methodology used	4 to 8 months (laboratory and field data generation)

4	Environmental setting assessment	ENV	Baseline water quality of the receiving river or lake prior to enzyme introduction, sampled per the BC Field Sampling Manual	4 to 8 months (concurrent with above)
5	Conceptual Site Model (CSM)	ENV	Contaminant source; transport pathways; receptors; complete versus incomplete exposure pathways	1 to 2 months (compiled once effluent and setting data are gathered)
6	Assimilative capacity and IDZ analysis	ENV	Dilution capacity of receiving water; IDZ boundary (surface water discharge)	1 to 2 months (compiled concurrently with CSM)
7	Pre-application consultation	ENV	Recommended given novel sampling scope	No fixed schedule; typically arranged 2 to 3 months ahead of filing
8	Ministry review	ENV	Formal review of complete application	3 months (acknowledgment), then up to 12 months

7.4 Alberta

Table 7.4. Alberta approval amendment requirements

#	Requirement / Notification	Responsible Body	Submission Details	Estimated Duration

1	Approval amendment application	AEPA	Amendment to existing individualized approval	2 to 4 weeks (compiling and finalizing the package for submission)
2	Technical data package	AEPA	Effluent quality data per AEP Standards; additional site-specific data as requested by director	4 to 8 months (laboratory and field data generation)
3	Ministry review	AEPA	No published target	No stated timeline (regulator uses case-by-case discretion)

7.5 Newfoundland and Labrador

Table 7.5. Newfoundland and Labrador permit amendment requirements

#	Requirement / Notification	Responsible Body	Submission Details	Estimated Duration
1	Permit amendment application	ECC, Water Resources Management Division	Amendment under s. 49, Water Resources Act	2 to 4 weeks (compiling and finalizing the package for submission)
2	Effluent compliance data	ECC	Effluent quality compliance per Environmental Control Water and Sewage Regulations	4 to 8 months (laboratory and field data generation)
3	Departmental review	ECC	No published target	No stated timeline (regulator uses

				case-by-case discretion)

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