Assessing your Environmental Impact during iGEM

Each stage of the DBTL cycle involves a degree of exposure and interaction with the environment that may bear short-term and long-term consequences. Designing a product, assembling the sum of its parts, testing its function and scaling it into a real-world product consumes energy and materials, and in some cases, may carry a risk associated with its release. As such, the European Union's Environmental Impact Assessment (EIA) directive, a legislative act of the European Union that is charged with setting mandatory results to be achieved by member states, requires that 'the effects of certain public and private projects on the environment' are assessed before projects are approved. The EU directive has designed an EIA framework to screen for such effects, leaving it up to individual countries to decide how to implement their screening strategies and results into national law.

The primary aim of an EIA is to protect the environment by making sure that a local planning authority (LPA) is fully informed on the likely significant impacts of a project when deciding whether to grant planning permission for it. A secondary aim is to offer opportunities for the public to partake in decision-making processes. At the stage of the iGEM competition, teams are encouraged to identify environmental risks associated with their projects - but most will not require an EIA, at least until their enterprise is built and requires larger-scale infrastructure. We have therefore adapted this framework to enable teams to achieve the following:

1) Identify whether their project and future company built upon it would legally fall under the EIA regulations.
2) Identify, evaluate and mitigate the negative environmental effects of their work at every stage of development, from the bench to the final product.

What is an EIA?

An EIA is a process used to predict the environmental effects of a proposed development before a decision is made on its approval, so that harmful effects can be avoided, reduced or offset. This document is then submitted to the LPA with the project planning application. In England and Wales, the legal framework for EIAs is governed by the Town and Country Planning Regulations 2017 - Scotland, Wales and Northern Ireland have their separate regulations. Nonetheless, these regulations integrate the EU's EIA directive, which continues to influence UK law despite Brexit in 2020. Please note that the Levelling-up and Regeneration Act 2023 will allow the UK Government to replace EIAs with a new system of Environmental Outcomes Reports - but this legislation is not currently enforced.

Who requires an EIA?

It is important to note that not all projects require an EIA - this is dependent on the type, scale and location advanced by the project developers (proponents). These regulations classify projects into 2 'schedules'.

Schedule	EIA required?	Examples
Schedule 1	Always. These projects are assumed to have significant environmental effects.	Motorways and airports, nuclear power stations, large-scale chemical plants, installations for disposing of hazardous waste
Schedule 2	Only if the LPA's screening identifies the project as likely to have significant effects. This tends to be when the project exceeds a specific size threshold or is located in a sensitive area.	Urban development such as roads, railways and pipelines, quarries and mines, energy facilities such as wind farms and solar panels, industrial installations including biotechnology and pharmaceutical manufacturing

Schedule 2 categories are likely where an iGEM-derived business would lie, as energy production facilities and industrial and manufacturing sites are common examples of scaled projects. A project may not meet the thresholds for Schedule 2 but may nonetheless require an EIA if it is located in an environmentally sensitive location, such as Sites of Special Scientific Interest, National parks or Areas of Outstanding Natural Beauty, Special Protection Areas or Special Areas of Conservation and World Heritage Sites. To determine whether an EIA is required for a Schedule 2 project, the LPA will issue a 'screening opinion' based on three criteria:

1) Project characteristics: size, complexity, use of natural resources, waste, potential emissions and risk of accidents.
2) Location: how sensitive the surrounding environment is.
3) Characteristics of the potential impact: how large, likely, durable and reversible the effects would be.

Benefits of an EIA

Beyond legal compliance, an EIA offers the benefits of increased transparency and accountability, improved communication between stakeholders and better brand recognition. As climate change continues places growing pressures on ecosystems and global health, more than 190 countries and major global economies now operate under some form of EIA in order to build environmental protection into the design of business models and other public projects.

The Five Stages of an EIA

This EIA can be subdivided into five categories that ensure that all potential predicaments arising from a project are assessed thoroughly before and after a project is built. Whilst the proponent will lead the work, the Environmental Statement

(Stage 3) is usually prepared with the help of expert environmental consultants who possess the tools to measure how a project interacts with its surroundings.

Stage	**Stakeholder in charge**	**Output**
1. Screening	Proponent requests; LPA decides	Screening opinion: is an EIA needed?
2. Scoping	Proponent proposes; LPA advises	Scoping opinion: what must the EIA cover?
3. Environmental Statement	Proponent working alongside environmental consultants	The Environmental Statement
4. Publication & Consultation	LPA, public, other consultees	Comments and feedback
5. Decision-making	LPA	Planning permission granted, with conditions, or refused

1) **Screening** involves making a preliminary check to whether a proposed project is covered by current regulations and standards to date. Proponents must gauge how likely significant environmental impacts might be and how closely different stages of the project, and the project as a whole, should be monitored. LPAs can be asked for a ‘screening opinion’ to clarify if their project requires an EIA.

2) **Scoping** is performed if an EIA is deemed necessary. This delineates which issues must be addressed in the following Environmental Statement (for example: air quality, biodiversity or water management) and the methodology for conducting the assessment. Here, LPAs can also be asked for a ‘scoping opinion’ under the EIA Directive to clarify what to include.

3) **Preparing an Environmental Statement** is where the EIA itself is carried out and written up. This involves three steps:
    - **Baseline studies** first gather data on the existing environmental conditions of the site and surrounding area to establish a benchmark to assess potential impacts.
    - **An impact assessment** will consider how the project may affect all relevant social and environmental factors (listed in the table below) during construction, operation and where relevant, decommissioning. For each effect, proponents must consider nature, magnitude, duration, reversibility and sensitivity of the receiving environment, as well as including cumulative effects with other nearby projects.

- **Mitigation** must then put forth measures to mitigate or minimise these impacts. These may include: design amendments, construction management controls (such as noise barriers), habitat creation or enhancement and long-term management strategies.

The following factors and their interactions must be considered:

Factor	**Assessment**
General population	Effect on communities, livelihoods, local quality of life
Human health	Consider air, noise, traffic and pollution impacts that could affect public health
Biodiversity	Risks to species, habitats and ecosystem services near project site
Land, Water, Air & Soil Quality	Protection of natural resources, analysis of potential contamination, runoff, emissions and land disturbance from project activities
Culture	Protect heritage sites, traditions and local social practices
Landscape	Review visual, aesthetic and landform changes to ensure the project fits the environment

The regulations also require an assessment of the project's vulnerability to major accidents and disasters, such as a fire, and the effects that that could cause. Furthermore, in rare cases, developments may have transboundary effects. In this case, the Espoo Convention applies which is an agreement that ensures that environmental impacts are assessed where a project in one country can affect another.

The finished Environmental Statement must include a description of the project, the baseline and impact findings, the proposed mitigation and alternatives considered, and a non-technical summary for the public. It is then submitted to the LPA with the planning application.

4) **Publication & Consultation** comprises the Environmental Statement being published for review by the public. At this stage, stakeholders (eg: local residents, environmental groups) and authorities can provide feedback, ask for revisions or indicate that the proposal is satisfactory. The LPA must consider these responses when choosing whether to grant planning permission.

5) **Decision-making** is done once constructive input is received and the application has been sent to the competent authority for approval. The reasons for the decision must be made public. Where significant effects are expected, the LPA can then require monitoring to check that mitigation works as promised during construction and operation.

Failure to comply with EIA requirements can result in rejection of the planning application, legal challenges from environmental groups or stakeholders, as well as delays and additional costs. To avoid such complications, proponents are recommended to:

- **Engage early with the LPA** to request both screening and scoping opinions that will clarify EIA requirements and facilitate the planning process
- **Work alongside qualified environmental consultants** to conduct baseline studies and prepare a thorough and accurate Environmental Statement
- **Seek legal advice** from experienced solicitors to navigate the EIA process
- **Plan for and implement mitigation** measures to demonstrate a commitment to minimising environmental impacts

Our Environmental Impact Assessment

At our current scale, reGELerate is produced in shake flasks in a university lab abd consumes reagents in small quantities. However, three future developments would shift our position into making a planning application that would require an EIA:

Development	**EIA Stage**
Our own manufacturing facility to produce HET-s and sortase A at scale	Classifies as Schedule 2, as industrial installation is needed for large-scale manufacturing. Will require a screening opinion and an EIA will follow only if the LPA judges significant effects to be likely.
A dyehouse pilot using our CotA cartridge	No EIA required as the site already operates under an Environment Agency permit under the Environmental Permitting Regulations (England and Wales) 2016. Adding the cartridge would change how colour is removed, so the customer may need to vary its permit or notify the Agency.
Our scaffold reaching one tonne per year	This would trigger UK Reach registration which is separate to the EIA. Under this Health and Safety Executive framework,

	fees are £2,222 for a standard size company in the 1-10 and 1-100 tonne bands.

If screening returned a positive opinion, we would expect the scoping opinion to focus on water, waste and the question of a novel biological material. This would involve assessment of the following factors:

Factor	**Our assessment**	**Mitigation strategy**
General population	Minimal as a fermentation facility would be established on an existing industrial site, with no planned changes to local livelihoods.	Not applicable
Human health	Transformation products in treated effluent may reach water courses, and must contain this.	Supply a shed component panel and require the customer to confirm disassembly and discharge consent before sale. Require ecotoxicity screening alongside the absorbance readout as a condition of sale.
Biodiversity	Dominant risk factor as transformation products in treated effluent may reach water courses.	Supply a shed component panel and require the customer to confirm disassembly and discharge consent before sale. Require ecotoxicity screening alongside the absorbance readout as a condition of sale.
Land, water, air and soil quality	Fermentation waste, culture media from engineered *E. coli* will need to be disposed of via lab hazardous protocols for waste decontamination. End-of-life route for a gel that has absorbed aromatic pollutants is	Customers must declare a payload-specific disposal route themselves following disassembly, which will be verified by reviewers reading over their applications to purchase the scaffold components.For CotA, adsorbed aromatics follow

	payload-specific and cannot be determined from our side.	a dye-waste route.
Culture	Not applicable.	Not applicable.
Landscape	Standard for an industrial unit, no distinct assessment is anticipated.	Not applicable.

The regulations also require an assessment of vulnerability to major accidents, which would mean containment failure during fermentation of our recombinant *E. coli*, which falls under the GMO (Contained Use) Regulations 2014 and is enforced by the HSE, with Imperial biosafety officers reviewing the classification. The delivered product is cell-free so no engineered product will leave the laboratory and no transboundary effects under the Espoo Convention are anticipated.

Our minimum baseline panel for the incumbent treatment train and for a stream treated with our cartridge should measure chemical oxygen demand, ecotoxicity, leached metals, particularly from CotA's four-copper centre and shed protein fragments. What exits a site is dependent on flow rate, dilution, effluent matrix and treatment train, which cannot be determined from our side. Therefore, the customers must characterise their own discharge as stated in the terms of use whilst we supply the shed-component panel. Each use case will then be required to document its payload-specific parameters publicly.

Overall, engaging the user community before the regulator is what must be done at our stage of development, before approaching the LPA for screening and scoping opinions. This document, in line with our Biosecurity Framework, assesses the risks of our technology based on discussions with user communities to think about effluent, waste and end-of-life management to that when an Environmental Statement is eventually required, its scoping will begin from parameters that the field already measures rather than some that a regulator would have to approximate our project to.