



Eli Lilly Kinsale Ltd

IE2b Expansion

Environmental Impact Assessment Report

Volume 1: Non-Technical Summary

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Eli Lilly Kinsale Ltd.

IE2B Expansion

EIAR Volume 1 Non-Technical Summary

EIAR - Non-Technical Summary

Issue | August 2019

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Preface

The Environmental Impact Assessment Report (EIAR) for the IE2B Expansion planning application is presented in four volumes (see below).

- Volume 1 – Non-Technical Summary
- Volume 2 – Main Text
- Volume 3 – Figures
- Volume 4 – Appendices

This Volume 1 contains the Non-Technical Summary.

The non-technical summary (NTS) summarises the findings of the EIAR in a clear, accessible format that uses non-technical language and supporting graphics. The non-technical summary describes the proposed development, existing environment, effects and mitigation measures and relevant aspects of the EIAR in a manner that can be easily understood by the general public.

The information contained in this NTS is in compliance with the information required under Point 9 of Annex IV of the Directive 2014/52/EU.

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Non-Technical Summary

Introduction

Eli Lilly S.A. - Irish Branch (Lilly) is a bulk pharmaceutical manufacturing plant, located at Dunderrow, Kinsale, Co. Cork. Refer to the site location as shown on **Figures 1 and 2**.

Lilly proposes to construct an expansion to an existing pharmaceutical manufacturing facility, IE2, within the existing site boundary. The proposed development (referred to as IE2b expansion facility) will increase the production capacity for existing and future Lilly products. The proposed expansion will consist of a pharmaceutical manufacturing building over 3 floors and will also include a single storey electrical building, manufacturing material supply tanks, bunded waste tanks, conversion of temporary parking to permanent parking, revisions to underground services, modifications and extensions to existing pipe bridges, local landscaping and ground works, site lighting and ancillary items and modifications to roadworks and yard areas.

This document is a non-technical summary (NTS) of Eli Lilly's Environmental Impact Assessment Report (EIAR). The (NTS) summarises the findings of the EIAR in a clear, accessible format that uses non-technical language and supporting graphics.

Company Profile

Kinsale Lilly Ltd. is a wholly owned subsidiary of Eli Lilly & Company which is a leading innovation-driven pharmaceutical corporation committed to developing a growing portfolio of best-in-class and first-in-class pharmaceutical products that help people live longer, healthier and more active lives. Lilly manufactures a wide variety of pharmaceutical products and has major research and development facilities in eight countries.

The Kinsale facility has been in production since early 1981, construction having commenced in 1978. Since then, the facilities have expanded and now approximately 92% of the developed site is occupied by a mixture of production, production support and administration facilities.

The Kinsale facility uses complex chemical synthesis & biotechnology manufacturing processes to make active ingredients for medicines across therapeutic areas such as oncology, immunology and diabetes. The site is also involved in process development and optimisation across both manufacturing platforms.

There are approximately 700 permanent employees on site. The plant operates twenty-four hours per day, seven days per week, throughout the year.

Outline of IE2b Expansion Project

IE2, located within the Lilly site is a dedicated chemical synthesis manufacturing facility which produces small quantities of new. The proposed IE2b expansion, will allow for two additional small-scale manufacturing increments to increase capacity for existing and future Lilly products. Refer to **Figures 1 to 3** below.

The IE2b expansion will comprise of the following:

- A pharmaceutical manufacturing building extension to the existing IE2 pharmaceutical manufacturing building including production and plant accommodation, over 3 floors and intermediate mezzanine floors and platforms, and a ground to parapet height of 27.5 metres with roof mounted equipment and associated external plant and equipment and local roof mounted vents. All located to the south of the existing IE2 Building.
- Modifications to the existing IE2 Building including the demolition of the existing single storey entrance lobby to accommodate the proposed extension.
- A single storey electrical building 7 metres high.
- Demolition of the existing forklift parking shelter located on the eastern side of building IE1.
- The installation of 3 No. dedicated manufacturing material supply vessels located inside the existing bunded tank farm located to the east of the IE2 Building.
- The installation of 2 No. additional bunded waste vessels adjacent to the existing bunded tank farm south of the IE4 Building and a bunded aqueous waste vessel North of the IE8 Building.
- 60 number permanent parking spaces.
- The proposed works include revisions to underground services, modifications and extensions to existing pipe bridges and ground works, site lighting and ancillary items and modifications to roadworks and yard areas and modifications to the existing surface water drainage system including surface water attenuation.

Lilly is applying for a ten-year planning permission for development of the IE2b expansion. The proposed development when operational is anticipated to create c.70 permanent jobs created over a 2 – 10 year period.

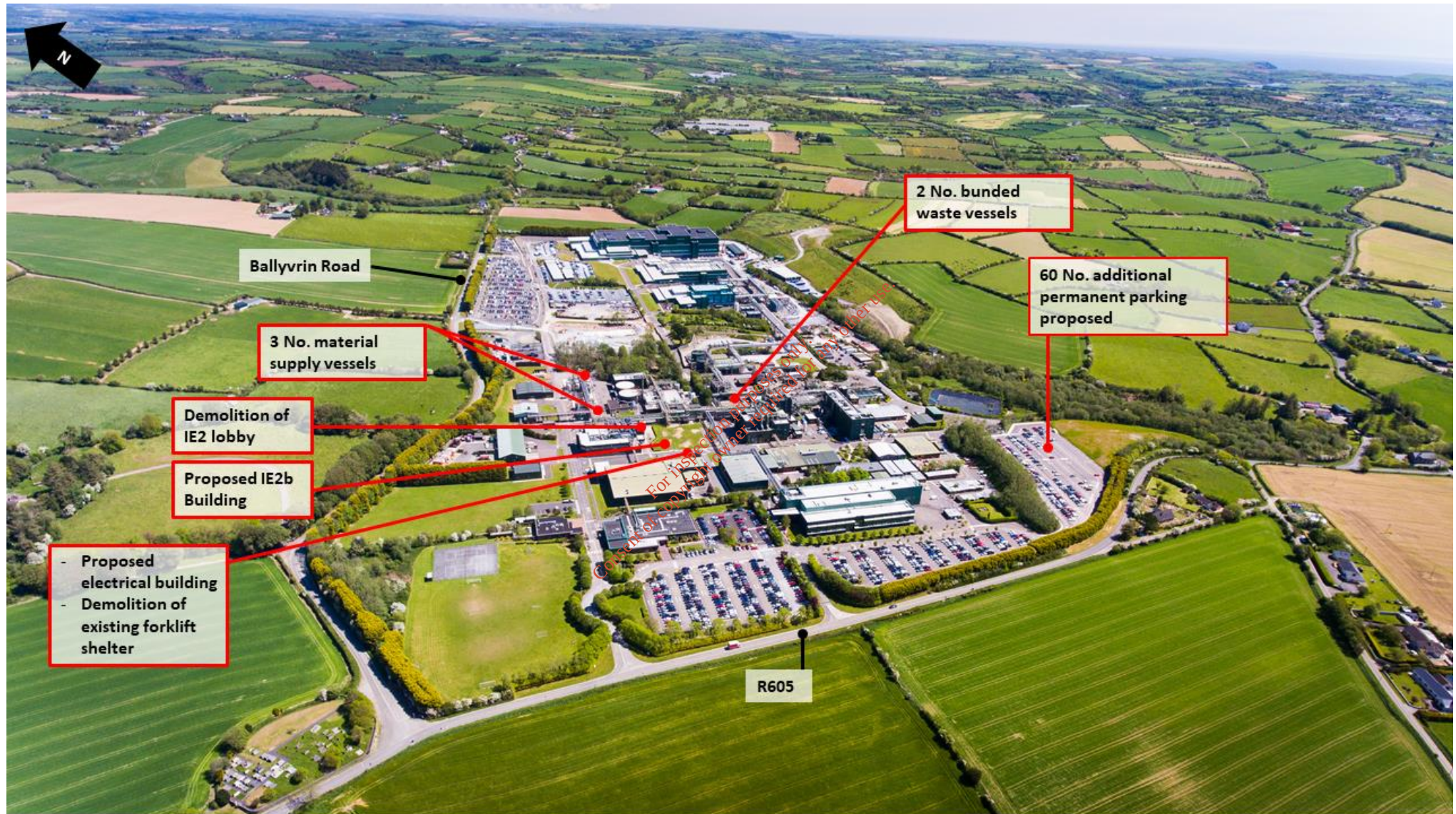


Figure 1: Overview of the Proposed Development, IE2b Expansion | Not to scale.

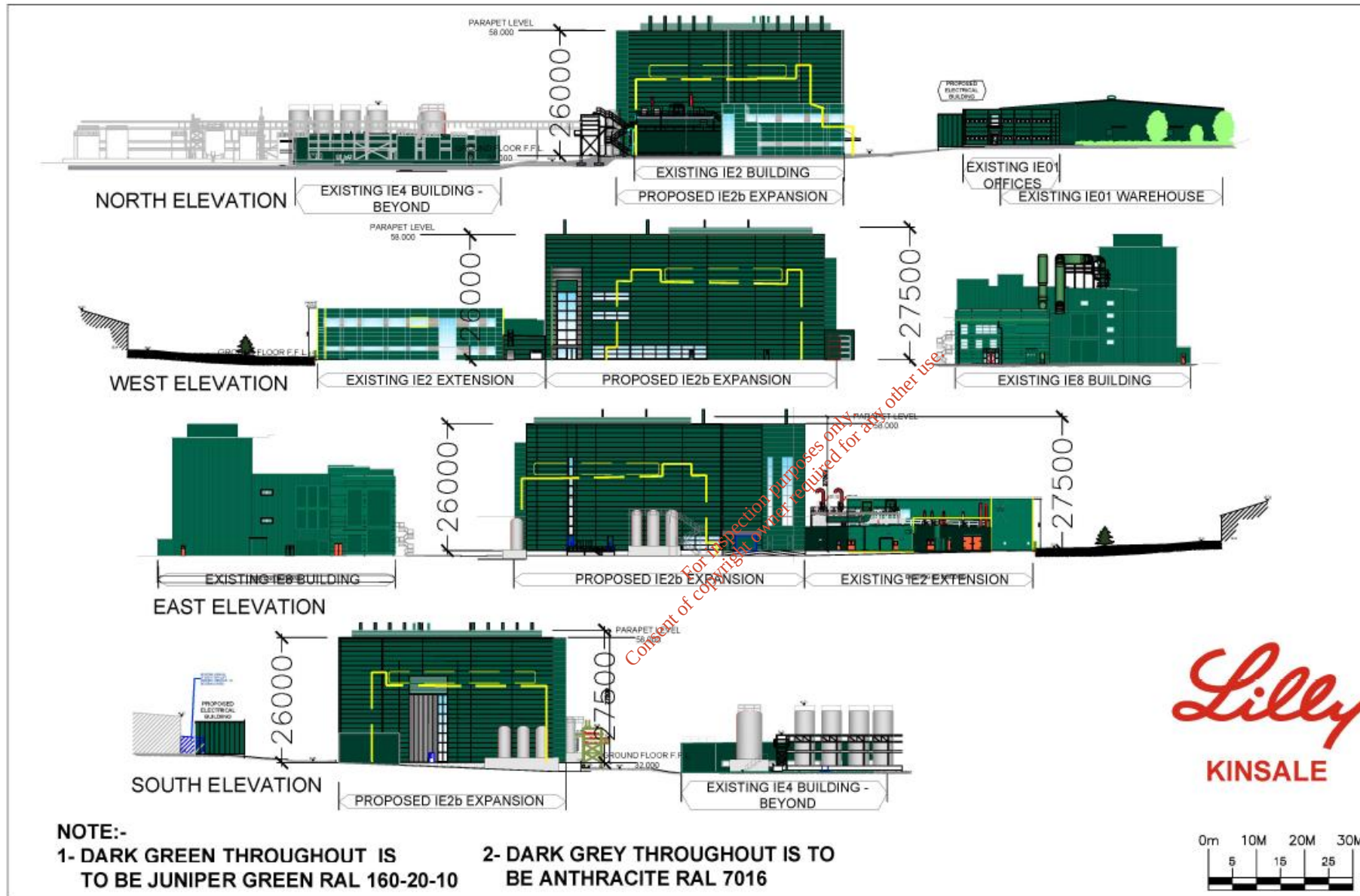


Figure 2: IE2b Expansion – Site Elevations | Not to scale.

Environmental Impact Assessment Report

The Environmental Impact Assessment Report (EIAR) has been prepared to report the findings of an appraisal of the environmental effects of the development, and to support the planning application for the proposed IE2b expansion development.

In Ireland, the requirements for EIA in relation to planning consents are specified in Part X of the Planning and Development Act, 2000, as amended and in Part 10 of the Planning and Development Regulations, 2001, as amended. The EIAR has been prepared in accordance with the European Union (Planning and Development) (Environmental Impact Assessment) Regulations 2018 (S.I. No. 296 of 2018), which transpose the requirements of Directive 2014/52/EU into existing planning consent procedures.

Due regard has also been given to guidelines and advice notes for the preparation of EIARs, published by the Environmental Protection Agency and European Commission.

Need for the Proposed Development

Eli Lilly is among the leading producers of pharmaceutical and biotechnology products in the world. The company has a strong pipeline of products in Clinical Trials and Development which subsequently require manufacturing facilities available as they emerge as likely successful commercial products. Kinsale would compete with other Lilly sites and Commercial Manufacturing Organisations (CMO's) for the manufacturing of these new products and any associated investment. The successful facility and employment growth of the Kinsale site and its employment is due in no small part to the demonstrated ability to deliver, start-up and technically support new manufacturing facilities for New Product Introductions (NPIs).

For the last 10-15 years, the scale of products being manufactured by chemical synthesis has greatly reduced. This has led to the requirement for facilities with smaller scale equipment capable of producing multiple products on a campaign basis. On the Kinsale site this has led to the fit-out of a portion of the existing IE2 building as a 50 US Gallon Reactor scale (approximately 189 litres) suite followed by the fit out of the 250 US Gallon scale (approximately 946 litres) suite in another portion of the IE2 building. This was followed by a change of technology for the production of small scale products from batch production in relatively large vessels to Small Volume Continuous Processing Technology (SVC). The construction of the IE2 SVC manufacturing facility (an extension of IE2) provided the capability for the Kinsale site to compete for the emerging generation of products requiring a facility to produce varying small volumes of product in a continuous rather than a batch mode.

The IE2 SVC facility is currently successfully being operated for materials for clinical trial and commercial supply.

Lilly's production pipeline is such that the next generation of products in clinical trials identify a need for commercial manufacturing capability from early 2022 onwards. In order to meet this need the Kinsale site has been chosen to manufacture a number of steps of these emerging products and at a scale that is greater than the current capacity of the IE2 SVC facility. It is also a requirement that available capacity be maintained for parallel products through all existing chemical synthesis rigs which requires a process rig with technology similar to the existing SVC facility but can run completely independent from existing production rigs.

The proposed IE2b expansion is intended to provide the required additional capacity for future commercial manufacture of emerging products using appropriate SVC technology and will help secure the Kinsale sites position as a key manufacturing site for the Lilly corporation.

Alternatives Considered

Three alternative scenarios of the proposed development were considered as described below.

Do-Nothing Scenario

A do-nothing scenario would involve making an alternative investment decision to either construct a facility at another Lilly site or engage a Contract Manufacturing Organisation (CMO) to manufacture intended future products for Lilly. In that eventuality, manufacturing operations at the Kinsale site would continue using the current facilities. Given the need for additional commercial manufacturing capability, the do-nothing scenario was not considered to be a reasonable alternative. The options of an alternative investment decision or engaging external contract manufacturing capability were considered which ruled out the do-nothing option for Lilly.

Alternative Sites

In assessing the optimum location for the proposed development (leading to the proposed IE2b expansion at the Kinsale site) other Lilly sites and Contract Manufacturing Organisations (CMO's) were considered. Given that the required SVC technology has only been developed to commercial scale at the Kinsale site, it was considered to be the preferred location and most strategic option. To build the Commercial SVC capability required for this process, either at a CMO or another Lilly facility, would require considerably more investment in supporting technology and resources than Kinsale, who has developed this technology successfully over the last number of years. In fact, Lilly Kinsale recently received a prestigious award from the International Society for Pharmaceutical Engineering (ISPE) for Innovation for its use of SVC technology in Pharmaceutical manufacturing. The Kinsale site also has a very strong track record, through its technical workforce, of delivering New Product Introductions (NPIs) in a timely manner. NPI's require very complex co-ordination across a number of engineering, quality, regulatory and other disciplines.

The availability of local specialist engineering expertise and the successful delivery of recent IE2 SVC, IE43 and IE43 extension manufacturing facilities were also important considerations in selecting the Kinsale site over the other alternatives. Therefore, other Lilly sites or CMO's were not considered to be reasonable alternatives.

Alternative Locations within the Kinsale Site

The Kinsale site conducts Site Master Planning reviews to ensure manufacturing, support and infrastructure considerations evolve as the site changes. The most recent review in 2017 identified a number of possible locations for manufacturing facilities including the proposed site adjacent to IE2. Alternative locations explored on the Kinsale site were:

- Site south of and adjacent to IE2 on previously demolished IE3 site;
- Site west of IE30; and
- Site within existing IE2 building.

Site south of and adjacent to IE2 on previously demolished IE3 site

The site adjacent to IE2 was the previous location of the IE3 manufacturing facility. The structure of the IE3 facility has been demolished (under Cork County Council planning reference 14/6065) and with demolition of foundations and remaining slabs underway provides an ideal site for such a facility with extremely good service and infrastructure access routes.

There are other significant operational efficiencies for the proposed site due to the adjacency to similar process operations (e.g. SVC and other chemical synthesis production facilities), associated operational and technical personnel and the ability to share elements of staff facilities (such as locker rooms, office space etc). While the chosen proposed site is physically constrained from development beyond the facility proposed, its adjacency to similar operations and support was a significant factor in reaching the decision for this location over the alternative to the west of IE30 facility.

The available foot print for a building at this location is adequate and would be similar in nature and height to the adjacent IE8 facility. It is also within a line of chemical synthesis facilities strategically bounded to the west by existing support functions (Laboratory, Maintenance, Administration and Warehouse facilities) and to the east by existing Utility and Waste Treatment functions.

The site was previously occupied by IE3 which has since been demolished and foundations are currently being excavated. Therefore, the area has already been significantly disturbed. Thus, the potential effects on biodiversity and archaeology and waste generation by using a previously disturbed and excavated site vs an undisturbed site would be much less.

The proposed location within the site for the IE2b expansion therefore provides an optimum operational solution in comparison to other potential locations with the site. It also avoids extensive re-routing of services if a more remote location within the site was used.

The fact that the chosen location already was the site for a Chemical synthesis facility (IE3), which was also a large multi-storey pharmaceutical manufacturing facility, since 1980, will have less of an environmental impact given it is an already disturbed site.

Site west of IE30

In comparison, the site to the west of IE30 is an undeveloped area which would require significant investment in additional infrastructure and would also require significant excavation of material from the site which would need to be managed. This is the case as it is a relatively unserviced site when compared to the proposed site (from the perspective of underground and overground services). While offering a site that would allow for future expansion, it would be remote from all other support functions required for the operation of the intended process and employees. Further, the potential effects on biodiversity and archaeology and waste generation by using an undeveloped site would likely be greater than using a previously disturbed and excavated site.

Site within existing IE2 building

Consideration was also given to locate the proposed expansion within the existing IE2 building which has a limited area of space currently available in the north-east corner of the building. However, this option would only provide less than half the required floor area on a similar number of levels compared to the preferred option as there is less foot-print available. This option would potentially have a greater visual impact from outside the site boundary given it is closer to the boundary to the north. Potential safety concerns would also need to be addressed due to its height and proximity to the Solvent Tank-farm and Unloading bay.

Since this option would not meet the operational requirements and potentially result in a greater visual effect than the chosen option, it was discounted. This existing space within IE2 also offers another opportunity for alternate use in the future given the proposed extension will be physically constrained from expanding further.

Preferred site location option

The proposed location within the site for the IE2b expansion therefore provides an optimum operational solution in comparison to other potential locations with the site. It avoids extensive re-routing of services if a more remote location within the Lilly site was used. In addition, it makes manufacturing sense to use the existing (but expanded) IE2 SVC teams and adjacent support functions to start-up, operate and maintain the existing facility in comparison to siting the facility further away from its related support services. Efficiencies will be gained in cross training, staff scheduling and supervision. The fact that the chosen location already was the site for a Chemical synthesis facility (IE3) which was also a large multi-storey pharmaceutical manufacturing facility, since 1980, will have less of an environmental impact given it is an already disturbed site.

Alternative Process Design

The process design for the IE2b expansion will for the most part replicate that in the existing IE2 SVC building but with some differences due to the larger scale of production. It will be a combination of SVC technology and small volume batch production.

The continuous processing aspect allows variable production of required quantities of product leading to less waste being generated. Given the scale of the SVC equipment (fits in fume-hoods) it is easier to contain any emissions and is also less hazardous from a process safety perspective.

Full batch production, similar to other site production operations, would not be a reasonable alternative due to the significant number of process steps involved which would either require a significant number of process vessels (which would require a significantly larger production facility) or to run the steps sequentially which would add significantly to the time to produce a single batch, which would challenge the hold time requirements of the product.

There is no other viable nor reasonable process alternative, known to Lilly, to those considered above.

Neighbouring Land Uses

The Lilly facility is surrounded by land in pasture and tillage, in a rural setting. It is bounded to the north by a local minor road, the Ballyvtrin Road, and to the west by the R605 regional road as shown on **Figure 1** above. Fields adjoin the eastern and southern boundaries of the site. Dunderrow village is located to the north west of the Lilly site on the R605 regional road which is the main road from Kinsale to Innishannon. The N71 national secondary route passes through Innishannon and Bandon to the north of Dunderrow.

A stream flows in an approximate northeast-southwest direction along the Lilly facility southern boundary and discharges into the Bandon Estuary at Doon Creek, refer to **Figure 2**. The Bandon Estuary is situated to the west of Dunderrow and extends southwards to the sea at Kinsale harbour.

Current Plant Layout, Facilities and Activities

The Lilly facility is approximately 62.7 hectares (155 acres) in area. The developed site is 42.5 hectares (105 acres) with 92% of this currently occupied. There are six main production buildings on the site, namely IE2, IE8, IE16, IE30, IE42 and IE43. An extension to IE43 is also currently under construction, due to be completed in mid-2020, refer to **Figure 3** below.

Organic synthesis is undertaken in the older production buildings on the site (IE2, IE8, IE16 and IE30). In organic synthesis processes, final products are manufactured from raw materials by chemical reactions through a sequence of steps. These steps are distinct processes and the products from the steps are known as 'intermediates', to distinguish from the 'final product', which is the drug substance. Each production step comprises a number of unit operations.

In each unit operation, the intermediate molecule undergoes physical and/or chemical changes.

The current IE2 facility makes a range of Active Pharmaceutical Ingredients (API's) manufacturing medicines at a medium to small scale for product development, clinical trials and commercial use. The facility uses innovative continuous manufacturing processes as well as small scale batch API processes.

The functional areas are as follows;

- Fume hood room for continuous processing
- Batch processing areas including reactors and filter dryers
- Tank charging and mixing areas
- All necessary utilities, feed tanks and waste tanks

The proposed IE2b Expansion project will largely use similar processes and functions but will produce larger volumes of API. The existing facility is generally a two-storey facility supported by laboratories, administration and technical areas.

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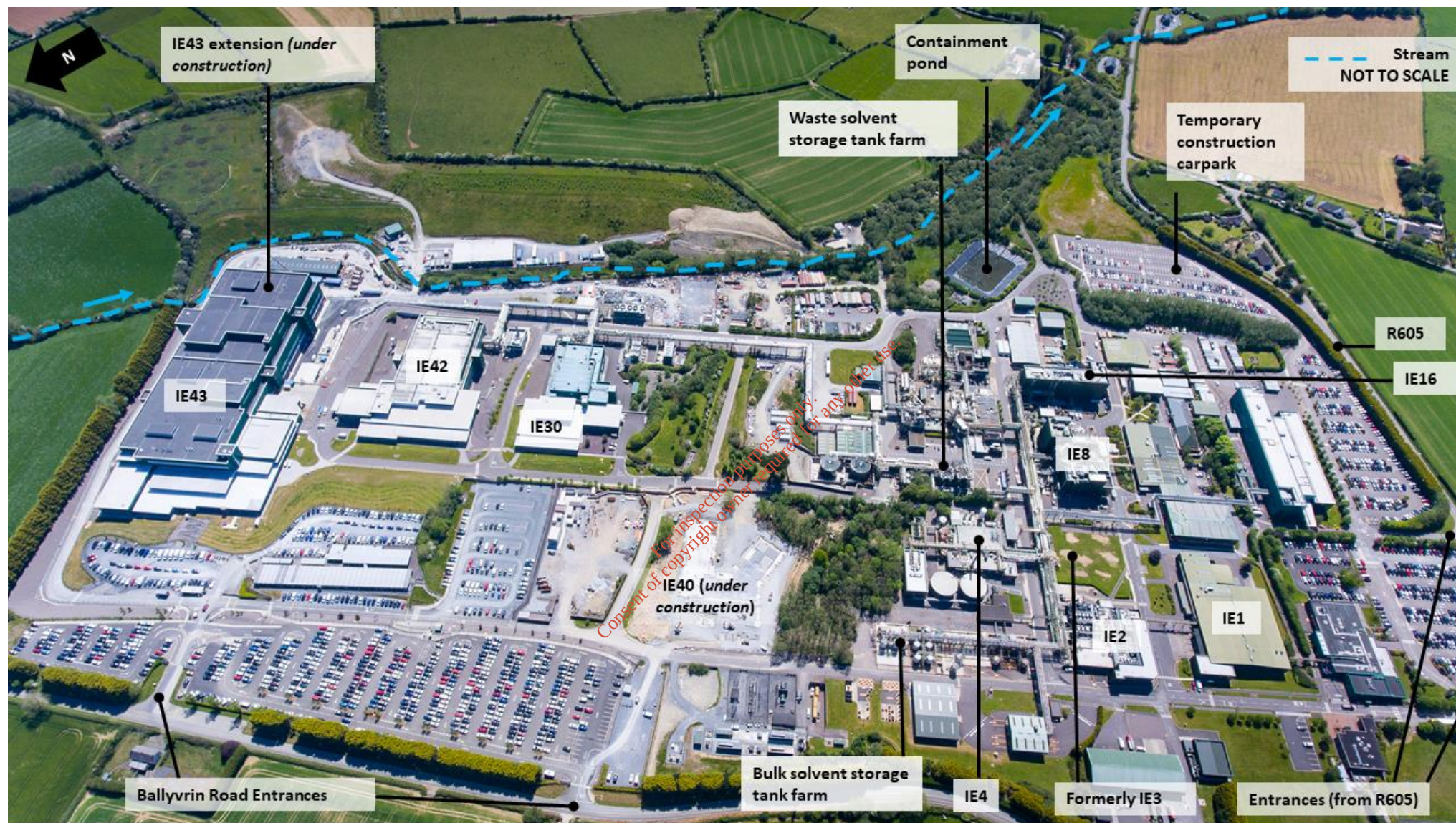


Figure 3: Current Plant Layout and Facilities. | Not to scale.

Industrial Emissions Licence

Lilly currently operates under an Industrial Emissions (IE) licence (P0009-04) granted by the Environmental Protection Agency. The licence requires Lilly to take various actions to meet its environmental obligations, particularly by monitoring emissions and reporting the results to the EPA, the maintenance of the site environmental management programme, and the continuation of efforts at waste minimisation and utilisation of clean technology. The current licence (P0009-04) can be viewed on the Environmental Protection Agency website www.epa.ie.

Seveso Directive

The Lilly site is an establishment to which SI 209 of 2015 (Control of Major Accident Hazards involving Dangerous Substances) Regulations apply. These Regulations require operators of establishments where dangerous substances are present, in quantities equal to or in excess of defined thresholds, to take all measures necessary to prevent and mitigate the effects of major accidents to man and the environment.

The requirement to prepare, submit to the competent authorities and make available to the public a Safety Report applies to all establishments with dangerous substances quantities equal to or greater than those specified in Column 3 of Parts 1 and 2 of Schedule 1 of the Regulations.

The proposed IE2b expansion development will not impact on the status of the Lilly facility in relation to the Seveso Regulations.

Other Permits and Consents

Lilly has a Greenhouse Gas (GHG) Emissions Permit, number GHG023-10352-8.

Lilly also has a Genetically Modified Micro-organisms (GMMs) licence (GMM Register No. 267). The genetically modified organisms contained use activities in Lilly are classified as Class 1 which is associated with the least onerous GMM product containment requirements. The proposed IE2b expansion development will not impact on the status of the current GHG permit nor the GMM licence.

Construction Activities

The proposed IE2b expansion will take approximately 34 months in total to construct; phase 1 is expected to be 22 months and phase 2 is expected to be 12 months. It is expected that phase 1 would commence in 2020 (subject to grant of planning permission) and phase 2 is expected to be 12 months with works commencing circa 2023. Refer to **Figures 4** and **5** below.

The initial construction, phase 1, of the proposed development involves completion of the following:

- IE2b manufacturing facility structure and external envelope which will extend outwards from the southern façade of the existing IE2 manufacturing facility and associated external items of bunded tanks, plant and equipment;
- fit out of the northern and eastern part of the IE2b facility;
- installation of fire safety systems in the shell space at the western part of the IE2b facility;
- demolition of the existing entrance lobby at the south of IE2;
- construction of the first phase of the single storey electrical building and demolition of a forklift parking shelter to the east of the building IE1;
- conversion of 60 number existing temporary construction related car spaces for additional staff car parking;
- installation of the 3 no. dedicated manufacturing material supply tanks located inside the existing bunded tank farm located to the east of the IE2 Building and 2 no. additional bunded waste tanks adjacent to the existing bunded tank farm south of the IE4 Building; and
- modifications and extensions to underground services and existing pipe bridges, local landscaping and ground works, site lighting and ancillary works such as modifications to roadworks and yard areas.

The second and final phase (phase 2) of construction involves fit out of the shell space in the western part of the IE2b manufacturing facility and construction of phase 2 of the electrical building. Construction activities for phase 2 of the proposed project are anticipated to include the following:

- Utilise the contractor's compound and contractor facilities area established for phase 1. The existing temporary parking will be used for phase 2 also;
- Establish construction phase power supply, fencing and securing of the site;
- Excavation for and construction of concrete foundations for phase 2 of the electrical building;
- Erection of steelwork, cladding and roofing for phase 2 of the electrical building;
- Mechanical installation of internal tanks, process skids, piping, pumps and valves;
- Electrical installation of cabling and electrical panels and transformers;
- Installation of internal building finishes;
- Modification of fire safety systems;
- Minor landscaping in the vicinity of IE2b; and
- Testing and commissioning of process, mechanical and electrical installations.

Normal construction working hours will be observed during the construction phase (08.00 – 19.00 Monday to Friday; 09.00 – 16.00 on Saturday). It may be necessary to work overtime, including nights or weekends, at certain stages.

Working outside normal hours may be necessitated through considerations of safety, weather and sub-contractor availability. Heavy or noisy construction activities will be avoided outside normal hours and the amount of work outside normal hours will be controlled.

Throughout the construction phase there will be some variation in workforce on the site. The proposed development is expected to take approximately 22 months to construct the initial phase (phase 1) and it is envisaged that the average number of construction personnel on site will be 300 personnel and that the peak will be in the region of 350 personnel. The workforce for activities such as commissioning and qualification (phase 2) will be less.

The recent demolition of the idled IE3 production building (Planning ref: 14/6065) including excavations required for the removal of the existing concrete foundations. Only minor excavations will be required for the proposed development. The construction of the proposed development will require some movements of materials to and from the site. It is envisaged that the majority of the material arising from the minor excavations will be retained on site for use as fill in the vicinity of the IE2b expansion. Imported quarried stone will primarily be required as structural fill to infill under the ground floor slab.

As part of the proposed development, it is required to demolish the IE2 lobby and a forklift parking shelter. Only very small quantities of material from the overall demolition and enabling works which are unsuitable for reuse on site will require offsite disposal.

Site preparation works will also include the facilities for the contractors and the construction management team. These will include (but not limited to) setting up of access control to the site, site offices, site facilities (canteen, toilets, drying rooms, etc), secure compound for the storage of all on-site machinery and materials and permanent and temporary fencing and hoarding.

An additional 60 staff car parking spaces will be provided as part of the proposed development. This will be provided by the conversion to permanent use of 60 existing temporary construction related car spaces located east of the existing R605 entrance.

As the construction site and compounds will be within the existing developed site, the rain water run-off from the proposed IE2b expansion construction site will be drained to the existing Lilly site stormwater drainage system. This system discharges to the stream via the containment pond and the site monitored surface water discharge point which is continuous monitored. Any areas which will involve the storage of fuel will be paved and bunded and hydrocarbon interceptors installed to ensure no spillages will get into the surface water or groundwater.

An outline Construction Environmental Management Plan (CEMP) has been prepared for the proposed development. This outline CEMP will be developed further by the Contractor prior to the commencement of construction. The CEMP will include at a minimum, the construction mitigation measures, which are set out in this EIAR, as well as any additional measures which are required by the conditions attached to the Cork County Council decision. Implementation of the CEMP will ensure disruption and nuisance are kept to a minimum.

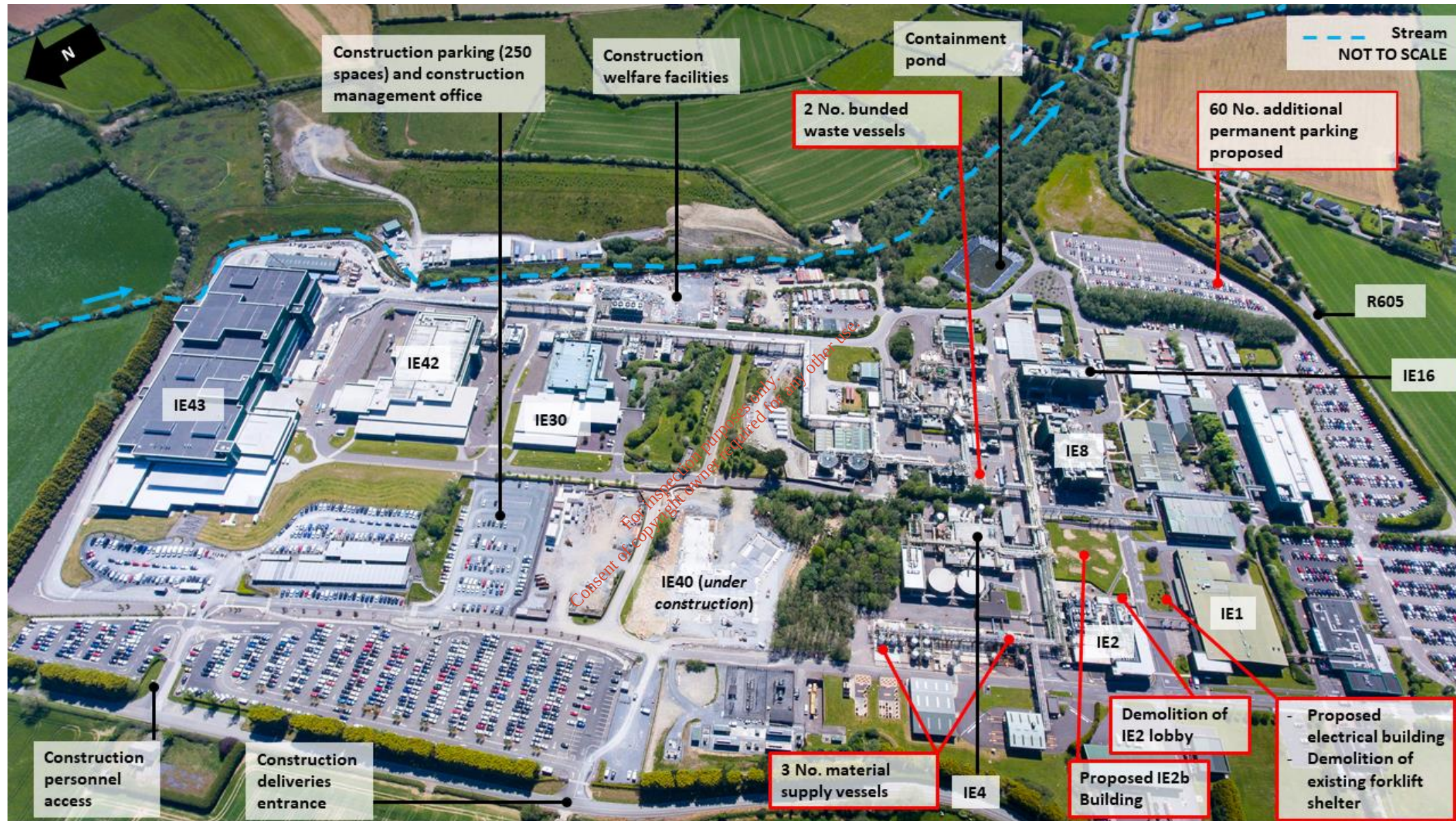


Figure 4: Construction Site Layout (Aerial). | Not to scale.

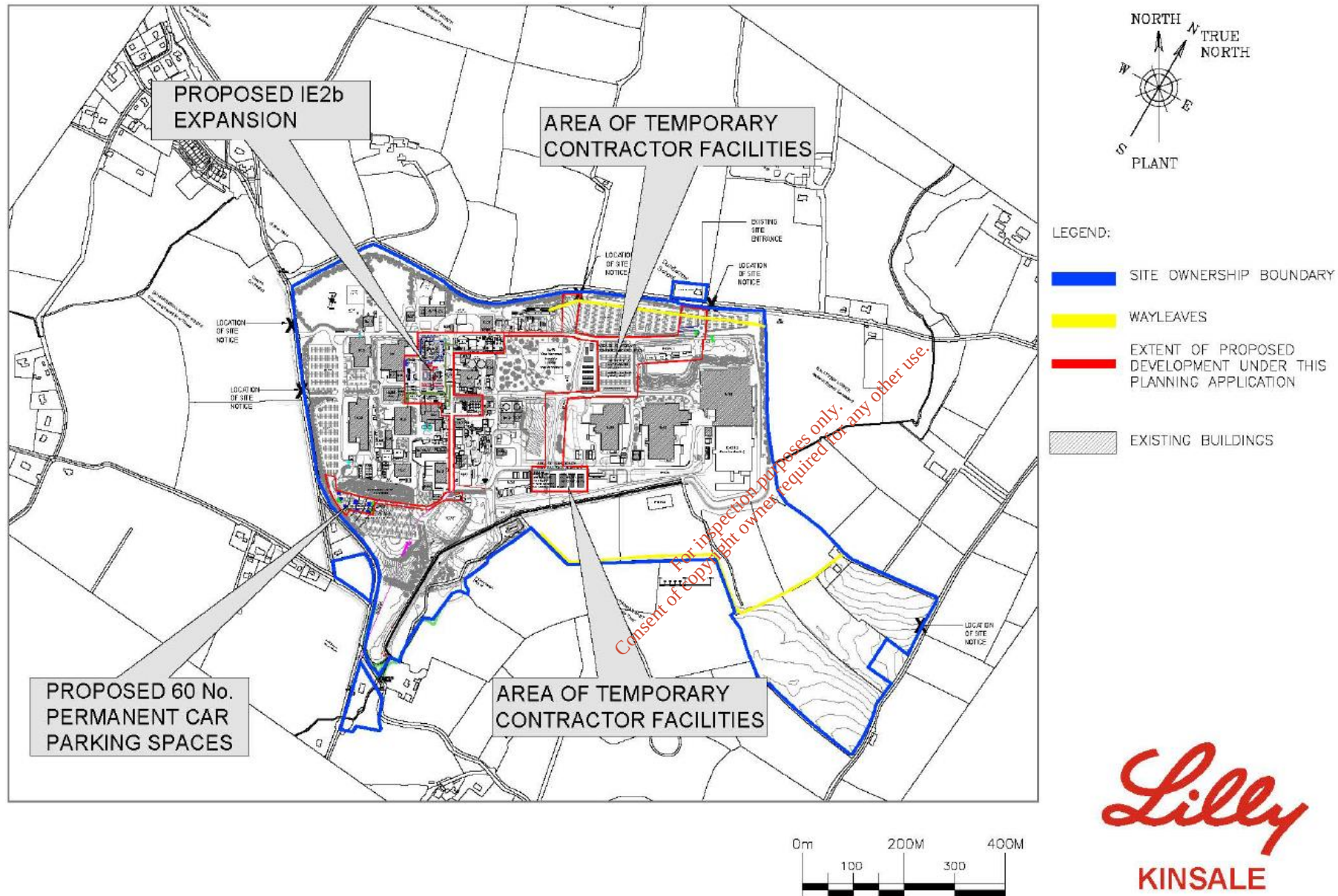


Figure 5 Construction Site Layout Drawing. | Not to scale.

Population and Human Health

The proposed development will have a significant positive effect in terms of employment on the area. Initially an average of 300 workers during the construction phase will be required, with a peak of 350 personnel. There will also be associated secondary off-site employment and economic activity associated with the supply of construction materials and services to the site. There may be some temporary disruption to nearby residents and roads users during the construction phase. The traffic levels generated will not result in significant negative air or noise emissions which could affect sensitive receptors in the area. Some dust emissions are expected to occur however considering the nature and scale of the proposed construction works and the distance to the nearest offsite sensitive receptor, no significant negative effect on population or human health is predicted. Overall, no significant negative effect is predicted on the population during construction.

During operation, the proposed development is expected to create 30 permanent jobs for the initial phase created over a two-year period with the maximum anticipated staff for the fully developed building being c. 70. The mitigation measures proposed throughout the EIAR will ensure that the IE2b expansion will not have a significant negative effect on the neighbouring residents. No significant noise or vibration will be generated during the operational phase of the proposed development. As such, no likely significant effect on population and human health is predicted.

A moderate positive long-term residual effect on population and human health is predicted to occur as a result of the economic and employment opportunity associated with the operation of the proposed development.

Landscape and Visual

This section assesses the impact of the proposed IE2b development on the landscape and visual environment. The proposed development is located centrally within the existing Eli Lilly pharmaceutical plant at Dunderrow, Co. Cork, c.6km to the northwest of Kinsale.

The character of the landscape is primarily agricultural in nature with rolling topography and patchwork of various field sizes, bounded by mature but relatively low broadleaf hedgerows. There are views of the facility from a number of areas in the surrounding landscape, which includes residential properties, Dunderrow village, R605/R606 regional roads and local access roads. Sections of these roads are designated as scenic in the Cork County Development Plan.

Over the past 30 years the Lilly plant has expanded and now much of the site is occupied by a mixture of production, production support and administration facilities. Considering the size of the site and the buildings and structures at the plant, it is quite well integrated into this predominantly rural landscape.

This been achieved through the utilisation of topography, hedgerows, perimeter tree and hedgerow screening, and dark green building colours which when seen against the backdrop of the surrounding elevated landscape, help to incorporate the existing buildings into the landscape.

The proposed development will be located in the western part of the Lilly Kinsale site on the former and now demolished IE3 building site and will replicate the building colour and treatment of existing buildings on site, helping to integrate the development into the existing landscape and visual environment. A series of accurate and verifiable photomontages illustrating the existing and proposed development have been prepared and accompany the application and which were used as a tool in informing the landscape and visual assessment (see **Appendix 7, Volume 4**).

The proposal is a relatively large development in terms of its scale and height within a predominantly rural landscape, but also within an established industrial complex. The perception of landscape effect will be complex in nature with factors of employment, traffic, disturbance and alterations in the local landscape all influencing the degree of an individual's response and longer-term perception of the proposed development.

The location within the overall site and the massing of the building is such that the landscape and visual effects will generally be slight from much of the surrounding landscape and views. There will be more localised, open views of the proposed development and existing Lilly facility between the gates on the Ballyvrin road. As screen planting establishes and grows, these will recede. Within this context the landscape has the capacity to absorb the proposed development with minimal impact.

Roads and Traffic

A Traffic Impact Assessment was undertaken to assess the impact of the proposed development on the local road network.

The proposed site is served by the R605 regional road serving Kinsale, Innishannon and West Cork and secondary by the L-3205 (Rising Sun Road) onto the R607 serving Cork City. In addition, the site is served by Ballyvrin Road, which is very lightly trafficked. Refer to **Figure 6** below.

The key traffic impact associated with the proposed development will be during the construction stage. During the construction stage, the traffic movements will be associated with construction personnel and deliveries of material to the site. Overall the construction phase of the proposed works will have a slight, short-term effect on the local road network.

The operational stage will be associated with personnel employed for IE2b and will have low traffic movements associated with it.

Eli Lilly prepared a Road Safety and Car Pooling Strategy which will be applicable to all IE2b project personnel for both the construction and operational phase. The document sets out procedures which all IE2b extension personnel are obliged to adhere to, including use of permissible routes only to and from the site,

in particular instructing no access to/from Ballyvrin Road east, driver behaviour such as no speeding, no using mobile phones while driving and wearing seatbelts, etc., vehicle safety checks, introduction of signage and a reporting mechanism to allow personnel to report use of non-recommended routes by staff and deliveries or unsafe driving.



Figure 6: Local Road Network. | Not to scale.

A Mobility Management Plan (MMP) will be submitted with this planning application which will highlight the measures that will be implemented by Eli Lilly in order to manage the no. of vehicles trips made to the site by both operational and construction staff generated by the proposed IE2b expansion.

A construction traffic management plan (CTMP) has been prepared for this project. The CTMP will be regularly reviewed and updated to take into account the changing patterns of both the existing traffic and the construction traffic, following consultation with Cork County Council. The implementation of this plan will be monitored by the Lilly site management team during the construction phase and will also be reviewed at the main site meetings. This will include discussing the effect of the works on the public road pavement with the local Area Engineer.

Noise and Vibration

As part of the requirements for the Industrial Emissions Directive (IED) licence, Lilly undertakes annual noise surveys. These surveys have been used in the noise and vibration impact assessment, and all survey work was carried out in accordance with relevant international standards. The surveys have determined that the plant is in compliance with the IED licence limits.

The effects of the predicted noise and vibration from the proposed development were appraised. The potential noise effects during the construction phase and during the operational phase were considered.

Construction activities which are of relevance for noise and vibration include; the building construction of the IE2b expansion, including the demolition of the IE2 lobby and forklift shelter; construction of a number of tanks and bunds across the site; construction of the proposed electrical building and the conversion of approximately 60 temporary car parking spaces to permanent staff car parking spaces.

During site construction works, the maximum predicted total noise level due to the construction phase of the IE2b expansion is predicted to comply with the BS5228 daytime limit. No works that are likely to generate noise are envisaged during the evening or night-time periods.

Given the relatively short-term nature of these “worst-case” operations and the predicted compliance with the BS5228 limit, the likely noise effect on the local environment is not considered to be significant. Construction works are not anticipated to give rise to any appreciable vibration.

The predicted effect of noise on the environment during the operational phase is long term and neutral. There will be no change to the noise levels experienced at the nearest sensitive receptors and levels will continue to comply with IE licence limits.

Air Quality and Climate

Construction activities which are of relevance for air quality include demolition of the existing IE2 lobby and IE1 forklift parking shelter, limited excavations, general construction activities and movement of vehicles on site during construction. The potential for dust emissions will arise during site clearance, demolition, and excavation in dry weather, and during such activities the levels of dust are likely to be small. Dust may be raised by wind from dry surfaces and stockpiles.

In accordance with the Transport Infrastructure Ireland (TII) guidance, the effect of the proposed development is deemed to be of a moderate scale, with soiling effects predicted at distances up to 50m from the site works. As there are no sensitive receptors within 50m of the works, no significant construction dust effects are likely.

Negligible effects on air quality are predicted as a result of the potential change in traffic volumes due to the proposed development.

The operational phase of the proposed development will be according to BAT principles and in compliance with the IE licence for the Eli Lilly Kinsale site (P0009-04).

No new main emission points are proposed as part of the proposed development.

Vents from the proposed processes will be collected and piped to two scrubbers that will remove corrosive materials and reduce the solvent quantities in the vent stream that will go to the existing on site Reeco fume incinerator system. The current licensed emission limit values for the Reeco fume incinerator system and other sources will continue to be complied with.

In considering that no new main emission points make up part of the proposed development, and that all emissions to atmosphere will continue to be compliant with BAT, and with the conditions of the sites existing IE Licence P0009-04, no likely significant effect on air quality is predicted as a result of process operations.

No likely significant effects on air quality are expected to arise as a result of operational traffic.

Carbon emissions from Lilly are regulated through Greenhouse Gas Emissions Permit. Eli Lilly will be required to continue to comply with the requirements of this permit. The construction and operation of the IE2b facility will not have a significant effect on the local or global climate.

Effluent Generation and Treatment

Wastewater arises from several sources in the Lilly facility including process wastewater (directly and indirectly from manufacturing); utility wastewater (steam and hot water generation), sanitary/foul wastewater, surface water, and incinerator quench water.

The wastewaters generated by the Lilly facility are either recovered for reuse, incinerated for energy recovery or treated in the inorganic or biological wastewater treatment plants. Wastewater on site is initially segregated on site for reuse, recovery, incineration or treatment by the concentration of solvents.

During the construction phase of the proposed development no process waste water associated with the proposed development will be generated. Sanitary wastewater will be generated (toilets in welfare facilities etc). The existing wastewater treatment facilities have sufficient capacity to treat any wastewater generated from the above activities during the construction phase.

Treated wastewater is currently discharged through a pipeline to a diffuser about 1km offshore near Sandy Cove Island in the outer Kinsale harbour. No change in this status would arise as a result of the introduction of the proposed IE2b expansion project as the existing biological wastewater treatment plant has adequate capacity to manage both the organic and hydraulic load associated with the proposed IE2b facility during construction and operation.

The operation of proposed IE2b expansion will generate wastewater from the production and cleaning activities to be adopted.

No physical modifications are necessary to the wastewater treatment plant to accommodate the increased volume of wastewater from the proposed IE2b expansion.

Therefore, the existing wastewater treatment system has sufficient capacity to treat the wastewater from the proposed IE2b expansion during construction and operation and as a result there will be no change in the status of the receiving waters of Kinsale harbour from the treated wastewater emissions during construction and operation. No significant effects on the existing wastewater treatment system will arise.

Waste Management

The proposed development will be constructed largely within the footprint of the recently demolished IE3 building, which minimises excavation requirements. Waste generated during construction will include excavated material, building materials removed from the existing IE2 structure (lobby) and forklift parking shelter as well as waste building supplies. Excavated materials will be used on site for landscaping activities or in other construction activities. Asphalt material will be taken off site to be recycled by a registered waste contractor.

Waste building supplies and materials will be segregated for recycling where possible and removed off site for disposal. Waste indirectly associated with the construction of the proposed IE2b expansion will include waste from the contractor's canteen and facilities in the construction compounds including food, recyclables, sanitary and solid municipal waste. This waste will be source segregated as far as is practicable and recovered and disposed of off-site. Sanitary waste will be treated at the on-site biological wastewater treatment plant as discussed above in *Effluent Generation and Treatment*.

No significant effects on the environment are envisaged from waste associated with the construction of the proposed development.

The programme of waste minimisation will be continued during the construction and operational phases of the proposed IE2b expansion. Lilly has a well-developed waste management strategy, which is aimed at determining the most environmentally beneficial methods for controlling the generation, management and ultimate reuse or disposal of all wastes. Lilly will minimise wastes arising from the processes, and also endeavour to find re-use, recovery and recycling options for wastes. The increase in the volume of solid waste will be accepted by the existing permitted waste contractors as is the case for the existing IE2 facility. The nature of waste generated by the proposed development is expected to be similar to that generated for the existing IE2 facility.

No significant effects on the environment are envisaged from waste associated with the operation of the proposed development, due to the existing treatment capacities on site and the existing waste management procedures and controls in place.

Biodiversity

The construction works will require the removal/disturbance of the habitats of low ecological value and the predicted effects on habitats are imperceptible and short term. The potential for effects on habitats adjacent to the site area is low and will be imperceptible and short term. The effect on vegetation in adjoining habitats from wind-blown dust is predicted to be imperceptible and short-term.

Given the industrial nature of the Lilly site and given that the habitats are of limited value for fauna, the predicted effects on fauna are imperceptible and short-term. Whilst increased noise and disturbance is predicted to occur during construction and to a lesser degree during operation, the effect is predicted to be imperceptible. The site area does not provide suitable feeding habitat for bat

species. No mature trees with potential as bat roosts will be affected. Overall the effect on bats is predicted to be imperceptible and short-term.

The potential for effects on the stream along the southern boundary of the Lilly site is imperceptible and short-term due to the nature of the works proposed and due to lack of a direct pathway to the stream. Refer to **Figure 3** above for the approximate location of the stream. Any surface water runoff will enter the existing surface water drainage system which is already strictly controlled.

In summary, the effects on biodiversity during the construction phase (Phases 1 & 2) will be imperceptible and short-term.

The potential for direct or indirect effects on habitats adjacent to the site area during the operational phase is imperceptible and long term. Discharges to the stream and outfall are already strictly controlled. There is already sufficient capacity within the existing surface water drainage system and wastewater treatment system for the proposed IE2b expansion. The plant will continue to operate under an Industrial Emissions (IE) Licence P0009-04 which specifies limits that ensure that no adverse environmental effect will or can arise from any discharge. Given that IE limits are adhered to, the effect on water quality and aquatic ecology due to the discharge of treated effluent is predicted to be imperceptible and long term. In summary, the effects on biodiversity during the construction phase (Phases 1 & 2) will be imperceptible and short-term.

Potential effects on designated Natura 2000 sites (European sites) (SAC/cSAC/SPA) are specifically addressed in a Report for Appropriate Assessment Screening which has been submitted as part of this application. The conclusion of that report is that significant effects on Natura 2000 sites can be ruled out.

Land, Soils and Water

The recent demolition of the idled IE3 production building (Planning ref: 14/6065) including excavations required for the removal of the existing concrete foundations will result in only minor excavations being required for the proposed development, to bring it to the required formation level.

Potential sources of pollution during the construction phase are leaks or spills of fuels, lubricants and paints. The potential for effects on the stream along the southern boundary of the Lilly site is imperceptible and short-term due to the nature of the works proposed and due to lack of a direct pathway to the stream. Any surface water runoff (during construction and operation) will enter the existing surface water drainage system which is already strictly controlled and drains into a containment pond, as outlined in *Construction Activities* above, located in the south western area of the site. Small or minimal groundwater inflow(s) is therefore anticipated during excavation works. The potential risk of silt/pollution entering the underlying ground during construction is very low due to the minor excavations required.

In summary, the effects on land soils and water during the construction phase (Phases 1 & 2) will be imperceptible and short-term.

During operation the handling, use and storage of the solvents and hazardous chemicals required for the proposed IE2b expansion operations will be undertaken inside the facility. Any leaks or spills will be contained within the building and will be removed by a spill control team. The additional tanks to be provided as part of the proposed development will be fully bunded, minimising any risk of leakage or spill. In the unlikely event of leaks or spills

Any firewater flows will discharge to the aqueous waste water drainage system, with any overflow collected in the stormwater drainage system and routed to the firewater retention pond. This will ensure that, in the event of a fire in the plant, the water used for firefighting which could become contaminated, will not drain into the ground or, via the storm water system, into the stream.

All external areas will be paved and drained, via the stormwater drainage system, to the site containment pond, therefore, there is little risk that spills, or leaks will enter the ground and groundwater or into the stream which flows through the site during the operational phase due to the existing surface water drainage network as outlined in *Construction Activities* above.

The predicted effects on land, soils and water will be imperceptible during the operational phase.

A flood risk assessment (FRA) has been undertaken for the proposed development which concluded that there is no significant risk of fluvial flooding to the site associated the nearby stream nor is it considered that there will be an impact on flooding elsewhere as a result of the proposed development.

Archaeology, Architectural and Cultural Heritage

The cultural heritage chapter assesses the potential for archaeological, architectural and cultural heritage effects from the construction and operation of the proposed IE2b expansion.

The assessment outlines the methodology followed, examines the receiving environment and describes the elements of the proposed development that relate to cultural heritage. The likely significant impacts are examined, mitigation measures proposed, and residual impacts described.

There are 44 recorded archaeological sites listed in the Record of Monuments and Places (RMP) for Co Cork and the Sites and Monuments Record (SMR) Database of the National Monuments Service within 2km of the proposed development site. These sites reflect human activity in the landscape extending back to the Bronze Age (circa 2,400-500BC). Of the 44 known archaeological sites, ten are within the Lilly complex or in adjoining lands. There are no protected structures listed in the Cork County Development Plan (2014) within the proposed development site. The nearest protected structure is in the townland of Ardclloyne, 1.8km to the southeast of the Lilly complex. There are nine buildings included in the National Inventory of Architectural Heritage within 2km of the proposed development site, the closest of which is Dunderrow House, 200m north of the Lilly complex.

All elements of the proposed development lie within previously disturbed ground. No in situ archaeological deposits survive within the proposed development

footprint or associated construction footprint. On this basis no construction mitigation or operational mitigation is proposed. If development proceeds there is no predicted residual impact on the archaeology, architecture or cultural heritage of the area.

Material Assets

Water required for the construction activities for the proposed IE2b expansion will be supplied from the existing site water supply which is sourced from both on-site groundwater sources and the municipal water supply.

The construction of the proposed IE2b expansion and associated works will utilise existing hardstanding on site for the construction compounds and construction staff car parking. No significant effects with respect to land use, zoning and local settlement are predicted during the construction and operational phases.

The current site infrastructure has the capacity for the additional demands on water, power, gas and steam during both construction and operation.

The current site infrastructure also has the capacity for the additional demands on waste, storm water drainage and process effluent during both construction and operation, refer above to *Effluent Generation and Treatment, Waste Management and Land, Soils and Water*.

The existing Lilly plant consumes water, natural gas and electricity. The existing supplies of water to the site (groundwater and municipal water supply) have capacity for any additional water required for the operation of the proposed facility according to studies undertaken.

The current site infrastructure also has the capacity for the additional demands on power, gas and steam during both construction and operation. The current site infrastructure also has the capacity for the additional demands on waste, storm water drainage and process wastewater during both construction and operation.

The proposed development is not expected to have a significant effect on material assets.

Major Accidents and Disasters

The EiAR describes likely significant effects on the environment arising from the vulnerability of the proposed development to risks of major accidents and/or disasters. A site-specific risk assessment analysis methodology was used which covers the identification, likelihood and consequence of major accidents and/or disasters as a result of the construction and operation of the proposed development.

A site-specific risk assessment identified and quantified potential risks focusing on unplanned, but possible and plausible events occurring during the construction and operation of the proposed development. Risks identified were assessed for the likelihood of the risk occurring and consequence of the risk. For both the

construction and operation of the proposed development, the risk of fire and/or explosion on site was identified as having the highest risk scores.

As with any industrial development or place of work where solvent and electricity lines/infrastructure exist, there is a potential risk of fire/explosion at the proposed development. However, the scope of this assessment has been based on the understanding that the proposed development will be designed, built and operated in line with best international current practice.

During construction and operation, the site surface water run-off will be routed to the existing site stormwater drainage network which is directed to the containment pond before being discharged to the stream via a monitored outlet. Therefore, the risk of the secondary impact of fire water reaching nearby receptors is considered 'low' as surface water drainage networks will mitigate such potential risks.

Cumulative and Interactive Effects

Interactive effects can arise as a result of the interaction between the various effects within this proposed development. No significant interactive effects were identified for the proposed IE2b expansion development.

The proposed development was also considered in combination with other on-site permitted developments, for example IE43 extension and the IE40 building which are both currently under construction, and also with planned and permitted developments in the vicinity of the Lilly site.

No significant cumulative environmental effects are predicted (either during construction or operation) from the proposed development in combination with these proposed developments on site and other planned or permitted developments.

Summary

The Lilly IE2b expansion development will secure current employment and it is expected that c. 70 direct jobs will be created, and a significant number of jobs will be secured in the wider economy as a result of these permanent Lilly jobs. There will be a construction workforce on the site of approximately 300 on average.

It is Lilly's intention to reduce any adverse effects of the proposed development on the environment to a practical minimum. Where unavoidable environmental effects have been identified during the environmental impact assessment process, measures have been proposed to mitigate these effects where possible. Key mitigation measures include:

- Incorporation of design features and building finishes to reduce the apparent mass and visual impact of the buildings; and
- Construction traffic management plan and dust control measures to minimise construction impacts.

These will be adopted, as appropriate, throughout the construction and operation of the proposed development.

Viewing and Purchasing the Environmental Impact Assessment Report

The full Environmental Impact Assessment Report, of which this is a non-technical summary, can be viewed and purchased at the offices of the Planning Authority (Cork County Council), County Hall, Carrigrohane Road, Cork.

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