# 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 sets 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 sets out 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 of 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 take part 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 any 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. The resulting document, the Environmental Statement, is then submitted to the LPA with the project's planning application. In England, the legal framework for EIAs is set by the Town and Country Planning (Environmental Impact Assessment) Regulations 2017; Wales, Scotland and Northern Ireland have their own separate regulations. Nonetheless, these regulations incorporate 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 allows the UK Government to replace EIAs with a new system of Environmental Outcomes Reports, but the regulations needed to bring this into force have not yet been made, so EIAs still apply.

### Who requires an EIA?

It is important to note that not all projects require an EIA: this depends on the type, scale and location of the project put forward by its developers (proponents). The regulations classify projects into two ‘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. | Infrastructure such as urban development, 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 area, such as a Site of Special Scientific Interest, a National Park, an Area of Outstanding Natural Beauty, a Special Protection Area, a Special Area of Conservation or a World Heritage Site. 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 to place growing pressure 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**

The EIA process can be subdivided into five stages that ensure all potential impacts arising from a project are assessed thoroughly before and after the project is built. Whilst the proponent leads the work, the Environmental Statement (Stage 3) is usually prepared with the help of expert environmental consultants who have 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, granted with conditions, or refused |

1) **Screening** is a preliminary check of whether a proposed project is covered by the current regulations. Proponents must gauge how likely significant environmental impacts are and how closely different stages of the project, and the project as a whole, should be monitored. Proponents can ask the LPA for a ‘screening opinion’ to clarify whether their project requires an EIA.
2) **Scoping** is performed if an EIA is deemed necessary. It sets out which issues must be addressed in the Environmental Statement (for example, air quality, biodiversity or water management) and the methodology for conducting the assessment. Proponents can also ask the LPA for a ‘scoping opinion’ under the EIA Regulations 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 against which potential impacts are assessed.
    - An **impact assessment** considers 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 its nature, magnitude, duration and reversibility, the sensitivity of the receiving environment, and cumulative effects with other nearby projects.
    - **Mitigation** then puts forward measures to avoid 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 and local quality of life |
| Human health | Air, noise, traffic and pollution impacts that could affect public health |
| Biodiversity | Risks to species, habitats and ecosystem services near the project site |
| Land, Soil, Water, Air & Climate | Protection of natural resources; analysis of potential contamination, runoff, emissions (including greenhouse gases) and land disturbance from project activities; the project's vulnerability to climate change |
| Cultural heritage & material assets | Protection of heritage sites, traditions, local social practices and existing assets |
| Landscape | Visual, aesthetic and landform changes, to ensure the project fits its environment |

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

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

4) **Publication & Consultation:** the Environmental Statement is published for public review. At this stage, stakeholders (e.g. 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 deciding whether to grant planning permission.
5) **Decision-making** takes place once consultation responses have been received and the application has been passed to the competent authority for approval. The reasons for the decision must be made public. Where significant effects are expected, the LPA can 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 other stakeholders, and 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 and consumes reagents in small quantities. However, three future developments would change our regulatory position, and one of them could require a planning application accompanied by an EIA:

| Development | EIA position |
|---|---|
| Our own manufacturing facility to produce HET-s and sortase A at scale | Falls under Schedule 2, as an industrial installation would be needed for large-scale manufacturing. It 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 expected: fitting a cartridge to an existing treatment train is not new development, and the site already operates under an Environment Agency permit under the Environmental Permitting (England and Wales) Regulations 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 from the EIA. Under this Health and Safety Executive framework, the registration fee for a standard-size company is £2,222 in both the 1–10 and 10–100 tonne bands (lower fees apply to SMEs). |

If screening concluded that an EIA was required, 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 watercourses; these must be contained. | 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 watercourses. | 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. |

| Factor | Our assessment | Mitigation strategy |
|---|---|---|
| Land, water, air and soil quality | Fermentation waste and culture media from engineered *E. coli* will need to be decontaminated and disposed of following the lab's hazardous waste protocols. The end-of-life route for a gel that has absorbed aromatic pollutants is payload-specific and cannot be determined from our side. | Customers must declare a payload-specific disposal route themselves following disassembly, which will be verified by reviewers reading their applications to purchase the scaffold components. For CotA, adsorbed aromatics follow a dye-waste route. |
| Culture | Not applicable. | Not applicable. |
| Landscape | Standard for an industrial unit; no separate assessment is anticipated. | Not applicable. |

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

Our minimum baseline panel, for both the incumbent treatment train and a stream treated with our cartridge, should measure chemical oxygen demand, ecotoxicity, leached metals (particularly copper from CotA's four-copper centre) and shed protein fragments. What exits a site depends on flow rate, dilution, effluent matrix and treatment train, which cannot be determined from our side. Therefore, 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, at our stage of development the right step is to engage the user community before the regulator, and only then approach 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 about effluent, waste and end-of-life management, so that when an Environmental Statement is eventually required, its scoping will begin from parameters the field already measures, rather than ones a regulator would have to approximate for our project.