

Receiving Environment Report

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Limerick site
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1. Introduction

This report was completed in accordance with the Environmental Protection Agency's (EPA) Licence Application Form Guidance – Industrial Emissions (IE), Integrated Pollution Control (IPC) and Waste. It is to be included as Attachment 7.1.3.3 of the Industrial Emissions (IE) licence application (LA010883) and should be read in conjunction with Attachment 7.1.3.2 Emissions Impact Assessment.

2. Stormwater emissions

2.1 Stormwater drainage

Details of the stormwater drainage network and stormwater emission points are presented in Attachment 4.8.1 (Operational Report). In accordance with Best Available Techniques (BAT), clean stormwater will be kept separate from wastewater and there is no inherent risk of cross-contamination.

2.2 Receiving Environment

There is an existing storm water sewer running through the site that conveys surface water runoff from the Regeneron site, Roches Avenue and Ballycummin Avenue to the Loughmore Canal. The sewer will be diverted as part of the site enabling works to accommodate the new development.

The storm water discharge from the Raheen Business Park exits the estate and follows the route of a culvert and pipe to Loughmore Common Canal, which enters the Barnakyle River, which in turn flows into the Maigue River, which ultimately discharges to the River Shannon Estuary. For the purposes of this assessment, the receiving environment is considered to be the Barnakyle River; however, this will ultimately have implications for the River Shannon Estuary as well.

Further information on the surface water environment can be found in Attachment 7.1.3.2 Emissions Impact Assessment, and in the Screening for Baseline Report provided in Attachment 4.8.2. The main pressure to the Barnakyle River as identified in the Shannon International River Basin District River Management Plan 2009-2015 is diffuse agricultural pollution. It can therefore be considered that nitrogen, phosphorus, and total suspended solids (TSS) are relevant parameters. As per the EPA's Envision Database the Barnakyle River is not considered to be a salmonid river. A Flood Risk Assessment was carried out as part of the planning permission application. Flooding was considered for the Barnakyle River and the Maigue River. Under the OPW's online National Flood Hazard Mapping (<http://www.floodmaps.ie>), the only recorded downstream flood event was at the Maigue Embankments Sept 1992. The OPW flood mapping (www.floodinfo.ie) application also showed that the Barnakyle River was not at high risk of flooding into its flood plain.

2.3 Impact on receiving environment

The following outlines the impact of the proposed emissions on the Barnakyle River.

2.3.1 Local hydrology

All the surface water runoff from the site will be infiltrated into the ground, within the site boundary, via numerous sustainable drainage system (SuDS) features, positioned at strategic locations around the site.

The management of surface water runoff using SuDS features aims to provide an effective system to mitigate the adverse effects of urban storm water runoff on the environment by reducing runoff rates, volumes and frequency, reducing pollutant concentrations in storm water, and by contributing to amenity, aesthetics and biodiversity enhancement. In addition, SuDS features aim to replicate the natural characteristics of rainfall runoff by providing control of run-off at source.

The proposed SuDS will consist of a detention basin, numerous bioretention swales and a vegetated terminal infiltration basin. This is incorporated into the design by having swales along the entire perimeter edge of the site, as well as additional swales within the site to capture runoff from the roads, grassed verges, embankments, natural ground and roofs. Wherever it has not been possible to construct a swale, the ground profile has been defined such that the runoff in the nearby catchment will be captured by the nearest swale. For roof drainage, there are downpipes from the buildings which discharge to the nearest swale.

All of the SuDS features will be fitted with an overflow facility that will be connected to a large densely vegetated terminal infiltration basin located in the northwest end of the site. No outfall is proposed in the terminal basin so that all the surface water that arrives there will infiltrate into the ground. The terminal infiltration basin will have a storage volume of at least 8500m³ meeting the storage volume requirements of the catchment for all extreme events up to the 1% AEP design storm in accordance with the GSDS 6.3.1.4. Swales are connected by ductile iron pipes to allow for water to flow through until eventually reaching the terminal infiltration basin. Ductile iron pipes are used as they are stronger and there is insufficient cover depth for steel pipework.

Linear drains or gullies are positioned to collect run-off from the proposed loading bay ramps, yard areas and roads where there is no nearby swale. These are connected to sumps and run-off which collects here will be pumped back into the nearest piped network or swale.

The surface water runoff will pass through a densely vegetated infiltration SuDS feature which will sufficiently capture and break down the hydrocarbon contaminants in the water prior to discharge to ground, through the pollutant removal mechanisms of photolysis and volatilisation.

The construction of the permeable paving and the dense vegetation proposed in the other infiltration SuDS features is considered appropriate water quality treatment for the road run-off prior to infiltration into the ground. This is justified because the pollution hazard level for run-off from these areas is considered between low and medium in accordance with Table 26.2 in the guidance set out in Chapter 26 of The SuDS Manual (CIRIA C753) and the pollution hazard indices for this hazard level are all less than or equal to the pollution mitigation indices associated with the infiltration SuDS features being proposed, as per Table 26.4 in the SuDS Manual (CIRIA C753). Both tables are included in Appendix A of this document.

Further information on SuDS is available in Attachment 7.7.1 SuDS Overview

2.3.2 Surface water quality

Stormwater run-off from buildings and car parks will be kept separate from wastewater and there is no inherent risk of cross-contamination. The only relevant Principal Pollution Substances of concern, with regards to S.I. No. 283/2013 - Environmental Protection Agency (Integrated Pollution Control) (Licensing) Regulations 2013, are hydrocarbons, specifically diesel and biocides.

Diesel will be used to power the six emergency generators. It will be stored in belly tanks within each unit in the generator compound which will be bunded.

Biocides will be stored in bunded chemstore and will be kept in relatively low volumes onsite

Tanks and bunds are designed in accordance with the requirements of the EPA Guidance Note on the Storage and Transfer of Materials for Scheduled Activities. In the event of an overflow/spillage within the bund, the excess liquid will be pumped to the appropriate storage tank and tested. Integrity testing of all onsite concrete bunds is undertaken every 3 years in accordance with the requirements of the IE licence. In an event of a chemical spill or diesel spill to the storm water drainage system there will be an emergency response procedure (ERP) in place to deal with such an event. Spill kits will be located across the site in highly visible and mobile units. These include absorbent socks, mats, pads, disposable bags, and PPE. Spill kits will be utilised in the event of a spill outside the designated bunds and staff will be trained in the use of spill management materials. The potential risk to the Ballinakyle River or the River Shannon is therefore not significant. A diesel spill during transfer/delivery of the diesel would be captured within the Class 1 full retention interceptor. A leak in a tank would spill into the bund. Any fuels from road run-off will also be managed through the use of the SuDS features.

The management of surface water runoff using SuDS features aims to provide a system to mitigate the adverse effects of urban stormwater runoff on the environment by reducing runoff rate, volume and frequency and reduce pollutant concentrations in stormwater (by infiltration, settlement, and UV exposure). It also contributes to amenity, aesthetics, and biodiversity. SuDS features aim to replicate the natural characteristics of rainfall runoff by providing control of any possible contamination at source. Any hydrocarbons from road run-off is expected to be managed through the use of the SuDS pollutant removal mechanisms of photolysis and volatilisation

3. Sewer emissions

3.1 Wastewater Management

Wastewater discharged from the facility will comprise the following:

- Process wastewater, such as excess volumes of buffer or media solutions, or cell waste from the harvest centrifuge;
- Cleaning wastewater from clean-in-place (CIP) or steam-in-place (SIP) of fixed (i.e., not single-use) process equipment;
- Cleaning wastewater from production areas, or in equipment preparation rooms, from cleaning equipment (e.g., autoclaves, parts washers);
- Deactivated biowaste;
- Utilities wastewater from boilers, chillers etc;
- Domestic effluent.

Process and utilities wastewater will be sent to the wastewater neutralisation area prior to discharge to the IDA sewer. Discharge and monitoring points are shown in the drainage drawing included as part of this licence application.

The maximum estimated wastewater characteristics are presented in Table 3-1.

Wastewater characteristic	L/day	
Volume	625000	
Wastewater characteristic	Peak concentration (mg/L)	Peak load (kg/day)
Biochemical oxygen demand	3300	1580
Chemical oxygen demand	4000	1890
Suspended solids	500	150
Total nitrogen	310	145
Total phosphorus	100	35

Table 3-1: Wastewater characteristics

3.2 Offsite Wastewater Treatment Plant

The existing wastewater treatment works at Limerick City and Environs Wastewater Treatment Plant (WWTP) at Bunlicky, Co. Limerick has a capacity of 186,233 population equivalent (PE) and is currently receiving and treating a daily load of approximately 111,377 PE according to the latest available Annual Environmental Report (AER) from 2021. The Bunlicky WWTP has been in compliance with its ELVs (BOD, COD, TSS, ortho phosphate, and pH) for 3 of the past 5 years (2018 information is unavailable from Irish Water), as presented in the installation’s Annual Environmental Reports (AERs). In 2019 there was one exceedance of the ortho-phosphate ELV. Ambient water quality monitoring undertaken by Irish Water over the recent years, under the requirements of

the Bunlicky WWTP discharge licence, has indicated that the water quality downstream from the Bunlicky WWTP discharge has typically been compliant with the relevant Environmental Quality Standards (AERs 2016, 2017, 2019, 2020 and 2021).

There are no current known restraints on the capacity of this plant.

In the 2021 AER for the Bunlicky WWTP it is stated that:

- The WWTP was compliant with its ELVs with the exception of suspended solids
- The ambient monitoring results meet the required EQS. The EQS relates to the Oxygenation and Nutrient Conditions set out in the Surface Water Regulations 2009.
- Based on ambient monitoring results a deterioration in ortho phosphorus concentrations downstream of the effluent discharge is noted.
- The discharge from the wastewater treatment plant does not have an observable negative impact on the Water Framework Directive status

Pre-application discussions with Irish Water have been undertaken on the capacity of the WWTP to accept the proposed volume of wastewater. Irish Water advised during these high-level discussions that the receiving wastewater treatment facility will have the capacity to accept the proposed discharge. As outlined in Attachment 7.3.2, the ELVs set by the Bunlicky WWTP discharge licence comply with the relevant BAT AELs from the Sectorial BAT document, namely the EU Decision BAT Conclusions on Wastewater and Waste Gas Treatment / Management Systems in the Chemical Sector

3.3 Impact on Receiving Environment

As outlined in Attachment 7.3.2 Equivalent Level of Protection, the off-site wastewater treatment plant has sufficient capacity to treat the proposed wastewater discharges without having a significant impact on the receiving environment. The WWTP holds a discharge licence with ELVs that are compliant with the relevant sectorial BAT limits for pharmaceutical facilities. As such, it is anticipated that the Bunlicky WWTP will be sufficient to appropriately treat all wastewater discharges from the installation including Principal Pollution Substance of concern (see S.I. No. 283/2013) relevant to the installation including organophosphorus compounds, suspended solids, BOD, COD, and nitrogen compounds.

Heavy metals in the wastewater streams will exist in trace quantities only (due to wash down of metal equipment, etc) and therefore do not pose a risk to the receiving environment. There is no potential for biological material to leave the installation through the wastewater streams as processes are closed and process wastewater from cell culture and harvest/depth filtration will be treated via a heat inactivation skid prior to being combined with other process wastewater and utilities wastewater.

4. Air emissions

4.1 Emissions to air

The primary air emissions from the installation will be from the two steam boilers and the two LTHW (low temperature hot water) boilers. Further details of these emissions can be found in Attachment 4.8.1. The locations of these units are shown on the main air emission point drawing. There are a number of minor and potential emissions to air from the installation as outlined in the Operational Report (Attachment 4.8.1). However, they are considered insignificant for the purpose of the assessment on ambient air quality.

4.2 Receiving environment

Air quality monitoring programs have been undertaken in recent years by the EPA and Local Authorities. The most recent annual report on air quality "Air Quality in Ireland 2020" (EPA, 2021) details the range and scope of monitoring undertaken throughout Ireland. As part of the implementation of the Framework Directive on Air Quality (1996/62/EC), four air quality zones have been defined in Ireland for air quality management and assessment purposes (EPA, 2017). Dublin is defined as Zone A and Cork as Zone B. Zone C is composed of 23 towns with a population of greater than 15,000. The remainder of the country, which represents rural Ireland but also includes all towns with a population of less than 15,000 is defined as Zone D. In terms of air monitoring, the area of the proposed development in Limerick is categorised as Zone C. NO₂ monitoring was carried out at the Zone C monitoring stations of Kilkenny, Portlaoise and Mullingar for the period of 2015-2019 (see <http://www.epa.ie/air/quality/data/>). The NO₂ annual average in 2019 ranged from 5 – 14 µg/m³. Long-term average concentrations measured at all locations were significantly lower than the annual average limit value of 40 µg/m³. The maximum 1-hour limit value of 200µg/m³ (measured as a 99.8th percentile; i.e., 18 exceedances allowed per year) was not exceeded in any year for any of the Zone C locations. The average results at the Zone C locations over the last five years suggests an upper average limit of no more than 13 µg/m³ as a background concentration. Based on the above information, a conservative estimate of the current background NO₂ concentration for the location of the proposed development is 14 µg/m³.

4.3 Impact on Ambient Air Quality

Air dispersion modelling was carried out using the United States Environmental Protection Agency's regulatory model AERMOD (Version 16216r) and the report is provided as Attachment 7.1.3.4. The air dispersion modelling input data consisted of information on the physical environment (including building dimensions and terrain features), design details from all relevant emission points on-site and five full years of appropriate meteorological data. Using this input data, the model predicted ambient ground level concentrations beyond the site boundary for each hour of the modelled meteorological year. The model postprocessed the data to identify the location and maximum of the worst-case ground level concentration. This worst-case concentration was then added to the background concentration to give the worst-case predicted environmental concentration (PEC). The PEC was then compared with the relevant ambient air quality standard to assess the significance of the releases from the site. In relation to the annual average background, the ambient background concentration was added directly to the process concentration with the short-term peaks assumed to have an ambient background concentration of twice the annual mean background concentration.

The modelling assessment determined that the proposed operations would lead to ambient NO₂ concentrations (including background) which are in compliance with the relevant limit values, reaching at most 31% of the 1-hour limit value (measured as a 99.8thile) and 39% of the annual limit value at the worst-case receptor.

With regard to NO_x, proposed operations will lead to ambient NO_x concentrations (including background) which are in compliance with the relevant limit values, reaching at most 55% of the annual limit value at the worst-case sensitive habitat receptor. The N deposition flux for the worst-case year is 0.068 kg/ha/yr and is below the range of worst-case critical loads for the various sensitive habitat vegetation types.

Therefore it is predicted that air emissions from the installation will not have a significant impact on the local environment.

In terms of climatic impacts, on-site emissions of greenhouse gases are not expected to be significant for two reasons. Firstly, one of the sources of greenhouse gas emissions from the proposed development would be from the generators on site, however, these will only be in use during emergency operations i.e. when there is a power outage from the national grid. Thus, given the likely very low usage of the emergency generators, the likely on-site emissions of greenhouse gases will not be significant. Secondly, the current CO₂ emission factor for electricity from the National Grid is 0.324 tonnes CO₂/MWh which is significantly lower than the 2008 emission factor (0.533 t/MWh). It is expected that this emission factor will decrease further over the coming years as the reliance on renewable energy grows. Thus, the indirect generation of greenhouse gases due to the electricity requirements of the site is likely to decrease in the future.

Thirdly the facility, once operational will be certified gold under the Leadership in Energy and Environmental Design (LEED) system, the most popular green building rating system in the world. Energy saving measures which will be in place upon completion of the facility include but are not limited to the following:

- Installation of 3.7 hectares of photovoltaic solar panels which will generate 3,326MWh/year which will cover between 20-25% of the site's electricity usage;
- Use of Eco Design Directive Tier 2 transformers throughout the campus;
- Use of high efficiency fan motors in air handling units and high efficiency lighting throughout the site which contribute to significant energy reductions.

Overall, due to the site and nature of the development, emissions of CO₂ and other greenhouse gases are likely to be insignificant in terms of Ireland's national emissions and Ireland's agreements under the Kyoto Protocol and other climate strategies.

Therefore, any impact to climate will be imperceptible overall. Other Principal Pollution Substance of concern (see S.I. No. 283/2013) including Volatile Organic Compounds (VOCs) are not relevant to the installation as solvents are only used in small quantities for cleaning of surfaces. Solvents used in cleaning, Isopropyl Alcohol (IPA), will be stored in sealed wipes packaging and sealed bottles in the warehouse until used. IPA impregnated wipes and spray bottles will be used for cleaning workspaces and used wipes / cloths will be put in flammable waste containers for disposal.

Vents from individual process users (each with a 0.2 micron filter) are manifolded in a given area (e.g., buffer prep, media prep, etc.) and vented to atmosphere.

Areas where powders are processed will be controlled using HEPA filters. As dust is a Principal Pollution Substance, careful controls are in place to prevent emission of

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powders into the air. The weigh and dispense suites and media preparation suites include a localised downflow HVAC with low air returns to ensure dust from powders will be minimised and contained.

All charges larger than 5kg will be via closed connections, with the occasional small volume open charge. Prevention of the formation and migration of dust will be tightly controlled within the facility as this has significant GMP impacts. Other particulate sources include the emergency diesel generator (during the combustion of fuel oil); however, these are small, and the total emissions are likely to be negligible.

5.0 Noise emissions

Details of the noise survey carried out are presented in Section 3 of the noise impact assessment which is provided as Attachment 7.1.3.4. Once operational, the main noise sources will be the building services and process plant associated with the installation. Due consideration has been given to these issues at the detailed design stage to ensure that the new development will operate within acceptable noise limits at the nearest noise sensitive locations (NSL). Where possible, external plant layout has utilised barrier screening of on-site buildings, low noise generating plant items have been selected and noisy plant items have been located within buildings. Rooftop AHUs will have acoustic attenuators fitted as standard. A noise management plan including noise monitoring will be outlined in the installation's Environmental Management System (EMS). Annual noise monitoring is proposed under the new licence as is standard for biopharmaceutical facilities.

The following restrictions are anticipated at the nearest NSL:

- Daytime (07:00 to 19:00hrs) 55dB L_{Ar}, 15min
- Evening (19:00 to 23:00hrs) 50dB L_{Ar}, 15min
- Night time (23:00 to 07:00hrs) 45dB L_{Aeq,15min}

A preliminary noise impact assessment has been conducted for the proposed installation and it has been calculated that operational noise will be within the relevant day time and night time limits at the nearest noise sensitive receptors. The results are presented in the noise impact assessment, Attachment 7.1.3.5).

The assessment determined that the impact would be not significant to moderate. The impact of noise from additional vehicular traffic on public roads was assessed as part of the EIAR. It was concluded that the resultant change in the noise levels resulting from the increases in road traffic would be imperceptible. In summary, the noise or vibration effects are not expected to affect the sensitivities of the receiving environment and will be compliant with the relevant day time and night-time limits.

6.0 Emissions to ground

There are no proposed emissions of effluent or liquid waste to ground. The potential impact of accidental emissions resulting from leaks or spills are considered in Attachment 7.1.3.2 and the Baseline Report, Attachment 4.8.3. As outlined in section 2 of this attachment, the stormwater from the facility will be managed through a system of a detention basin, a soakway, numerous bioretention swales and vegetated infiltration basins, permeable paving and the rain water harvesting of roof water.

As such, the risk of contaminants entering the ground and groundwater environments is low.

7.0 Conclusions

Following a review of the emissions from the proposed Eli Lilly installation it can be concluded that site operations will have an imperceptible or insignificant impact on the receiving environment, specifically from air, noise, stormwater, and sewer emissions.