



Eli Lilly SA - Irish Branch, Kinsale, Co. Cork

IE43 Biotech Manufacturing Facility Extension

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Environmental Impact Statement

October 2016

ARUP

Eli Lilly SA - Irish Branch
**IE43 Biotech Manufacturing
Facility Extension**
Environmental Impact Statement

249544-00

Issue | 12 October 2016

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Ove Arup & Partners Ireland Ltd

One Albert Quay
Cork
T12 X8N6
Ireland

ARUP

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			Prepared by	Checked by	Approved by
		Name	Alexandra Fleming	Fiona Patterson	Clodagh O'Donovan
		Signature	<i>Alexandra Fleming</i>	<i>Fiona Patterson</i>	<i>Clodagh O'Donovan</i>
		Filename			
		Description			
			Prepared by	Checked by	Approved by
		Name			
		Signature			
		Filename			
		Description			
			Prepared by	Checked by	Approved by
		Name			
		Signature			
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			Prepared by	Checked by	Approved by
		Name			
		Signature			

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Glossary of Impacts

Reference is made in this report to environmental impacts of various qualities, significance, duration and types. These follow the relevant Environmental Protection Agency guidance on the subject.

Quality of Impacts

Positive Impact

A change which improves the quality of the environment (for example, by increasing species diversity; or the improving reproductive capacity of an eco-system, or removing nuisances or improving amenities).

Neutral Impact

A change which does not affect the quality of the environment.

Negative Impact

A change which reduces the quality of the environment (for example, lessening species diversity or diminishing the reproductive capacity of an eco-system; or damaging health or property by causing nuisance).

Significance of Impacts

Imperceptible Impact

An impact capable of measurement, but without noticeable consequences.

Slight Impact

An impact which causes noticeable changes in the character of the environment without affecting its sensitivities.

Moderate Impact

An impact that alters the character of the environment in a manner that is consistent with existing and emerging trends.

Significant Impact

An impact which, by its character, magnitude, duration or intensity, alters a sensitive aspect of the environment.

Profound Impact

An impact which obliterates sensitive characteristics.

Duration of Impacts***Temporary Impact***

Impact lasting for one year or less.

Short-term Impact

Impact lasting one to seven years.

Medium-term Impact

Impact lasting seven to fifteen years.

Long-term Impact

Impact lasting fifteen to sixty years.

Permanent Impact

Impact lasting over sixty years.

Types of Impacts***Cumulative Impact***

The addition of many small impacts to create one larger, more significant, impact.

‘Do Nothing’ Impact

The environment as it would be in the future, should no development of any kind be carried out.

Indeterminable Impact

When the full consequences of a change in the environment cannot be described.

Irreversible Impact

When the character, distinctiveness, diversity or reproductive capacity of an environment is permanently lost.

Residual Impact

The degree of environmental change that will occur *after* the proposed mitigation measures have taken effect.

Synergistic Impact

Where the resultant impact is of greater significance than the sum of its constituents.

‘Worst Case’ Impact

The impacts arising from a development in the case where mitigation measures substantially fail.

List of Contributors

This Environmental Impact Statement (EIS) is based on an appraisal of the environmental effects of the proposed Lilly IE43 Extension development undertaken by Arup and its sub-consultants. The Arup study team drew on in-house resources including environmental sciences, traffic engineering and graphics.

The following specialists, working in accordance with specifications prepared by Arup, supplemented these resources:

- Brady Shipman Martin – Landscape and Visual impact assessment, including preparation of the photomontages;
- Lane Purcell Archaeology – Archaeology, Architectural and Cultural Heritage assessment;
- Dixon Brosnan consultants – Ecology and Screening for Appropriate Assessment;
- RPS – Flood Risk Assessment; and
- White Young Green – Hydrogeological Groundwater Development Investigation.

Jacobs Engineering, the design engineers for the project, and Eli Lilly S.A. – Irish Branch Kinsale, Co. Cork contributed to the preparation of the EIS.

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Glossary of Terms

AADT	Annual Average Daily Traffic
ACA	Architectural Conservation Areas
AER	Annual Environmental Report
API	Active Pharmaceutical Ingredient
AQS	Air Quality Standard
BAT	Best Available Techniques
BOD	Biochemical Oxygen Demand
BREF	BAT Reference
BS	British Standard
CASP	Cork Area Strategic Plan
CHP	Combined Heat and Power
CIRIA	Construction Industry Research and Information Association
CIP	Clean-In-Place
CO	Carbon Monoxide
CO ₂	Carbon Dioxide
COD	Chemical Oxygen Demand
CSO	Central statistics Office
dB	Decibel
dB (A)	A logarithmic noise scale (decibel). The "A" indicates that a frequency weighting has been applied to take account of the variation in the sensitivity of the human ear as a function of frequency.
DMBR	Design Manual for Roads and Bridges
EHS	Environment, Health and Safety
EIS	Environmental Impact Statement
EMP	Environmental Management Programme
EPA	Environmental Protection Agency
ESRI	Economic and Social Research Institute

EU	European Union
EWC	European Waste Code
FDA	Food and Drug Administration (USA)
FDI	Foreign Direct Investment
GHGs	Greenhouse Gases
GMM	Genetically Modified Micro-organisms
GMO	Genetically Modified Organisms
g/s	grams per second
GSI	Geological Survey of Ireland
GVA	Gross Value Added
ha	Hectares
HFO	Heavy Fuel Oil
HGV	Heavy Goods Vehicles
HVAC	Heating Ventilation and Air Conditioning
IED	Industrial Emissions Directive
IFI	Inland Fisheries Ireland
IGSL	Irish Geotechnical Services Ltd
IPPC	Integrated Pollution Prevention and Control
ISO	International Standards Organization
Kg/yr	Kilograms per year
kVA	Kilovolt-ampere
LAP	Local Area Plan
L _{Aeq}	The average noise level during the measurement period, which includes all noise events. The L _{Aeq} value has been found to correlate well with human tolerance of noise, and is the value normally used in setting and monitoring industrial noise limits.
m	metre
mg/Nm ³	milligrams per normal cubic metre
mg/m ³	milligrams per metres cubed
MJ	Megajoule

MLSS	Mixed Liquor Suspended Solids
mOD	m above Ordnance Datum
m/s	metre per second
MS&T	Magnetic Science and Technology
MWh	Megawatt hours
MW	Megawatt
N	Nitrogen
NMI	National Museum of Ireland
NMS	National Monuments Service
NO _x	Nitrogen Oxides expressed as Nitrogen Dioxide
OS	Ordnance Survey
PCI	Percutaneous Coronary Intervention
pH	Indicator of acidity/alkalinity
PICADY	Priority Intersection Capacity and Delay analysis software
PM ₁₀	Particulate matter less than 10µm in diameter
Project Site	land to which planning application relates, 7.3 ha in area
RMP	Record of Monuments and Places
RPG	Regional Planning Guidelines
RPS	Record of Protected Structures
RTO	Regenerative Thermal Oxidiser
SI	Statutory Instrument
SO ₂	Sulphur Dioxide
SO ₄	Sulphate
SMR	Sites and Monuments Record
SS	Suspended Solids
SUDS	Sustainable Urban Drainage Systems
TOC	Total Organic Carbon
TU	Toxicity Unit
µg/m ³	micrograms per metre cubed

vph	Vehicles per hour
VOCs	Volatile Organic Compounds
WEEE	Waste Electrical and Electronic Equipment
WWTP	Wastewater Treatment Plant

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1 Introduction

1.1 Project Overview

1.1.1 Introduction

Eli Lilly S.A. - Irish Branch (Lilly) intends to construct an extension to an existing biotechnology manufacturing facility (IE43) situated within the current Lilly pharmaceutical manufacturing plant, located at Dunderrow, Kinsale, Co Cork. Refer to **Figure 1.1 Site Location - Overview** and **Figure 1.2 Site Location**. The proposed extension will be located in the eastern part of the site. The proposed development will also include internal site roads, service, hard standing, landscaping, fencing and additional car parking.

The current site layout is shown in **Figure 1.3 Existing Site Layout**. The site is owned by the applicant.

This chapter outlines the background to the project. This chapter also describes the methodology used to prepare this EIS and the consultation process that has been carried out to date. For ease of reference, the IE43 biotechnology manufacturing facility extension is referred to as “proposed development” or “IE43 extension” in this chapter and throughout the EIS.

1.1.2 Overview of the proposed IE43 Biotech Manufacturing Facility Extension development

Eli Lilly S.A. - Irish Branch (Lilly) is a bulk pharmaceutical manufacturing plant, located at Dunderrow, Kinsale, Co. Cork. Refer to **Figure 1.1 Site Location – Overview**.

IE43, located within the Lilly site is a dedicated biotechnology manufacturing facility which produces biotechnology products in bulk form for the treatment of cancers and other ailments. IE43 is located at the eastern end of the Lilly site. Refer to **Figure 1.3 Existing Site Layout**. The IE43 building houses a biologics production train (T1) with a number of areas typical to a biotechnology facility. Lilly proposes to construct an extension to IE43 which will allow for a second biologics train (T2) to increase capacity for existing Lilly molecules and future products.

The extension to the existing IE43 biotech manufacturing facility will include administration and manufacturing accommodation over three floors with intermediate service platforms. The manufacturing element of the IE43 extension will extend outwards from the southern façade of the existing IE43 facility. The administration element of the IE43 extension will extend outwards from the north eastern façade of the existing IE43 administration block.

The proposed development is anticipated to create in excess of 150 permanent jobs created over a 2 – 5 year period.

Additional staff car parking for approximately 136 cars will be provided. Internal site roads, services, hard standing and landscaping are also proposed as part of the development.

Full details of the proposed development are provided in Chapter 3 *Description of Proposed Development*. Refer also to the **Figures 3.1 to 3.5** presented in Chapter 3 which indicate the site location, site plan and site sections of the proposed development. Refer also to the drawings which accompany the planning application for further details on the proposed development.

1.1.3 Duration of Planning Permission

The construction of the proposed development including site development works will take circa 30-36 months. Lilly is applying for a five year planning permission to commence and complete the construction phase.

The first biopharmaceutical products are expected to be shipped from the facility in 2020. Once operational, the IE43 extension will be run 24 hours a day, 7 days a week in line with existing facilities at the Lilly Kinsale facility.

1.2 Company Profile

1.2.1 Eli Lilly & Company

Eli Lilly S.A. – Irish Branch is a wholly owned subsidiary of Eli Lilly & Company, Indianapolis, Indiana, U.S.A. which is a leading innovation-driven pharmaceutical corporation committed to developing a growing portfolio of best-in-class, first-in-class pharmaceutical products by applying the latest research from Lilly's own worldwide laboratories, by collaborating with eminent scientific organizations, by making use of the most up-to-date technological tools and by providing exceptional service to its customers.

Lilly manufactures a wide variety of pharmaceutical and animal health products employing approximately 38,000 people worldwide and marketing its medicines in 125 countries. Lilly has major research and development facilities in eight countries with approximately 20% of the workforce involved in research and development.

Eli Lilly & Company was founded in 1876 in Indianapolis. From the beginning, the company manufactured a range of health care products. Lilly's principal product developments are outlined below:

1923	Lilly produced Iletin®, the first commercially available insulin product.
1940s	Lilly was among the first companies to develop a method to mass-produce penicillin, the world's first antibiotic, marking the beginning of a sustained effort to fight infectious diseases.

1950s	The company introduced vancomycin, a powerful antibiotic that remains the last line of defence for patients suffering from serious hospital infections associated with certain types of resistant bacteria. Lilly launched erythromycin, an antibiotic whose broad antimicrobial spectrum expands the alternatives for penicillin-allergic patients.
1960s	Lilly launched the first of a long line of oral and injectable antibiotics in a new class called cephalosporins. Over the next two decades, the company pioneered important chemical breakthroughs that allowed the large-scale production of these products, which include Keflex® and Kefzol®. The company also introduced vincristine and vinblastine, anticancer drugs known as vinca alkaloids that are derived from the rosy periwinkle plant.
1970s	Ceclor®, a member of the cephalosporin family, was launched and eventually became the world's top-selling oral antibiotic. Lilly introduced Dobutrex®, an innovative and lifesaving cardiovascular product.
1980s	The most significant breakthrough in diabetes care since the 1920s was marked by Lilly's 1982 introduction of Humulin® insulin identical to that produced by the human body. Humulin is the world's first human-health-care product created using recombinant DNA technology. Lilly later applied this technology to the introduction of Humatrope®, a new therapy for growth hormone deficiency in children. Lilly launched Prozac®, the first major introduction in a new class of drugs for treatment of clinical depression.
1990s	Lilly introduced a stream of innovative new products: Gemzar®, a drug for the treatment of pancreatic and non-small-cell lung cancer; ReoPro®, a cardiovascular drug that prevents blood clots following certain heart procedures, such as angioplasty; Zyprexa®, now the world's top-selling antipsychotic for the treatment of schizophrenia; Humalog®, a fast-acting insulin product that offers greater dosing convenience to improve blood-sugar control; and Evista®, the first of a new class of drugs to be used for the prevention and treatment of postmenopausal osteoporosis. In 1999, Takeda Chemical Industries, Ltd. and Lilly successfully launched Actos®, an oral antidiabetes agent.
2000s	In late 2000, Lilly submitted Forteo®, a novel treatment for osteoporosis, for regulatory review. The year 2001 brought a major milestone: Lilly launched another first-in-class product, Xigris®, for the treatment of severe sepsis in adult patients with a high risk of death. In 2001, Lilly also submitted several innovative new compounds for regulatory review - atomoxetine, for the treatment of attention-deficit hyperactivity disorder in children, adolescents and adults; Cialis®, for the treatment of erectile dysfunction; and duloxetine, for the treatment of major depressive disorder. In 2002, Cialis®, a medication to treat male erectile dysfunction, is approved for marketing in the European Union; the U.S. launch follows in 2004. Forteo®, a first-in-class medicine for osteoporosis patients to stimulate new bone formation, is approved. Strattera®, a non-stimulant, non-controlled medication to treat attention-deficit hyperactivity disorder, is approved. In 2004, Symbyax®, the first and only FDA-approved medication to treat bipolar depression, is launched in the U.S. Alimta® is approved for use with cisplatin, a standard chemotherapy agent, for the treatment of malignant pleural mesothelioma. Cymbalta® is approved as a new treatment for major depressive disorder and diabetic peripheral neuropathic pain. In 2005, Byetta®, a first in a new class of medicines known as incretin mimetics to treat type 2 diabetes, is approved and launched in the U.S. In 2006, Gemzar® was approved for use in the treatment of women living with recurrent ovarian cancer. This marked the fourth approval by the FDA for this anti-cancer agent.

	In 2007, the FDA approved osteoporosis drug, Evista®, to reduce the risk of invasive breast cancer in two populations of postmenopausal women: women with osteoporosis and women at high risk for invasive breast cancer. The FDA also approved Cymbalta® for the maintenance treatment of major depressive disorder in adults. In 2008, Cialis® was approved by the FDA for once-daily use for the treatment of erectile dysfunction. In 2009, Effient™ was approved by the FDA for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndromes who are managed with an artery-opening procedure known as percutaneous coronary intervention (PCI). PCI usually includes the placement of a stent to help keep the artery open. In 2009, Effient™ was approved by the FDA for the prevention of atherothrombotic events in patients with acute coronary syndrome undergoing percutaneous coronary intervention. Also in 2009, Adcirca™ was approved for pulmonary arterial hypertension.
2010 Onwards	In 2010, Livalo® was approved by the FDA which is indicated for adults as an adjunctive therapy to diet for the treatment of primary hyperlipidemia or mixed dyslipidemia. In 2011, Axiron® was approved which is a topical solution CIII for replacement therapy in males for conditions associated with the deficiency or absence of endogenous testosterone. In 2011, Tradjenta™ was approved by the FDA. These are tablets for the treatment of type 2 diabetes. Also approved in 2011, Bydureon® (exenatide 2 mg powder and solvent for prolonged release suspension for injection), the first and only once-weekly glucagon-like peptide (GLP-1) receptor agonist, for the treatment of type 2 diabetes.

1.2.2 Eli Lilly S.A. – Irish Branch

The Eli Lilly S.A. - Irish Branch (Lilly) Kinsale site is located in Dunderrow, approximately four kilometres from Kinsale, in Co Cork. Dunderrow is approximately 32 kilometres to the southwest of Cork City. The location of the site is shown in **Figure 1.1 Site Location - Overview** and **Figure 1.2 Site Location**. The Kinsale facility is approximately 62.7 hectares (155 acres) in area. The developed site is 42.5 hectares (105 acres) with 90% of this currently occupied.

The Kinsale facility has been in production since early 1981, construction having commenced in 1978. Initially the site manufactured only human pharmaceuticals. Production of animal health compounds was introduced during 1995 but this has ceased in recent years. Over the past 25 years, the facilities have expanded and now approximately 90% of the developed site is occupied by a mixture of production, production support and administration facilities.

The plant is one of 13 Lilly pharmaceutical manufacturing plants worldwide.

The mission of the Kinsale facility is to support the development, manufacture and supply of many of the medicines in Lilly's portfolio. The site uses advanced chemical and biological processes to produce a range of active pharmaceutical ingredients that produce a medical benefit.

The Kinsale facility manufactures active ingredients for a number of Lilly's most important human health medicines for use in the areas of schizophrenia, diabetes, autoimmune disease, postmenopausal health and cancer. These products are further processed to final dosage forms at various facilities to supply medicines to patients worldwide.

Active pharmaceutical ingredients (API) and intermediates for human use are manufactured at the plant.

Production in the older existing facilities is by organic synthesis and product purification. The bulk active materials are manufactured in a number of main chemical synthesis production buildings on site and then shipped to finishing plants for formulation, filling and finishing as tablets, vials or capsules.

Both IE42 and IE43, located at the eastern end of the Lilly site are biotech manufacturing facilities and they operate a cell culture based process, containing clarification steps and purification steps to produce purified biotechnology based products which are frozen for storage and subsequent shipment to finishing plants for formulation and filling.

The main milestones in the sites development were:

- 1978-81** Construction;
- 1981** New sterile Cephalosporin manufacturing facility commences in IE2
Production start-up of the dedicated facility IE3 for Benoxaprofen®;
- 1984** IE8, the second production facility added. IE2 small production
facility added. IE3 starts production of Ceclor® intermediates;
- 1985** IE8 production begins with Fluoxetine® and Dobutamine®;
- 1988** Site becomes known as Eli Lilly S.A. – Irish Branch. IE8 production
facility expanded to three rigs for campaigned production;
- 1991** IE8 Final Bulk facility added and starts production of Nizatidine®;
- 1995** Animal health products introduced in IE3. Worldwide supply of
Olanzapine® commences in IE8;
- 1998** Commercial supply of Raloxifene® starts in IE8;
- 1999** IE16 small scale, high containment facility introduced. New product
launches;
- 2000** IE16 large scale facility constructed;
- 2001** Atomoxetine® supply starts in IE16 large scale facility;
- 2004** New laboratory and office (IE28) constructed;
- 2006** New clean manufacturing facility (IE30) constructed;
- 2006** Complete validation of IE30 facility;
- 2008** Retrofit of IE2 to develop pilot scale facilities for commercialisation;

- 2011** Commissioning of new IE42 biotech manufacturing facility. Full production in 2012;
- 2012** IE43 construction commences;
- 2013** Cyramza® is produced in IE42; and
- 2016** IE43 is officially opened.

Approximately 600 permanent staff are employed at the Lilly facility in Kinsale. In addition to the permanent staff, normally there are between 200 and 300 contract personnel on site, depending on the level of construction and project activity. The plant operates twenty-four hours per day, seven days per week, throughout the year.

In 2015 it is estimated that Lilly made an annual contribution to the Irish economy in wages, payments to Irish contractors, service providers, materials sourced in Ireland and taxation of c. €150 million.

1.3 Environmental Impact Statement Methodology

1.3.1 Purpose and Screening

The prescribed classes of development and thresholds that trigger a mandatory Environmental Impact Assessment (EIA) are set out in Schedule 5 of the Planning and Development Regulations, 2001, as amended.

A review of the classes of development (requiring EIA) was carried out to determine whether the proposed development falls into any of the development classes contained therein.

The most relevant criterion is Class 13 of Part 2 of Schedule 5 which states:

13. *Changes, extensions, development and testing*

- (a) *Any change or extension of development which would:-*
- (i) *result in the development being of a class listed in Part 1 or paragraphs 1 to 12 of Part 2 of this Schedule, and*
 - (ii) *result in an increase in size greater than-*
 - *25 per cent, or*
 - *an amount equal to 50 per cent of the appropriate threshold, whichever is the greater.*
- (b) *Projects in Part 1 undertaken exclusively or mainly for the development and testing of new methods or products and not used for more than 2 years.*

In this case, Class 13(a)(ii) is the relevant criterion. As there is no appropriate threshold for the proposed development type, then the 25% size increase is the relevant criterion.

The “increase in size” can be interpreted in a number of different ways such as total floor area, process area, volumes etc.

The IE43 biotech manufacturing facility extension has been considered (in comparison with the existing facility) in terms of:

1. increase in total floor area (approximately 29% increase);
2. increase in production capacity (approximately 31% increase); and
3. increase in process area (approximately 112% increase).

The IE43 Biotech Manufacturing Facility Extension will clearly result in an increase in size of 25% or greater for all of the scenarios considered, i.e. total floor area, process area and bioreactor volume. Therefore it is concluded that an EIA (with preparation of an EIS) is required under Class 13 of Part 2 of Schedule 5 of the Planning and Development Regulations, 2001 as amended.

1.3.2 Statutory Requirements for the Contents of an EIS

This EIS has been prepared in accordance with the relevant provisions set out in the Planning and Development Regulations 2001, as amended ('the Regulations'), and the provisions of the codified Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment. Annex IV to the EIA Directive and Schedule 6 to the Regulations specify the information to be contained in an EIS.

Thus, pursuant to the provisions of Article 5(1) of the EIA Directive, the information specified in Annex IV is to be provided, in as much as the information is relevant to a given stage of the consent procedure and to the specific characteristics of a particular project or type of project and of the environmental features likely to be affected, having regard to current knowledge and methods of assessment.

This EIS has been prepared in compliance with the requirements of Directive 2011/92/EU and the Regulations. Moreover, although the requirements of Directive 2014/52/EU have not yet been transposed into Irish law, this EIS has had regard to the provisions of Directive 2014/52/EU.

1.3.3 Structure of Environmental Impact Statement

This Environmental Impact Statement (EIS) has been prepared to provide information on the likely significant effects of the project on the environment and, in particular:

1. a description of the project comprising information on the site, design, size and other relevant features of the project;
2. a description of the features of the project and/or measures envisaged in order to avoid or reduce and, if possible, offset likely significant adverse effects on the environment;
3. the data required to identify and assess the main effects which the project is likely to have on the environment;

4. an outline of the main alternatives studied by the developer, which are relevant to the project and its specific characteristics, and an indication of the main reasons for the options chosen, taking into account the effects of the project on the environment; and
5. a non-technical summary of the information referred to in the above four points.

The EIS has been prepared on behalf of Lilly by environmental specialists under the supervision of Arup.

The format used in the EIS is the grouped format, in which each topic is addressed in a separate section. This is designed to allow readers to access the issues of interest to them as easily as possible. However there is overlap of some topics. For example, effects on human beings are addressed in a number of chapters including Landscape and Visual Assessment, Air Quality and Climate Assessment, and Noise and Vibration, as well as Human Beings. Issues not directly addressed in individual chapters and interactions between environmental issues are described in Chapter 17 *Potential Cumulative & Other Impacts and Interactions* of this EIS.

The EIS comprises four main sections contained within one volume as follows:

- Non-Technical Summary;
- Environmental Impact Statement (Main Text);
- Figures; and
- Appendices.

1.3.4 EPA Guidelines and Other Guidelines

This EIS has been prepared with due regard to the guidelines on the preparation of environmental impact statements published by the EPA. These are contained in Advice Notes on Current Practice (in the preparation of Environmental Impact Statements) (2003), and Guidelines on the Information to be contained in Environmental Impact Statements (2002). Moreover, the EIS has been prepared having had due regard to:

- Revised Guidelines on the Information to be Contained in Environmental Impact Statements (Environmental Protection Agency, draft September 2015);
- Advice Notes for Preparing Environmental Impact Statements Draft September 2015;
- European Union (2013) Guidance on Integrating Climate Change and Biodiversity into Environmental Impact Assessment;
- European Commission (2012) Interpretation suggested by the Commission as regards the application of the EIA Directive to ancillary/associated works;
- European Commission (2006) Clarification of the application of Article 2(3) of the EIA Directive; and

- European Commission (1999) Guidelines for the Assessment of Indirect and Cumulative Impacts as well as Impact Interactions.

1.4 Difficulties encountered during the study

No particular difficulties were encountered during the preparation of this EIS.

1.5 Consultation

The following groups and organisations were consulted in the preparation of this Environmental Impact Statement:

- Cork County Council; and
- Inland Fisheries Ireland.

1.6 References

Environmental Protection Agency (2003) Advice Notes on Current Practice in the Preparation of Environmental Impact Statements.

Environmental Protection Agency (2002) Guidelines on the Information to be contained in Environmental Impact Statements.

Revised Guidelines on the Information to be Contained in Environmental Impact Statements (Environmental Protection Agency, draft September 2015).

Advice Notes for Preparing Environmental Impact Statements Draft September 2015.

European Union (2013) Guidance on Integrating Climate Change and Biodiversity into Environmental Impact Assessment.

European Commission (2012) Interpretation suggested by the Commission as regards the application of the EIA Directive to ancillary/associated works.

European Commission (2006) Clarification of the application of Article 2(3) of the EIA Directive.

European Commission (1999) Guidelines for the Assessment of Indirect and Cumulative Impacts as well as Impact Interactions.

2 Need for the Proposed Development and Alternatives Considered

2.1 Introduction

This chapter demonstrates the specific need for the proposed development. This section also addresses the main alternatives considered.

2.2 Need for the Proposed Development

Eli Lilly and Company is among the leading producers of pharmaceutical and biotechnology products in the world. A significant portion of the company's product portfolio is in the biopharmaceutical category and many of these products are currently under development in the company's research facilities.

In late 2006, the Kinsale facility was selected by the Lilly Corporation as the optimum site for the scale up and commercialisation of its biopharmaceutical products. This led to the construction of the first biotech manufacturing facility on site, IE42. This was followed by the construction of the IE43 biotech manufacturing facility commencing in 2012. By virtue of the successful establishment of the IE42 & IE43 facilities, local expertise and effective site development master planning, the Kinsale facility has again been favoured by Lilly to expand its biotech manufacturing facilities, to match Lilly's anticipated demand for additional global capacity.

The development of the IE43 facility extension not only meets Lilly's requirements for increased commercial scale capacity for its biopharmaceutical products but also establishes the Kinsale facility as a location of choice for the company's growing portfolio of biopharmaceutical products. The chosen location on site for the IE43 facility resulted directly from the site's development master plan, which identified the eastern end of the site as the preferred location for the development of biotech manufacturing facilities and future associated support facilities. IE42 and IE43 are both located in the eastern area of the site. Refer to **Figure 1.2**.

This project will increase the existing IE43 Biotech Manufacturing Facility production capacity. The IE43 facility was originally designed and constructed with provision for this extension and it provides an economical solution avoiding costly duplication of building utilities and some elements of production and staff facilities.

2.3 Alternatives Considered

2.3.1 Alternative Sites

In assessing the optimum location for the proposed IE43 facility extension, other Lilly sites were considered. However, the Kinsale site was considered the preferred location given the successful development of the IE42 & IE43 facilities, and the availability of local expertise.

2.3.1.1 Alternative location within Kinsale site

The IE43 facility was originally designed and constructed with provision for an extension to be incorporated if it was deemed necessary to increase capacity in the future. There are significant efficiencies to be gained from extending the existing facility rather than building a separate process and administration facility.

The existing IE43 building houses a biologics production train (T1) with a number of areas typical to a biotechnology facility. Lilly proposes to construct an extension to IE43 which will allow for a second biologics train (T2) to increase capacity for existing Lilly molecules and future products.

The proposed IE43 extension provides an economical solution avoiding costly duplication of building utilities and some elements of production and staff facilities. For example a significant part of the initial capital cost of IE43 included a pre-investment consideration for an extension. Therefore the design of IE43 included for sharing manufacturing spaces sized to support a second train (T2) and sharing utilities such as clean steam, cooling water etc. In addition to sharing with IE43, key services, staff facilities and utilities will also be shared with the entire existing site.

The proposed location within the site for the IE43 extension therefore provides an economical solution and avoids costly duplication. Refer to **Figure 3.2**. In addition, it makes manufacturing sense to use the existing (but expanded) IE43 teams to start-up, operate and maintain the existing facility. Efficiencies will be gained in cross training, staff scheduling and supervision.

Other examples of pre-investment during the development of the original IE43 building include aspects such as the stream diversion and ground preparation works. The inclusion of the stream diversion in the previous planning application for IE43 was to allow for the future extension of the process building to the south. Ground excavation works for IE43 also included excavation for the level platform of the IE43 extension footprint to the south.

2.3.2 Alternative Process Design

The process design for the IE43 extension will for the most part replicate that in the existing IE43 building to ensure optimum efficiency in production is gained while minimising duplication of utilities and services. The manufacturing planned for the extended IE43 is the same manufacturing platform as the existing IE43.

The position of the existing “long building” process design for IE43 is a deliberate facility design feature which was made at the initial IE43 design to place all major manufacturing spaces on the one level, as opposed to having manufacturing spaces over a number of levels which would have resulted in a shorter but possibly taller production building. For manufacturing operational reasons, the IE43 extension will follow the same design features.

2.3.3 Alternative Site Layout Design

The internal layouts and stack-up arrangement of the IE43 building and IE43 building extension are the combined influence of processing requirements and the sloping topography of the site. In addition the IE43 extension’s general appearance is influenced by the adjacent IE42 and IE43 facilities as there was a desire to have the two buildings complement each other.

These constraints offered little opportunity for further consideration of alternative site layout designs when designing the existing IE43 biologics train (T1). The proposed IE43 process block extension has been designed so the final structure of both the existing biologics train (T1) and proposed biologics train (T2) gives the appearance of one manufacturing unit and is in keeping with the style and appearance of the existing IE43 where possible.

A separate administration building was initially considered for the existing IE43 however efficiencies could be gained by siting production personnel in the production building next to the production floor. The existing administration block will now be extended to the north east (headblock extension) to support the extended process block for the same reasons the existing administration block was situated in a production building. Refer to **Figure 3.2** for the proposed site layout.

The height of the proposed extension was based on two main design objectives. The building height had to facilitate the process design and allow for the floor levels of both buildings to match for a seamless finish between the existing IE43 and the proposed extension. To minimise the visual impact of the existing IE43 building height, the site was excavated during the construction of the existing IE43 to reduce ground levels to approximately 29.000m (local bench mark level). These ground levels will be maintained for the proposed IE43 extension.

During the design process of the existing IE43 many iterations were performed on the building facades with the intention of offering a most aesthetically pleasing facility while mitigating visual impacts. For the proposed IE43 extension, the façade was reassessed during the design stage. The design objective was to break up the massing of the building and introduce new colours on the louvres to mitigate the visual impact of the proposed extension.

During the construction of the existing IE43, screening berms were constructed to the south of the building. For the proposed IE43 extension a screening berm will be provided along the eastern side of the proposed IE43 building extension. The levels of the existing berm located to the south east of the stream will also be raised and landscaped.

The final design and mitigation measures proposed for the proposed extension have arisen from reviews by the design team, Lilly management personnel, external consultants and consultations with Cork County Council. The final façade design is discussed further in Chapter 7 *Landscape and Visual Impact*.

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3 Description of the Proposed Development

3.1 Introduction

Eli Lilly S.A. Irish Branch intends to construct an extension to an existing biotechnology manufacturing facility (IE43) situated within the current Lilly pharmaceutical manufacturing plant, located at Dunderrow, Kinsale, Co. Cork. The proposed extension will be located in the eastern part of the site. The proposed development will also include internal site roads, services, hard standing, fencing and additional car parking. Refer to the **Figures 3.1 to 3.5** which indicate the site location, site plan and site sections of the proposed development. Refer also to the drawings which accompany the planning application.

This chapter presents a description of the proposed IE43 biotech manufacturing facility extension. Information is provided on the current site layout and facilities in addition to neighbouring land uses (**Section 3.3**). The design philosophy for the IE43 extension is described (**Section 3.4**). The main features of the proposed development are outlined (**Section 3.5**). Health and safety aspects (**Section 3.7**), regulatory control of the facility (**Section 3.8**) and site decommissioning are also described (**Section 3.9**).

3.2 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 **Figures 1.1 Site Location Overview, 1.2 Existing Site Layout and 1.3 Site Location**. Fields adjoin the eastern boundary 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, as shown on **Figure 14.2 Hydrology**. A section of the stream within the site was diverted as part of the development of the existing IE43 building. Refer to **Figure 1.2 Existing Site Layout**. The Bandon Estuary is situated to the west of Dunderrow and extends southwards to the sea at Kinsale harbour.

3.3 Current Site Layout and Facilities

3.3.1 General

Eli Lilly S.A. - Irish Branch manufactures bulk active pharmaceutical ingredients (API) and intermediate products, which are sent to other Lilly locations in Europe, USA and elsewhere for formulation and distribution.

In addition to production facilities, there is a comprehensive range of production support facilities on site including environmental facilities, laboratories, warehousing, external storage, utility generation, maintenance workshop, offices, staff facilities and a cafeteria.

The principal buildings on site at present are identified below.

Building No.	Use
IE1, IE9, IE14, IE15, IE18, IE19, IE26, IE27	Warehouses and drum stores
IE2	Laboratories & small scale manufacturing facility
IE4, IE34	Boiler house and utilities building
IE5, IE10	Administration facilities and offices
IE6	Pump house
IE7, IE11	Waste treatment building & Wastewater treatment plant
IE8, IE16	Multipurpose small molecule manufacturing facilities
IE9, IE21	Engineering offices, workshops and stores
IE20	Main Tank Farm
IE22	Nitrogen plant compressor house
IE28	Laboratories and offices
IE30	Dedicated clean manufacturing facility
IE31, IE33	MCC (motor control centre) compressor house
IE42	Biotechnology manufacturing facility
IE43	Biotechnology manufacturing facility (currently being commissioned for commercial production)

The current developed site layout is shown in **Figure 3.2 Existing Site Layout**, with the main features identified.

3.3.2 Existing Production Facilities

There are six main production buildings on the site, namely IE2, IE8, IE16, IE30, IE42 and IE43. Details of the production buildings are as follows:

- IE2 laboratory and production building has been in operation since 1981 and contains laboratory and small scale manufacturing facilities. Upgrades to IE2 have been carried out in recent years and an extension and partial upgrade to IE2 is currently being constructed to provide improved commercialisation facilities.
- IE8 production building was established in 1984 and is a multipurpose plant for bulk manufacture of the intermediate and final steps of various compounds such as drugs for schizophrenia and osteoporosis. It has undergone significant upgrades over the past several years.
- IE16 production building is a multipurpose plant comprising two production areas containing equipment for large-scale and small-scale chemical synthesis.

The small-scale production suite commenced operation in 1999 and is used to produce an oncolytic drug. The large-scale production suite commenced operation in 2001. It is similar to the IE8 facility in that it is used to manufacture schizophrenia, osteoporosis and attention deficit disorder drugs.

- The IE30 production facility was a dedicated clean manufacturing plant used to produce an aseptic product for schizophrenia. It is currently de-commissioned for most of the year except for the utilities section which supplies IE42.
- The IE42 biotech manufacturing facility comprises cleanroom production areas for a cell culture based process, containing clarification steps and purification steps to produce a purified biotechnology based product which is frozen for storage and subsequent shipment to finishing plants for formulation and filling. The products manufactured in IE42 building currently are for treatment of cancer, diabetes and autoimmune disease.
- The recently completed and commissioned IE43 biotech manufacturing facility also comprises cleanroom production areas for a cell culture based process, containing clarification steps and purification steps to produce a purified biotechnology based product which will be frozen for storage and subsequent shipment to finishing plants for formulation and filling. The products manufactured in IE43 building initially will be for treatment of cancer and autoimmune disease.

3.3.3 Ancillary Facilities

In addition to the production facilities, there are various ancillary facilities on site which are described below.

3.3.3.1 Bulk Storage and Tanker Unloading

The bulk solvent storage tank farm on site contains 29 tanks; 13 of which are in service for the storage of solvents required for the production processes and 11 of which have been decommissioned and will be demolished. Of the remaining five tanks, one can be used for solvent storage and four are used for glycol, diesel and bund waste. Recovered and spent solvent are no longer stored in the tank farm.

All the fixed bulk storage tanks are located in containment bunds. The bunds have the capacity to contain 110% of the contents of the largest tank in the bund, in the event of a leak or spill. The tanker loading and unloading bay is also bunded. Fixed foam and firewater protection systems are installed in the tank farm in compliance with current standards of good engineering and safety practice.

3.3.3.2 Waste Solvent Storage

All of the tanks in the waste solvent tank farm were replaced with new tanks in 2009, built to a much higher specification than the original tanks. There are seven new tanks used to store liquid wastes for treatment on site. There are two categories of liquid wastes.

Primary liquid wastes are mainly waste organic solvents. Secondary liquid wastes are aqueous, comprising mainly water, which contains some solvent and other organic residues.

All the waste solvent storage tanks are located in containment bunds. Fixed foam and firewater protection systems are installed in this area.

3.3.3.3 Warehousing

The main production materials storage areas on site are:

- IE1, IE14 and IE9B warehouses which are used to store dry goods, including powders, intermediates which are stored in flexible intermediate bulk containers and final products. The recently constructed IE27 warehouse will house freezers where the biotech final products from IE42 & IE43 will be stored.
- Smaller warehouses for staging of biotech materials are located in the IE30, IE42 and IE43 buildings.
- Hydrogen storage pad.
- IE15 drum store, and cylinder store.
- IE15B water-reactive material storage.
- IE26 biotech raw material storage.

Most materials are delivered to warehouses IE15, IE1 or IE9B. Warehouse personnel are responsible for acceptance, storage and dispensing of most materials. Materials not directed to the warehouses include:

- organic solvents, which are delivered directly to the tank farm,
- gases, which are directed to the hydrogen storage pad, and
- bulk oxygen, carbon dioxide and nitrogen which are delivered to storage tanks at IE42 and IE43.

3.3.3.4 Environmental Control

Most of the liquid wastes generated on site are sent to the environmental controls area for either incineration or biological treatment in accordance with the sites' philosophy of treating or recovering its own waste streams where possible.

Most of the aqueous wastes are treated in the wastewater treatment plants (WWTPs). The facility currently has both a biological WWTP (refer to Figure 11.2 Biological Treatment Plant) and an inorganic WWTP (refer to Figure 11.1 Inorganic Treatment Plant).

The liquid wastes from the existing IE43 process are segregated into two waste systems, aqueous waste and biowaste. The aqueous waste system is waste that does not contain activated cells and also the waste from the cleaning processes. The aqueous waste stream is sent to the site inorganic waste water treatment plant.

A biowaste system handles any streams which potentially could contain activated cells.

In this biowaste system, cell matter is inactivated by means of a retention tube and a steam ejector which allows the tank contents to be heat in-activated so that only inactivated cell matter is sent to the site biological wastewater treatment plant (WWTP) with biodegradable aqueous waste.

There is also secondary treatment of the quench waters from the incinerators. The combined treated effluent is discharged through a pipeline to a sea outfall close to Sandy Cove Island, near Kinsale (Figure 11.3 Approximate Location of Outfall). In 2005, an upgrade project for the inorganic wastewater treatment plant (WWTP) was undertaken. This involved the installation of sand filtration technology to reduce suspended solids in the incinerator effluent and the provision of a standby clarifier for the incinerator effluent stream. A further WWTP upgrade was also completed in recent years, involving sulphite oxidation and other upgrades to existing environmental control equipment to enhance operational performance.

The site has one liquid waste incinerator, manufactured by John Zink with the capability to partially recover waste heat generated in the oxidation process.

A regenerative thermal oxidiser is used for the treatment of off-gases from the production processes. Off-gases from the production processes are condensed and pre-treated in scrubber units and the residual diluted air streams are treated in the regenerative thermal oxidiser. A second regenerative thermal oxidiser was commissioned in 2006. This provides the site with a backup fume treatment unit.

3.3.3.5 Utilities Area

Utilities on site include three steam boilers, a purified water plant, a nitrogen plant, air compressors, two emergency generators, two chillers and four cooling towers. There is a site wide fire protection system and a retention pond to retain water used in firefighting, which may need to be treated prior to discharge.

IE30 has its own standalone utilities which support production in IE30 and the IE42 building. The utilities in IE30 consist of three clean steam generators, two purified water plants, a nitrogen storage tank, four air compressors, four chillers (R134a) and six cooling towers. Two standalone chillers (R134a) are located in IE42 exclusively for cooling that building.

A combined heat and power (CHP) plant was installed in the Kinsale facility to facilitate production in IE30, IE42 and IE43. Waste heat from engine exhausts is recovered in the boiler as steam. The steam feeds the site steam header. Waste heat is recovered from the engine jacket as hot water and supplies building hot water systems in IE30, IE42 and IE43.

IE43 has its own standalone utilities including two clean steam generators, a purified water plant, a nitrogen storage tank, four air compressors, three chillers and three cooling towers.

3.3.3.6 Engineering and Maintenance

Engineering and maintenance are significant activities on site.

The site maintenance staff, accommodated in IE9, consists of four groups – mechanical fitters, electricians, instrumentation technicians and co-ordinators. Chemical, mechanical, instrumentation and electrical engineers support the production activities either directly or through capital projects. Chemists and engineers, accommodated in the IE28 building provide technical support for the production areas, as well as maintaining quality control. Additional technical support personnel include the environmental, health and safety departments. The environmental, health and safety departments execute the site wide preventative maintenance programme.

3.3.3.7 Laboratory Support

There are extensive laboratories on site to provide production support including the testing of incoming raw materials, in-process assays and testing of intermediate compounds. Extensive analytical work is undertaken for final products. The IE28 laboratory building has been in operation since 2004. The quality control laboratory, microbiology laboratory and MS&T laboratory are based in this building.

3.3.3.8 General Administration

IE5 is the general administrative offices building. Administrative functions on site include procurement, finance and human resources. The site cafeteria is also located in IE5. Adjoining IE5 is a smaller building, IE10, which accommodates site security, a health centre and a conference facility.

3.3.4 Description of Current Production Activity - Organic Synthesis

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. Organic synthesis is undertaken in the older production buildings on the site, as described in **Appendix A3.1**.

3.3.4.1 Batch Manufacture

Product is manufactured in batches and a number of batches of the same product are manufactured in a campaign. In multi-purpose production buildings, once a campaign is finished, a new campaign, producing batches of a different product, commences. This takes place when the equipment is cleaned to acceptable levels.

3.3.5 Description of Current Production Activity - Biotech

Production buildings IE42 & IE43 use biotechnology processes to manufacture pharmaceutical products.

In the biotech process undertaken in IE42, final products are manufactured through the cultivation of cells by a sequence of steps. Each production step comprises a number of unit operations. Unlike production by organic synthesis there are no chemical reactions or chemical changes. The main unit operations are shown diagrammatically in **Figure 3.7 Typical Biotech Facility – Process Flow Diagram**, and are discussed below.

3.3.5.1 Cell Culture

Frozen cells in small vials are transported from the cell bank to the inoculation laboratory and thawed. The cells are then combined with appropriate media and put under appropriate physical conditions for cell growth. After the laboratory scale the cells are passed through a seed bioreactor train. The final cell culture stage is performed in production bioreactors. The production bioreactor is inoculated with product from the seed bioreactor and maintained at desired back pressure, temperature, agitation, pH, and air flow/dissolved oxygen, generally for a multi-week cell culture cycle. “Raw cell culture broth,” the product of this operation, contains media components, cell mass, host cell protein and other by-products.

The bioreactors are cleaned between lots with dilute solutions of cleaning materials. After cleaning each bioreactor is sterilised with clean steam. The bioreactors are then filled with media and are ready for the next cell culture operation.

All cell based operations are carried out in closed equipment and, before any cell-containing equipment is opened, a thermal inactivation of the cells is carried out to prevent operator contact with the cells.

3.3.5.2 Cell Culture Clarification

The “raw cell culture broth” is clarified by passing through a centrifugation step followed by several stages of depth filtration which removes cell mass and produces a “clarified broth” or “cell-free media” which contains the desired product protein. After the depth filters there is a further filtration step: sub-micron, to ensure all cell mass is removed from the product stream. For each lot, the centrifuge and filter system is thermally inactivated with clean steam prior to change out of the filter cartridges and the system is cleaned between lots with CIP solutions and rinsed with water. After each clarification, the depth filter cartridges are discarded.

3.3.5.3 Detergent Inactivation Operations

In this operation, detergent is added to the “clarified broth” to inactivate lipid-enveloped unwanted components. After an appropriate period of agitation, the media is filtered, producing “detergent inactivated cell-free media.”

This solution is passed on to the capture charge tank, where temperature adjustment is carried out in sections so that partial lots can be processed through the purification area. Prior to each lot, the centrifuge and filter set are cleaned/sanitized with cleaning solutions and rinsed with water.

3.3.5.4 Purification Operations

There are a number of purification operations which take the cell free media, which has been detergent inactivated, and pass it through various chromatography purification steps. In addition, nano-filtration and tangential flow filtration steps will be introduced as required to meet the final product quality expectations.

Chromatography Purification/Concentration Operations

Chromatography Buffer Preparation

The buffer solutions used in chromatography operations are prepared as needed. Between preparations of each batch of buffer, the buffer preparation tanks are cleaned with clean-in-place (CIP) solutions and rinsed with water.

Chromatography

The general operational sequence in chromatography (for each batch) includes the following:

- Ancillary equipment rinsed with water. The column matrix is regenerated/sanitized using appropriate buffers.
- The product stream is charged to the column matrix to “load” product; product and other proteins bind to the matrix, while cell culture media components flow through the column.
- The column is equilibrated using appropriate buffers to remove DNA, non-product protein, endotoxins, and other impurities from the column – while the product remains on the column matrix.
- Product is then eluted using appropriate buffers (or a concentration gradient between two buffers) to produce purified, concentrated product.
- After elution, the chromatography column is regenerated/sanitized and washed with appropriate buffers and the column is filled with storage buffer. Storage buffer is left in the column until the next use.

Low pH or High Temperature Inactivation

Product streams may be treated at low pH circa 3.4, with a dilute organic acid and/or high temperature to inactivate pH- and temperature-sensitive unwanted components. After an appropriate agitation period, the pH is re-adjusted to neutrality. The solution is cooled (if needed) and filtered. The resulting product stream is called “neutralized low pH inactivated product mainstream.”

Filtration via Nano-Filtration

Product streams may be filtered using nano-filtration to remove unwanted cell components. Prior to each batch, nano-filtration cartridges are flushed with water.

After each batch, nano-filtration cartridges are discarded. The product of the operation is called “nanofiltration filtrate”.

Product Concentration/Diafiltration via Tangential Flow Filtration

In this step the buffer matrix that leaves the chromatography steps is exchanged to a buffer which is required by the next stage of processing. In addition the concentration of the product can be adjusted.

Prior to each lot, the retentate and permeate sides of the membrane system are flushed with water, caustic, and diafiltration buffer. In this operation, product is concentrated and diafiltered (i.e. the buffer is exchanged) via nano-filtration and a stabilizer will be added. The nano-filtration system is filled with dilute caustic until the next batch.

3.3.5.5 Final Product Packaging

The concentrated/diafiltered product solution from the tangential flow filtration step is dispensed into suitably sized containers and transferred to a storage freezer until the product can be shipped offsite to another facility for final formulation and filling.

3.4 IE43 Extension Project Design Philosophy and Constraints

3.4.1 Principal Design Objectives

The key user requirements considered were:

- The process design in IE43 extension will for the most part replicate that in IE43 building to ensure optimum efficiency in production is gained while minimising duplication of utilities and services.
- Provision of cleanroom environment for critical process operations.
- Provision of bulk mammalian cell culture production capabilities for a range of products.
- The facility should be flexible and adaptable for manufacture of future products with minimum modifications.
- Systems designed for closed processing where handling cells to protect the products.
- Shared mechanical utilities from existing IE43 building and main site.
- Inactivation of cell-containing equipment prior to opening.
- Cross-contamination prevention of process or product.
- Safe and robust operability and maintainability, meeting Lilly’s corporate and regulatory requirements.
- Safety and industrial hygiene, current Good Manufacturing Practice compliance and environmental controls to meet local and corporate standards.

- All emissions of vapours, liquids and solids to be within the treatment capacity of the site's existing abatement systems.
- In addition the facility's general appearance is influenced by the adjacent IE42 facility as there was a desire to have the two buildings complement each other.

3.4.2 Main Design Features

The main design features are:

- Buffer and media make up areas (for small and large volume make up);
- Bioreactor train;
- Purification area with sufficient bays to allow a number of chromatography steps, tangential flow filtration steps and a nano-filtration step;
- Separate area for final purification;
- Separate area for bag bottle filling of final product;
- Suitable refrigerated storage of raw materials;
- Safety and industrial hygiene, current Good Manufacturing Practice compliance and environmental controls to meet local and corporate standards;
- The extension to the existing IE43 facility has an orientation parallel to the existing IE42 biotech manufacturing facility; and
- Extension of the administration block with additional locker rooms, offices, new kitchens, stores and extended break room canteen.

3.4.3 Design Constraints

There were a number of constraints on the design of the new extension facility, including the following:

- Location at the eastern end of the site consistent with existing site master plan;
- Extension of the process elements to the south of existing IE43;
- Expansion of administration elements to the north east of existing IE43;
- Building internal arrangements and stack-up to meet processing requirements;
- The architectural treatment of the proposed development has to be compatible with the colours and materials of the adjacent building and existing IE43; and
- Achieve optimal use of available capacity in all site systems and processes with a view to minimising the requirements for additional valuable resources.

3.5 Main features of the IE43 Biotech Manufacturing Facility Extension

3.5.1 Introduction

IE43, located within the Lilly site is a dedicated biotechnology manufacturing facility which produces biotechnology products in bulk form for the treatment of cancers and other ailments. IE43 is located at the eastern end of the Lilly site.

The IE43 building houses a biologics production train (T1) with a number of areas typical to a biotechnology facility such as dispensing, inoculation laboratory, cell culture suites, primary recovery/clarification, purification areas, final product packing, cold rooms, shipping/receiving area, warehouse space, general administration and utility support area.

Lilly proposes to construct an extension to IE43 which will allow for a second biologics train (T2) to increase capacity for existing Lilly molecules and future products. The process design for T2 will largely leverage the existing IE43 design for T1 in order to compress the process design time and procurement time for equipment. In general, the upstream design of the T2 process will be very similar to T1, with the exception of two additional bioreactors in T2. Downstream equipment will generally have twice the capacity of T1 and will include a few additional steps. In some cases, utilities will be shared between T1 and T2, and in some cases, new utilities will be provided. This is the case also for some support functions.

3.5.2 Main features of proposed development

3.5.2.1 Overview

The extension to the existing IE43 biotech manufacturing facility will include administration and manufacturing accommodation over three floors with intermediate service platforms. The development will consist of the following:

1. The construction of an extension to the existing IE43 Biotech Manufacturing facility (referred to as process block extension in this EIS), including production and plant accommodation with a total floor area of 25,196m² gross floor area, over three floors with intermediate platforms and a ground to eaves height of 32 meters. The process block extension will extend outwards from the southern façade of the existing IE43 facility.
2. The construction of an extension to the existing administration area of the IE43 facility (referred to as headblock extension in this EIS), consisting of a two story extension with a floor area of 1,676m² and a ground to eaves height of 14.25 meters, located to the north east of the existing facility. The headblock extension will extend outwards from the north eastern façade of the existing IE43 administration block.
3. Extension to the existing staff car park to provide an additional 136 permanent car parking spaces.

4. All associated site development works including modification to internal site roads and site services, construction of external hard standing areas and external items of plant and equipment, site lighting and fencing and the formation of landscaped areas, including berms and visual screening with tree planting and contractor's temporary car parks totalling 450 temporary car spaces for contractors and temporary staff entrance.

Refer to **Figure 3.1 Site Location Plan** and **Figures 3.3 to 3.5** which show the extent of the proposed development.

The proposed IE43 biotech manufacturing facility extension will have a total floor area of approximately 26,872.6m² (comprising 25,196 m² for the process block extension plus 1676m² of for the headblock extension).

The project will take approximately 30-36 months to construct.

It is expected that 150 additional personnel will be required once the proposed IE43 facility is operational. They will be recruited over a two to five year period. These personnel will be responsible for the day-to-day operation of the plant and ancillary facilities. The plant will run twenty-four hours a day, seven days a week in line with the existing Kinsale facility. The first biopharmaceutical products are expected to be shipped from the facility in 2020.

3.5.2.2 Process Block Extension Layout

The process block extension will include production and plant accommodation with a total floor area of 25,196m² gross floor area, over three floors with intermediate platforms and a ground to eaves height of 32 meters. The facility will comprise three main floor levels in a split level configuration: a lower ground utility floor, a ground floor level with a production floor topped on the upper level by a building services area above the production floor. The facility will be approximately 89.57m in length by 70.95m in width. The building footprint is presented in **Figure 3.3** whilst the building site sections are presented in **Figure 3.5**. Refer also to the planning drawings which accompany the planning application for further details on layout.

The top floor will house the air handling systems required to service the cleanroom areas associated with the production floor level. The lower ground floor will house the aqueous waste handling system, the biowaste system, the CIP skids, the glycol system, the process vessel heating and cooling modules, the water for injection and clean steam generation equipment, motor control centre, control system hardware, and various ancillary utilities.

The ground floor will comprise various operating rooms in the process area, to carry out the functions described in previous sections above. The process rooms will be designed and classified as cleanrooms to ISO grade 7 and ISO grade 8. All process vessels, that contain a vent, will be vented to the roof via a submicron filter.

As an essential element of cross contamination prevention, airlocks will be provided to maintain product segregation within process areas. Separate personnel and materials air locks will be provided for all critical areas.

A goods lift will be provided which will facilitate the transfer of raw materials and consumables from the warehouse area to the process level.

A hardstanding area including bunded tanker unloading area will be provided to the south of the process block. A site road will provide access around the eastern and southern perimeter of the building.

Within the biotech manufacturing facility building extension the main features will include:

- Process support including utility generation, distribution and handling situated on the lower ground floor;
- Process operations located on the ground floor;
- Facility support including lockers, office space, break room on the ground floor;
- A HVAC plant room on the first floor;
- Some utility plant will be located externally including cooling towers, steam reduction station and nitrogen, oxygen and carbon dioxide storage tanks;
- The facility will be provided with water and steam from the existing plant. Effluent treatment will be undertaken in the site effluent treatment plant; and
- Laboratory functionality to support biotech manufacturing will be accommodated in the existing IE28 laboratory building.

The production processes to be carried out in the IE43 extension will be the same as those which will be undertaken in IE43 and which are described in previous sections. The IE43 extension has been designed to be multipurpose and it will have the capability to process a range of mammalian cell culture based products.

3.5.2.3 Headblock Extension Layout

The proposed headblock extension will consist of an extension to the existing administration area with a floor area of 1676m² and a ground to eaves height of 14.25 meters, located to the east of the existing facility.

The extension will be a one part single storey, part two storey, part three storey extension located at the north and east sides of the existing headblock. This part will provide new ground floor locker rooms, a supervisor's office, an extension of the existing break room canteen including kitchens, stores and staff facilities, new first floor offices and a new second floor plant room.

- Ground Floor – Approximately 38.35m in length by 42.62m in width;
- First floor – Approximately 38.35m in length by 19.96m in width; and
- Second floor plant room - Approximately. 12.5m in length by 6.35m in width.

Associated with this administration block extension will be reconfiguration works including relocation of an existing nitrogen storage tank, three new parking spaces for disabled persons, two new parking spaces for kitchen deliveries, two new parking spaces for despatch vehicles and one new parking space for nitrogen delivery, new screen walls and new bin store, together with realignment of an existing access road for emergency vehicles.

3.5.2.4 Staff Car Parking

Additional staff car parking will be provided via new car parks. The existing staff car park located just west of the existing Ballyvrin road entrance will be extended. A second staff car park will be located east of the existing Ballyvrin road entrance, north of IE43. The additional parking facilities (136 spaces) will facilitate the additional employees (approximately 150 people) that Lilly expects to employ as a result of increased production. Refer to **Figure 3.1 Site Location Plan** and **Figures 3.3 to 3.5** which show the extent of the proposed development.

Lilly staff car parking and access/egress to the eastern end of the site will be kept separate from construction traffic during the construction phase. A temporary staff car park will be located west of the existing staff car park off Ballyvrin Road. A temporary staff entrance plus the temporary car park and the western section of the existing car park will be used by Lilly staff during the construction period. Contractor's temporary car parks will total 450 temporary car spaces for contractors. Post construction the temporary entrance will be closed off.

Refer to **Figure 3.3 Proposed Overall Site Plan** and **Figure 4.1 Construction Site Logistics Plan** which shows the location of the temporary entrance and temporary car park. Refer also to **Chapter 4 Construction Activities** for further details on construction.

3.5.2.5 Other features of the proposed development

All site development works associated with the proposed development will be carried out including modification to an internal site service road and site services, as well as the construction of external hard standing areas and external items of plant and equipment, site lighting, fencing and the formation of landscaped areas, including berms and visual screening with tree planting.

In particular, landscaping is proposed in the following areas:

- Landscaping along the eastern boundary along a new berm above and along the existing berm to the south east; and
- Post construction the temporary entrance will be closed and the area will be planted to provide site screening.

Refer to **Figure 3.3 Proposed Overall Site Plan** and **Figure 3.4 Proposed Landscaping Plan**. Refer also to **Chapter 4 Construction Activities** and **Chapter 7 Landscape and Visual** for further details.

Finally, the proposed development includes a concrete wall adjacent to the stream bank.

The flood risk assessment (FRA) (**Appendix 14.1**) carried out by RPS on behalf of Lilly found that there may be a fluvial risk from the existing stream to the proposed development. The proposed development is located within Flood Zone C and while the meteorological conditions required to generate a flood risk to the proposed development will not occur frequently, there still is a risk which needs to be considered. Therefore proposed top of the concrete wall level is 31.5 m (site datum). This will provide protection to the site should an event of greater magnitude occur.

Refer to **Chapter 14 Soils, Geology, Hydrology and Hydrogeology** for further details on flood risk, attenuation and the drainage system proposed for the IE43 extension.

3.5.2.6 Equipment Cleaning

The process vessels and equipment will be designed for 'clean-in place' (CIP). There are two CIP solutions used, CIP 100 (2% sodium hydroxide solution) and CIP 200 (3-4% phosphoric acid solution). Fixed spray devices will be provided in each piece of equipment. Aqueous cleaning agents will be used, which will be diluted with water for injection and heated and recirculated through the process equipment via a CIP skid. The waste from the CIP process will be directed to the building aqueous waste system.

Small items of equipment will be cleaned in the equipment wash room, which will contain a cabinet washer. An autoclave will also be provided for sterilisation of parts. The quantities of water and chemicals used per lot are listed in Table 3.1 below. The cleaning of the various pieces of equipment will be sequenced over 14-16 days.

Table 3.1: IE43 Raw Materials Used for Cleaning Per Lot

Cleaning Components	Quantity Kgs
Water (for cleaning)	335,000
CIP 100	600
CIP 200	290

3.5.2.7 Process Control System

The plant will be capable of operating continuously in a safe, reliable and consistent manner. Production operations in the IE43 building extension will be controlled and monitored by a process control system in the existing IE43 building. The process control system assists plant operations, by providing monitoring and control functions for process equipment.

Control of the automated production process will be under a batch sequence regime. The system is capable of implementing process safety controls and interlocks to ensure the plant adheres to current Irish safety and environmental legislation and IE licence requirements.

To maximize computer control, the proposed IE43 building extension will be designed to have a high level of process instrumentation for measuring process parameters including pressures, flows, temperatures and levels. Instrumentation will be drawn from the latest proven technologies available to communicate to the process control system. The system to be used will have a proven track record in the production of bulk pharmaceuticals in a validated batch environment, and will be compatible with the systems in use in the other facilities in the Kinsale plant.

The process control system will provide the following key functions:

- provide secure and reliable interface with IE43 controls (for both T1 and T2);
- provide interfaces for operations and maintenance personnel;
- accurately record and log parameters and events;
- link with the site monitoring and alarm systems;
- ensure reliable and secure automatic and remote manual control;
- enable the systematic and comprehensive display of plant conditions and major operating parameters to plant operators, and
- ensure the safety of plant, the environment and personnel at all times.

The design and installation of control and instrumentation equipment will be in conformance with all applicable regulations.

3.5.2.8 Utility Requirements

To support the proposed IE43 biotech manufacturing facility extension, the following utilities will be required:

- Ethylene glycol (4°C) heat transfer medium;
- Ethylene glycol (50°C) heat transfer medium;
- Liquid nitrogen for cell bank
- Plant steam;
- Carbon dioxide gas;
- Oxygen gas;
- Water for injection;
- Clean steam;
- Potable water;
- Compressed air;
- Cooling water; and
- Water for operations.

Of these utilities, the following will be supplied from the existing site:

- Plant steam;
- Water for operations; and
- Potable water.

3.5.2.9 Modification to various existing services and utilities

No significant modifications are envisaged to the existing site services and utilities.

3.5.2.10 Environmental Controls and Waste Systems

Waste generated from the proposed IE43 extension facility will be treated in the exact same manner as waste generated in existing IE43.

The existing waste treatment facilities as described in Section 3.3.3.4 above have sufficient capacity to treat the solid and liquid wastes from the proposed IE43 extension.

Refer to **Chapter 11 Effluent Generation and Treatment** and **Chapter 12 Waste** for further information on the liquid waste streams and solid waste streams respectively.

3.6 Construction Activities

Construction activities are addressed in **Chapter 4 Construction Activities**.

3.7 Health, Safety and Environmental Aspects

3.7.1 Operational Safety and Environmental Management

Figure 3.6 indicates the management structures relating to health, safety and environmental issues on site.

The site environmental management system has been certified to be in compliance with the requirements for ISO 14001 Environmental Management Systems for many years (since November 2001). The main objectives of the site environmental management system are:

- To develop Lilly's Environmental Policy Statement;
- To implement an effective programme of environmental protection and conservation measures to meet the objectives of the Environmental Policy; and
- To set targets to improve its environmental performance. This is done through the implementation of the annual Environmental Management Programme.

In order to maintain this certification status, Lilly strives to make continual improvements in waste minimisation and recycling efforts, undertakes ongoing development of the environmental management system, carries out regular internal audits and frequently reviews operating procedures.

The environmental management system will be extended to include the IE43 extension.

3.7.2 Fire Prevention and Emergency Response

There is a site-wide fire protection system, comprising:

- Bulk storage of water for fire-fighting;
- Fire main supplying water to hydrants sprinkler and deluge systems;
- Foam systems to main solvent and waste solvent storage tank farms;
- Portable fire extinguishers as appropriate; and
- Fire alarm system and detection systems.

These systems will be extended to the IE43 facility extension.

The site implements a major accident prevention policy and an emergency response plan. The emergency response plan sets out the response measures that are to be taken in the event of an emergency, the resources of people and equipment to be maintained to ensure an adequate response can be provided, and the organisation of the emergency response team. The emergency response plan is designed to ensure maximum protection for site personnel, the local community, the environment and property in the event of an incident on site. The emergency response plan utilises a dual control concept whereby separate emergency teams exercise control as follows:

- The Incident Response Team exercises control at the incident location, and
- The Management Control Group exercises control over the peripheral duties that are not directly related to on scene incident response.

3.7.3 Prevention of Accidental Emission or Spillage

Accidental emissions and spillages are prevented by paying particular attention to operational procedures, site safety and environmental procedures and by ensuring the highest standards of equipment and facilities are maintained. The site Safety Department staff implement and maintain various accident prevention programmes on site. These include Near Miss and Accident reporting, the investigation of the root causes of incidents and the implementation of countermeasures to avoid re-occurrence. Process safety activities are tracked by the Site Process Safety Management Committee, which meets frequently to set priorities and monitor performance.

3.7.4 Lilly Environmental Policy

Lilly operates in accordance with its Environmental Policy. The Policy is reviewed annually and was last updated in 2015. A copy of the policy is included in the Annual Environmental Report (AER) which is available on the EPA website - www.epa.ie.

3.7.5 Environmental Management Programme

As required by its Industrial Emissions (IE) licence, Lilly prepares an Annual Environmental Report (AER) for submission to the EPA. The AER brings together, in one document, all the individual reports required under the IE licence.

Lilly prepares an annual Environmental Management Programme (EMP), which is fully integrated into the site management system. This programme is included in the AER. The programme addresses the requirements of Lilly's IE licence. Targets are set, for between one and five years, for the programme objectives. At the end of each year the progress against the targets is formally reviewed at senior management level. The programmes are adjusted as required in the light of ongoing experience and advances in knowledge and technology.

Targets and goals in the programmes are set to ensure that resources and systems are put in place to achieve the targets. The success of the programme is measured by the effectiveness of the systems installed, as well as results in meeting targets.

A copy of the AER (which includes the EMP) for 2015 is available on the EPA website - www.epa.ie.

3.8 Regulatory Control of the Facility

3.8.1 Industrial Emissions Licence

Since 1995 Eli Lilly S.A. - Irish Branch has operated under an Integrated Pollution Prevention and Control Licence (IPPC), under Section 83(1) of the Environmental Protection Agency (EPA) Act 1992, as amended, by the Protection of the Environment Act 2003.

The licence has been revised over the years. The site currently operates under an Industrial Emissions (IE) licence (P0009-03). A revised IE licence (P0009-04) is currently in the proposed determination stage and is expected to be in place by year end. The proposed IE43 extension will be included in this revised licence. Lilly has assessed the proposed development against the conditions of P0009-04 which are in line with current regulatory requirements.

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.

Activities requiring an IE licence are listed in the First Schedule of the Environmental Protection Agency Acts 1992 and 2003. The First Schedule incorporates the activities listed in Annex I of the European Union Industrial Emissions Directive (2010/75/EU). This Directive was transposed into Irish law by the European Union (Industrial Emissions) Regulations 2013. The facility is licensed to carry out the following activities:

Class	Description
5.16	The production of pharmaceutical products including intermediates.

- 11.2 (b) Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving one or more of the following activities: - Physico-chemical treatment.
- 11.2 (c) Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving one or more of the following activities: - blending or mixing prior to submission to any of the other activities listed in paragraph 11.2 or 11.3.
- 11.2 (e) Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving one or more of the following activities: - solvent reclamation or regeneration.
- 11.3 (b) Disposal or recovery of waste in waste incineration plants or in waste co-incineration plants -: for hazardous waste with a capacity exceeding 10 tonnes per day.
- 11.6 Temporary storage of hazardous waste (other than waste referred to in paragraph 11.5) pending any of the activities referred to in paragraph 11.2, 11.3, 11.5 or 11.7.

The table of contents of the IE licence is as follows:

Glossary of Terms;

Decision & Reasons for the Decisions;

Part I Schedule of Activities Licensed;

Part II Schedule of Activities Refused;

Part III Conditions;

Condition 1. Scope;

Condition 2. Management of the Installation;

Condition 3. Infrastructure and Operation;

Condition 4. Interpretation;

Condition 5. Emissions;

Condition 6. Control and Monitoring;

Condition 7. Resource Use and Energy Efficiency;

Condition 8. Materials Handling;

Condition 9. Accident Prevention and Emergency Response;

Condition 10. Decommissioning & Residuals Management;

Condition 11. Notifications, Records and Reports;

Condition 12. Financial Charges and Provisions;

SCHEDULE A: Limitations;

SCHEDULE B: Emission Limits;

SCHEDULE C: Control & Monitoring; and

SCHEDULE D: Annual Environmental Report.

The licence can be viewed on the EPA's website www.epa.ie.

3.8.2 Site Status in Relation to the Seveso III Directive 2012/18/EC

3.8.2.1 Background to the 'Seveso' Directive

In Ireland, the requirements of Council Directive 2012/18/EU on the control of major accident hazards (COMAH) involving dangerous substances are implemented through SI 209 of 2015 European Communities (Control of Major Accident Hazards involving Dangerous Substances) Regulations 2015.

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.

3.8.2.2 Status of the Lilly Facility in Relation to the Seveso III Directive

Lilly currently is an establishment to which SI 209 of 2015 applies because the quantity of dangerous substances present at the site is above the upper qualifying thresholds specified in Column 3 of Part 1 or in Column 3 of Part 2 of Schedule 1 of S.I. 209 of 2015. Under the Seveso III Directive the Eli Lilly plant at Dunderrow is an 'Upper-Tier Seveso Site' under the above-mentioned regulations. It is envisaged that the status of the plant will remain unchanged following the development of the proposed IE43 extension.

Lilly has satisfied all of the requirements of S.I. 209 of 2015. Seveso sites are required to provide suitable information to the Central Competent Authority, the Health and Safety Authority (HSA). Both upper- and lower-tier Seveso sites must submit to the HSA, a major accident prevention policy (MAPP), a safety management systems report to implement the MAPP, a hazard identification risk assessment (HAZID) and internal and external emergency plans in certain cases. All Seveso sites must also provide information to the planning authorities and consider the inter-site domino effects of potential accidents.

The MAPP aims to:

- guarantee a high level of protection of human health and the environment;
- include the operator's overall aims and principles of action, including a commitment to ensure a level of protection of human health and the environment;
- include the role and responsibility of management in ensuring its proper implementation;
- include a commitment towards continuously improving the control major accident hazards; and

- take account of the principles specified in Schedule 2.

As an Upper-Tier Seveso site, the Eli Lilly site at Kinsale must submit a safety report and an internal and external emergency plan to the authorities. The Safety Report fulfils the requirements of Article 11 of the Seveso III Regulations. The purpose of the Safety Report is to effectively demonstrate that:

- a [MAPP] and a safety management system for implementing it have been put into effect in accordance with the [MAPP] requirements;
- major accident hazards and possible major accidents scenarios have been identified and that the necessary measures have been taken to prevent such accidents and to limit their consequences for human health and the environment;
- adequate safety and reliability have been taken into account in the design, construction, operation and maintenance of any installation, storage facility, equipment and infrastructure connected with its operation which are linked to major accident hazards inside the establishment;
- internal emergency plans have been drawn up and supplying information to enable the external emergency plan to be drawn up; and
- providing sufficient information to the competent authority to enable decisions to be made regarding the siting of new activities or developments in or around existing establishments.

Lilly has developed and provided a site-specific Safety Report (which includes a MAPP, a Safety Management System and a HAZID) to the HSA to fulfil the requirements of the Seveso Regulations.

The safety management system for major accident prevention is referred to on site as the globally integrated process safety management which incorporates the requirements of Schedule 2 of the Seveso III Regulations (S.I. 209 of 2015). All elements of the globally integrated process safety management, including the major accident HAZID assessment processes will be applied to the design, construction & operation of the proposed IE43 extension.

The proposed IE43 extension development will not impact on the status of the Lilly facility in relation to the Seveso III Directive.

3.8.3 Greenhouse Gas Emissions Permit

The member states of the EU, including Ireland, are signatories to the Kyoto Protocol, which requires reductions in emissions of greenhouse gases by specific amounts over a period from 2008 to 2012 and beyond. The EU has undertaken to reduce greenhouse gas emissions by 8% on average below 1990 levels. The EU Emissions Trading Directive (Directive 2003/87/EC) is being implemented to achieve this target.

The EPA is responsible for implementing the Emissions Trading Directive in Ireland. The Directive establishes an allowance-trading scheme for emissions to promote reductions of greenhouse gases, in particular carbon dioxide.

To implement the Directive, the EPA has developed a Greenhouse Gas Emissions Permit system. Installations covered by Annex 1 of the Directive require a Greenhouse Gas Emissions Permit. Each installation will receive an allocation of greenhouse gas emissions at the beginning of each year. If there is a gap between this allocation and the actual emissions, the installations can buy or sell allowances anywhere in the EU.

Annex 1 of the Directive includes combustion installations with a rated thermal input exceeding 20 MW (except hazardous or municipal waste installations).

The current installed capacity of the Lilly plant in Kinsale is circa 26MW. Thus, the Directive applies to the Lilly site.

Lilly applied for and was granted a Greenhouse Gas Emissions Permit, number GHG023-10352-5 in August 2016. The proposed IE43 extension development will not impact on the status of the current permit.

The table of contents of the permit is as follows:

Glossary of Terms;

Reason for the decision;

Activities Permitted;

Condition 1: The Permitted Installation;

Condition 2: Notification;

Condition 3: Monitoring and Reporting;

Condition 4: Allowances; and

Condition 5: Penalties.

The permit can be viewed on the EPA's website, www.epa.ie.

Lilly was given an allocation for emissions of carbon dioxide. Refer to **Chapter 10 Air Quality and Climate** for further information.

3.8.4 Genetically Modified Microorganism Licensing

Lilly currently hold a Genetically Modified Micro-organisms (GMMs) licence (GMM Register No 267) as genetically modified organisms contained use activities are carried out on the site. The GMM licence was issued by the EPA on 24th April 2008.

The EPA is the Competent Authority in Ireland for the implementation of the genetically modified organisms (GMO) Regulations on the contained use of genetically modified organisms.

EU Directives 90/219/EEC (contained use) was transposed into Irish law in December 1994 by the Genetically Modified Organisms Regulations, 1994 (S. I. No. 345 of 1994).

Directive 98/81/EEC amending Directive 90/219/EEC was transposed into Irish law on 15th March 2001 as genetically modified organisms (Contained Use) Regulations, 2001, S.I. No. 73 of 2001.

The 2001 Contained Use Regulations stipulate that genetically modified organisms contained use activities must be classified into one of four classes - Class 1, Class 2, Class 3, or Class 4 – as appropriate. This classification is directly related to the containment level required to control the risk as identified on completion of the Risk Assessment.

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. Users of Class 1 Genetically Modified Micro-organisms (GMMs) are not required to submit an annual report to the EPA.

The proposed IE43 extension development will not impact on the status of the current GMM licence.

3.9 Provisions for Site Decommissioning

The proposed IE43 extension will have a projected life span of 30 years, though this may be extended through upgrading or the replacement of equipment. Lilly has prepared a Residuals Management Plan, as required by a condition of its IE Licence. Should circumstances arise whereby it becomes necessary to shut down the facility, then Lilly will, at a minimum, implement the residuals management plan to ensure that any negative environmental impact is minimised.

The overall strategy of the decommissioning plan is to bring the facility to a state where minimal ongoing oversight would be needed to maintain the facility in a status where it would be suitable for future industrial use and its condition would not pose a risk to public health and safety. Lilly does not intend to remove all equipment, structures or systems from the site other than specialist items needed at other sites or items that are obsolete or non-serviceable.

The plan envisages the following activities:

- Setting up of a management structure to oversee implementation of the Residuals Management Plan;
- Development of a comprehensive Safety and Containment plan covering the duration of the activity;
- Cessation of all production activities, removal of all raw materials, intermediates, and final product from the site;
- Cleaning and decontamination of all equipment and buildings, secure archiving of all documentation required by licence;
- Shutting down of all environmental and utility systems;
- Production of a comprehensive status report on all aspects of the site within 60 days of completion of the plan activities; and
- Maintaining ongoing security and monitoring services.

The plan provided an estimate of the resource required and the cost of implementing the plan.

3.10 References

European Union (2003), Council Directive 2003/87/EC establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC.

European Union (1996), Council Directive 96/61/EC concerning integrated pollution prevention and control.

European Union (1996), Council Directive 96/82/EC on the control of major accident hazards involving dangerous substances as amended by Council Directive 2003/105/EC.

European Union (1990), Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

European Union (1998), Council Directive 98/81/EC amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

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4 Construction Activities

4.1 Introduction

This chapter describes the construction activities and sequencing for the proposed IE43 extension and outlines the mitigation measures which will be implemented to ensure the potential impacts of the construction activities on the environment are avoided, prevented or reduced.

It is anticipated that, with the proper implementation and management of construction activities described in this chapter the construction phase of the development will have no significant or long-term impact.

4.2 Overview

The extension to the existing IE43 biotech manufacturing facility will include administration and manufacturing accommodation over three floors with intermediate service platforms. The manufacturing element of the IE43 extension (referred to as process block extension) will extend outwards from the southern façade of the existing IE43 facility. The administration element of the IE43 extension (referred to as headblock extension) will extend outwards from the north eastern façade of the existing IE43 administration block. Additional staff car parking will be provided via new car parks. The existing staff car park located just west of the existing Ballyvrin road entrance will be extended. A second staff car park will be located east of the existing Ballyvrin road entrance, north of IE43. Internal site roads, services, hard standing and landscaping are also proposed as part of the development. Refer to **Figure 3.1 Site Location Plan** and **Figures 3.3 to 3.5** which show the extent of the proposed development. Refer also to the drawings which accompany the planning application for further details on the proposed development.

In addition to the areas required beneath the footprint of the proposed development during the construction phase, there will be a number of other areas required within the Lilly site to facilitate the construction phase of the IE43 extension development. These are described below.

Lilly staff car parking and access/egress to the eastern end of site will be kept separate from construction traffic during the construction phase. A temporary car park will be located west of the existing staff car park off Ballyvrin Road. A temporary entrance plus the temporary car park and the western section of the existing car park will be used by Lilly staff during the construction period. Refer to **Figure 3.3 Proposed Overall Site Plan** and **Figure 4.1 Construction Site Logistics Plan** which show the location of the temporary entrance and temporary car park. The extent of the proposed development incorporating all construction works is also shown in **Figure 3.3 Proposed Overall Site Plan**. Refer to **Figure 4.1 Construction Site Logistics Plan** which shows the construction site logistics for the duration of the construction phase.

Note the temporary staff car park and temporary staff entrance will not form part of the construction site – these will be constructed at the beginning of the construction phase and once constructed will not form part of the construction works zone.

Therefore they are not included within the “construction boundary” as shown in **Figure 4.1 Construction Site Logistics Plan**.

The eastern end of the existing staff car park in addition to a number of construction parking areas east of the existing Ballyvrin site entrance and north of IE30 and IE43 will be used for construction staff parking. These areas are all currently hardstanding. The existing Ballyvrin site entrance will be used for construction traffic only. A contractor’s laydown area will be located south of the IE43 process block extension, north of the recently diverted stream. Contractor facilities will be located south of IE42 and IE30, north of the existing stream. A contractor’s compound will be located south of the contractor facilities, south of the existing stream. Vehicular and pedestrian access across the stream to the contractor’s compound will be via the existing bridge across the stream. **Figure 4.1 Construction Site Logistics Plan**.

4.3 Duration and Phasing

The schedule for the construction of the proposed development is expected to be 30 - 36 months.

Construction activities for the proposed project will include the following:

- Establish the contractor’s laydown area, contractor’s compound, contractor facilities area and construction staff car parks;
- Establish construction phase power supply, fencing and securing of the site;
- Construction of the temporary staff entrance and additional staff car parking. Reconfiguration of existing car park to separate Lilly staff from construction staff;
- Construction of manholes;
- Installation of drainage and underground services;
- Excavation for and construction of concrete foundations, construction of berm and concrete wall along eastern boundary;
- Reuse of excavated material on eastern berm and south eastern berm for landscaping;
- Erection of steelwork for the structural frame of the building and internal piperacks, platforms, walkways and construction of concrete floor slabs;
- Installation of cladding and roofing;
- Mechanical installation of tanks, process skids, piping, pumps and valves;
- Electrical installation of cabling, instruments, control systems and electrical panels;
- Installation of internal and external building finishes;
- Installation of fire safety systems;
- Landscaping;
- Connections and modifications to existing site services, and miscellaneous works including of site lighting, site roads and road markings;

- Testing and commissioning of process, mechanical and electrical installations; and
- Closure of temporary staff entrance and landscaping of same, reconfiguration of temporary car park into existing car park. Reconfiguration of construction car park east of Ballyvryn Road into a new Lilly staff car park.

4.4 Construction Site Layout

Ground preparation works will be undertaken beneath the footprint of the proposed development. This is described below. Construction car parking, compounds and site entrance details are also provided below.

4.4.1 Construction Site Access and Car Parking

As discussed above in Section 4.2, the existing Ballyvryn Road entrance will be used for all construction related traffic. Construction related traffic will not be permitted to travel on the Ballyvryn Road going north east of the site. Therefore construction related traffic will be instructed to access the entrance on Ballyvryn Road, from the R605 only. This was identified in the Lilly Road Safety and Car Pooling Strategy developed and executed for the previous IE43 construction stage. Signage is currently in-situ at this entrance informing staff of this restriction.

In addition to the restrictions to traffic associated with the proposed development, HGV traffic associated with the proposed development will be contractually instructed to approach the site via the R605. HGV traffic will be instructed not to use the Ballydonaghy Road (L3025). This restriction was also included in the Road Safety and Car Pooling Strategy.

As discussed above in Section 4.2, a number of areas within the Lilly site will be designated for construction car parking, laydown and deliveries, access and construction staff facilities. Refer to **Figure 4.1 Construction Site Logistics Plan** which shows the proposed construction site layout plan.

The construction car parks will be located in the northeastern area of the site. The proposed construction car park located east of the existing Ballyvryn Road entrance was previously used as a construction laydown area during the construction phase of IE43. Refer to **Figure 4.1 Construction Site Logistics Plan**.

As discussed above in Section 4.2, the temporary entrance plus the temporary car park and the western section of the existing car park will be used by Lilly staff during the construction period. Refer to **Figure 4.1 Construction Site Logistics Plan**.

4.4.2 Construction Compounds

As discussed above in Section 4.2, a contractor's laydown area will be located south of the IE43 process block extension, north of the recently diverted stream.

This area was cleared during the construction of IE43 to facilitate the diversion of the stream. The original stream bed has been filled in. This area is currently under hardstanding.

Contractor facilities will be located south of IE42 and IE30, north of the existing stream. The contractor facilities will contain toilets, canteen, construction containers and site office. The contractor facilities area is currently under hardstanding with the exception of an existing drain which will be filled in as part of the proposed development. Refer to **Figure 3.3 Proposed Overall Site Plan** and **Figure 3.4 Proposed Landscaping Plan**.

A contractor's compound will be located south of the contractor facilities area, south of the existing stream. This area was used as a contractor's compound during the construction of IE43 and is currently under hardstanding. Vehicular access across the stream to the proposed contractor's compound will be via the existing bridge across the stream. **Figure 3.3 Proposed Overall Site Plan**

4.4.3 Temporary Staff Entrance and Temporary Staff car park

The temporary staff site entrance and temporary staff car park will be installed west of the existing Ballyvrin Road entrance. The site of the entrance consists of an earth berm with some laurel hedging along the road boundary whilst the temporary car park is currently under hardstanding. The earth berm and laurel will be removed to facilitate the entrance construction. Once construction is complete the entrance will be closed off and screen planting installed. Staff will then enter the site from the existing Ballyvrin road entrance as is the existing site arrangement. A small area of the temporary car park will be incorporated into the existing car park during operation.

4.5 Site Preparation

4.5.1 Introduction

This section outlines the site preparation activities required for the proposed development. The main site preparation activities required for the process block extension, headblock extension, staff car parks, internal roads, fencing and landscaping as well as any other elements are described below.

In general, no soil contamination is expected during the site preparation works. In the unlikely event that any evidence of soil contamination is found during work on site, the appropriate remediation measures will be employed. Any work of this nature will be carried out in consultation, and with the approval of the EPA and the Environmental Department of Cork County Council.

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 excavations will be retained on site for use as engineering fill or for landscaping.

Only very small volumes of material (approximately 900m³ tarmac / asphalt) which are unsuitable for reuse on site will require offsite disposal. This material will be removed off-site for recycling and reuse or disposal at a licenced site.

Uncontaminated soil and stone materials which are not suitable for re-use will be disposed of to an appropriate site which is permitted under the Waste Management (Facility Permit and Registration) Regulations 2007 and (Amendment) Regulations 2008, 2014, 2015 to accept soil and stone. The environmental impacts associated with the permitted site have already been assessed by the planning authority under the approval process specified in the Waste Management (Collection Permit) Regulations 2007 and 2008.

Materials required for the construction works will be sourced locally where possible. Materials required from quarries will only be sourced from quarries which are listed on the register maintained by the local authority. The environmental impacts associated with registered quarries have already been assessed by the local authority under Section 261 of the Planning and Development Act 2000, as amended. Approximately 8,000m³ of engineering fill will be required to be imported.

All traffic movements associated with the import and export of materials have been included in the construction traffic impact assessment. Refer to Chapter 8 *Roads and Traffic* of this EIS for further details.

Site preparation works will also include the facilities for the contractors and the construction management team. These will include the following:

- Setting up of access control to the site;
- Site offices;
- Site facilities (canteen, toilets, drying rooms, etc.);
- Offices for construction management team;
- Secure compound for the storage of all on-site machinery and materials;
- Temporary car parking facilities;
- Permanent and temporary fencing; and
- Site Security.

4.5.2 IE43 process block extension area

The eastern part of the Lilly site generally slopes downwards in a south-easterly direction, from higher ground adjacent to the local road, towards the stream, which crosses the site.

The existing IE43 is a split level facility with a single storey admin block at c. 38.0m (local bench mark level) and the process block lower ground floor at c. 29.7m (local bench mark level). The area of the proposed IE43 process block extension is currently at approximately 29.0m (local bench mark level) as this area formed part of the ground works scope for the existing IE43.

This will be close to the formation level for the lower ground floor slab of the proposed IE43 process block extension. This area currently consists of a yard area and hardstanding.

The only excavation required therefore for this area will be locally for foundations and services. This will be reused for landscaping purposes along the proposed berm just east of the process block extension and along the existing berm south east of the stream. Refer to **Figure 3.3 Proposed Overall Site Plan**.

The existing internal access road that borders the north eastern and southern part of the existing IE43 building will require removal to facilitate the process block and headblock extensions. Refer to **Figure 3.3 Proposed Overall Site Plan**.

There will be a new tarmac delivery yard constructed between the southern façade of the process block extension and the internal access road. An existing retaining wall is located just east of the existing IE43 building. This retaining wall will be extended by approximately 20 metres. A new concrete wall will be constructed just east of the internal access road along the eastern boundary of the process block extension facilitate the construction of a berm and subsequent planting of the berm. The southern section of this wall will also be designed for flood protection from the stream. Refer to **Figure 3.3 Proposed Overall Site Plan** and **Chapter 14 Soils, Geology, Hydrology and Hydrogeology** for further details on flood protection.

4.5.3 IE43 headblock extension area

The proposed IE43 headblock extension will extend outwards from the north eastern corner of the existing IE43 building. The following development works will need to be carried out to facilitate the extension: relocate the existing nitrogen storage tank, a number of car parking spaces for disabled persons, kitchen deliveries and dispatch vehicles, new screen walls, new bin store and removal of tarmac yard area (see section 4.5.2 above).

As discussed above, a small amount of the material (approximately 900m³) to be excavated from the internal road and tarmac yard area will contain asphalt. This material will be removed off site for recycling and reuse or disposal at an appropriately licenced site.

4.5.4 Additional car parking, landscaping and other features

An additional 136 car spaces will be provided as part of the new development. The existing staff car park located just west of the existing Ballyvrin road entrance will be extended. A second staff car park will be located east of the existing Ballyvrin road entrance, north of IE43. These areas are already under hardstanding.

As discussed in Section 4.4.2 above, an existing open drain will be infilled to facilitate the contractor facilities in this area. Refer to **Figure 3.3 Proposed Overall Site Plan** and **Figure 3.4 Proposed Landscaping Plan**.

Landscaping is proposed in the following areas:

- Landscaping along the eastern boundary along a new berm (see section 4.5.2 above) and along the existing berm to the south east; and
- A number of *leylandi* trees and one beech tree will require removal to facilitate the construction of the temporary entrance. Post construction the temporary entrance will be closed and the area will be planted to provide site screening.

4.6 Construction Methods

Construction specifications, procedures and methods will be similar to those employed during the construction of IE43. In fact the existing IE43 facility effectively provides the template for not only the physical aspects of the proposed IE43 extension but also the means and methods by which it will be constructed.

Due to vibration constraints and the proximity of the existing facility, it is not expected that drill or blast methods will be employed. It is envisaged that hydraulic breaking will be required to loosen the less weathered rock prior to digging with large tracked excavators.

The proposed IE43 extension building will be constructed as follows:

- Foundations in reinforced concrete;
- Structural frame will be steel;
- Floors will be reinforced concrete;
- Internal walls will mainly be stud partitions and cleanroom wall panels, the remainder being concrete block construction; and
- External walls will be a combination of block, glazing and/or cladding panels.

The fit out of the building will include the installation and commissioning of the many items of process equipment, most of which will be delivered as preassembled skids. The piping systems associated with the equipment will mainly be prefabricated offsite at a local contractors fabrication facilities prior to transportation to site for installation. An extensive network of cabling systems will be installed throughout the facility to provide power and controls to the equipment. Building services equipment such as air handling units will be installed in the plant room area. Metal ductwork systems will be installed throughout the facility to distribute air to the various rooms.

The majority of the fit-out works will take place indoors, following construction of the building. For greater efficiency some technical spaces that will have a high density of piped services will be constructed in modular form off site.

4.7 Materials Source and Transportation

In so far as is feasible, all construction materials will be sourced from local suppliers and adequate supplies or sources of these are available within the Cork area.

The selection and specification of construction materials will be informed by local availability of these materials. Within the necessary constraints of performance, durability and cost, construction materials will be sourced from local suppliers and manufacturers, where possible. Construction materials will be transported from the suppliers via the R605 and via the Ballyvrin Road (coming from R605 direction only) to the site. Refer to **Chapter 8, Roads and Traffic** of this EIS for an assessment of the impact of construction traffic.

4.8 Employment and Accommodation

The proposed development is expected to take approximately 30 – 36 months to construct and it is envisaged that the average number of construction personnel on site will be 450 personnel and that the peak will be in the region of 550 personnel. The workforce for later phases such as commissioning and qualification will be less. The majority of construction facilities requirements will be met by continuing to use existing facilities erected for the IE43 project, with some additional temporary office and storage facilities being provided, as required for the construction contractors. The construction site will be separated from the operational activities of the existing facility by fencing. Where work has to be undertaken within operational areas of the existing facility, a work permit system will be implemented. Refer to **Figure 4.1 Construction Site Logistics Plan** for the construction site layout.

The co-ordination of people and materials on site will be one of the key activities throughout the construction phase. In order to ensure that construction workers do not create any disruption of the normal ongoing operations of the existing Lilly facility, there will be a requirement that the contractors provide adequate site supervision to co-ordinate, monitor and implement site regulations.

Normal construction working hours will be observed. These are 08.00 – 19.00 Monday to Friday; 09.00 – 16.00 on Saturday. It may be necessary to work outside these hours, including at weekends and at night, at certain stages. Working outside normal hours may be necessitated through consideration of safety or 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 strictly controlled. Lilly will notify Cork County Council if works outside normal working hours are required. It should be noted that a significant portion of the work will take place indoors, once the IE43 extension building is constructed.

4.9 Services Requirements

4.9.1 Electricity

A temporary power supply, for the construction phase, will be provided by a connection to the site power system. It is anticipated that the peak electrical demand during construction will be approximately 250kVA.

4.9.2 Water

The volume of water required during construction on an average daily basis is estimated at approximately 50m³. This will be supplied from the existing site water supply which is sourced from groundwater and municipal water supply. Refer to **Chapter 14 Soils, Geology, Hydrology and Hydrogeology** for further details.

4.9.3 Construction Site Drainage

Alterations to the existing drainage system will be carried out within the confines of the site. Connections to existing drains within the construction compounds will be made in such a manner so as to minimise the risk of contamination of the surrounding soil.

As the majority of the construction site and compounds will be within the existing developed site, the majority of the rain water run-off from the proposed IE43 extension construction site will be drained via a hydrocarbon interceptor 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. The ground will fall away from the stream and berms will be provided to ensure all run off is directed to the drainage system. As the compounds and car parks contain hardcore at present, some rainwater will drain into the ground.

Refer also to the Jacobs report *Temporary Surface Water Control System* which accompanies the planning application for further details

Contractor's Compound

Rainwater run-off from the contractor's compound and berm south of the stream will be controlled in a temporary surface water control system comprising swales (ditches) and settlement ponds. The swales provide the rain water capture mechanism. The run-off is directed to settlement ponds to allow suspended soil particles to settle out. The settlement ponds will contain an outlet filter to filter out any remaining suspended particles and any flotsam. A straw bale filter will be configured to ensure that the anticipated discharge parameters are met. The final settlement pond discharges to the stream via the existing Lilly site licenced surface water discharge point which has continuous monitoring for TOC and pH.

The temporary surface water control system will essentially be an extension of the system put in place for the recent IE43 construction project. The function of the system is twofold; to provide proper control of rain water run-off to avoid land erosion, water ponding and uncontrolled run-off and to provide protection to the stream running through the site. An existing berm at the north of this compound will be maintained to ensure no run off to the stream arises.

Contractor's Laydown Area

Rainwater run-off from the contractors laydown area will drain northwards away from the recently diverted stream and will drain into the existing Lilly site storm water drainage system.

Contractor Facilities

Rainwater run-off from the contractor's facilities area will drain northwards into the existing Lilly site storm water drainage system.

Contractor Car Parks

Rainwater run-off from the construction car parks in the northeast corner of the site will drain to the existing Lilly site storm water drainage system.

Rainwater run-off from the temporary staff car park will drain to the existing Lilly site storm water drainage system.

During construction, part of the staff car park west of the Ballyvrin road site entrance will be used by construction contractors. Run-off from this area is connected to the main site stormwater drainage system which directs run-off to the containment pond.

Rainwater run-off from the temporary staff car park will drain to the existing Lilly site storm water drainage system.

The temporary surface water control system will be subject to a daily visual inspection as well as routine maintenance. The inspection frequency will be increased during periods of exceptional high rainfall. Written procedures will be maintained and a log recorded for the inspections.

The contractor facilities will contain toilets, canteen, construction containers and site office. The disposal of sanitary effluent during construction will be via a tie-in to the site sewerage system. A pumping station and holding tank will be installed locally. A grease trap will also be installed at the canteen. The sanitary effluent will be pumped in PE pipes within the existing redundant foul sewer along the road just north of LC13. This PE pipe will be connected to the over ground piperack.

Storm water will be managed carefully during construction. 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. Daily plant and machinery checks will be carried out as per Lilly requirements on all construction plant and machinery. Drip trays will be used both for refuelling and overnight parking and spill kits will be on hand at all times.

Refer also to the Jacobs report *Temporary Surface Water Control System* which accompanies the planning application for further details.

4.10 Construction Safety

As required by the Safety, Health and Welfare at Work (Construction) Regulations 2013, a Health and Safety Plan will be prepared which will address health and safety issues from the design stages through to the completion of the construction and maintenance phases. This plan will be reviewed as the development progresses. The contents of the Health and Safety Plan will comply with the requirements of the Regulations.

The Regulations require the developer of a project to appoint a “Project Supervisor Design Process” and “Project Supervisor Construction Stage”. Lilly has appointed Jacobs Engineering, Cork as Project Supervisor Design Process in accordance with the current legislation.

The Project Supervisor Design Process will assemble the Safety File as the project progresses.

The Safety File will be incorporated into the overall technical record system at the end of the project. Jacobs will also be the assigned certifier with regard to Building Regulations requirements.

Safety on site will be of paramount importance. During the selection of the contractors and subcontractors, their safety records will be investigated. Only contractors with high safety standards will be selected.

Prior to working on site, each individual will receive a full safety induction and will be provided with all of the safety equipment relevant to the tasks the individual will be required to perform during employment on site.

Safety briefings will be held regularly and prior to any onerous or special task. ‘Toolbox talks’ will be held to ensure all workers are fully aware of the tasks to be undertaken and the parameters required to ensure the task will be successfully and safely completed.

All visitors will be required to wear appropriate personal protective equipment prior to going on to the site and will undergo a safety briefing by a member of the site safety team.

Regular site safety audits will be carried out throughout the construction and the complied with at all times.

At any time that a potentially unsafe practice is observed, the site safety manager will have the right as well as the responsibility to halt the work in question, until a safe system of working is again put in place.

4.11 Commissioning Phase

Following completion of construction and installation of equipment, and before operation of the facility commences, there will be a testing and commissioning phase. This phase will comprise:

- Installation compliance checks;
- Commissioning tests; and
- Performance demonstration tests.

4.12 Construction Site Decommissioning Phase

On completion of construction, all construction facilities and equipment such as plant, materials, signage, contractors’ offices and laydown areas, etc. will be removed from site. The temporary entrance will be closed up.

Construction site fencing will be removed and the landscaping will be completed to integrate the development into the operational Lilly site.

4.13 Potential Construction Impacts

4.13.1 Introduction

The potential impacts identified in this section represent the “worst case” scenario predicted in the absence of any mitigation.

Potential construction phase impacts include emissions to air such as dust, noise and vibration, construction traffic, surface water runoff from the site, leaks or spills from construction plant and equipment and construction waste. Additional traffic on the road network will be generated by the construction works.

Potential construction phase impacts are also addressed in other chapters of this EIS. For example, the construction phase impacts on air quality, climate and noise and vibration are evaluated in **Chapters 10 Air Quality & Climate** and **9 Noise and Vibration** of this EIS respectively. Construction traffic is addressed in **Chapter 8 Roads and Traffic** of this EIS. There is an evaluation of the construction impacts on flora and fauna in **Chapter 13 Biodiversity** of this EIS. The construction impact on the archaeological, architectural and cultural heritage is addressed in **Chapter 15, Archaeological, Architectural & Cultural Heritage** of this EIS. Visual impacts and lighting impacts during construction are detailed in **Chapter 7 Landscape and Visual** of this EIS. Potential construction phase impacts on Soils, Geology and Water are addressed in **Chapter 14 Soils, Geology, Hydrogeology and Hydrology** of this EIS. Specific construction phase mitigation measures are described in the individual chapters and general mitigation measures are described below. In general it is anticipated, that with proper management, the construction phase of the development will have no significant or long-term negative impacts.

4.13.2 Do-Nothing Impacts

If the proposed development did not go ahead, it is likely that the lands would remain the same or would be developed by Lilly for another industrial purpose.

4.13.3 Predicted Impacts of Decommissioning Phase

In the event of decommissioning, measures will be undertaken by Lilly to ensure that there will be no significant environmental impacts from the closed facility. The decommissioning measures will have to be implemented to the satisfaction of the EPA.

A revised IE licence (P0009-04) is currently in the proposed determination stage and is expected to be in place by year end. IE43 extension will be included in this revised licence. Lilly has assessed the proposed development against the conditions of P0009-04 which are in line with current regulatory requirements.

A revised Closure, Restoration and Aftercare Management Plan (CRAMP) has been prepared in support of the licence review application. This was prepared in accordance with the document “Guidance on Environmental Liabilities Risk Assessment, Residuals Management Plans and Financial Provision”, EPA 2006 (which has subsequently been revised).

This CRAMP builds on previous Residual Management Plans and Environmental Liabilities Risk Assessments prepared, revised and submitted to the Agency under the current licence for the site.

In 2014 an Environmental Liabilities Risk Assessment (ELRA) was completed for the site in accordance with the Guidance on Assessing and Costing Environmental Liabilities (Draft) – July 2013.

Both ELRA and CRAMP submissions and associated costings have been approved by the Agency.

A Financial instrument to cover both ELRA and CRAMP is currently being agreed with the Agency.

A copy of the CRAMP and ELRA are included in Appendix 4 of the Application (Reference P00009-04). The licence application is available online at www.epa.ie.

4.13.4 Potential Cumulative Construction Impacts

The potential cumulative impacts arising during the construction phase are addressed in various chapters throughout this EIS and summarised in **Chapter 17 Cumulative Impacts, Other Impacts and Interactions**.

4.14 Mitigation Measures

4.14.1 General

It is Lilly’s policy to minimise the environmental impact of the construction activities. The construction planning will be geared towards keeping disruption and nuisance to a minimum.

Every effort will be made to ensure that any detrimental environmental effects will be avoided, prevented or reduced during the construction phase of this project.

A construction environmental management plan (CEMP) will be prepared prior to construction commencing. The CEMP will comprise all of the construction mitigation measures, which are set out in this EIS, and 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. The plan will have regard to the guidance contained in the handbook published by Construction Industry Research and Information Association (CIRIA) in the UK, Environmental Good Practice on Site Guide, 4th Edition (CIRIA 2015).

Lilly will have a construction management team on the project site for the duration of the construction phase. The team will supervise the construction of the project including monitoring the contractors' performance to ensure that the proposed construction phase mitigation measures are implemented and that construction impacts and nuisance are minimised.

Lilly will liaise with neighbours and the general community during the construction phase to ensure that any disturbance is kept to a minimum and to ensure that all anticipated nuisances are minimised and that the construction activity will have the lowest possible impacts on the neighbours.

Mitigation measures to address construction traffic are described in **Chapter 8, Roads and Traffic**. Measures to control rain water run-off and prevent contamination of soils and groundwater are addressed in **Chapter 14, Soils, Geology, Hydrology and Hydrogeology**.

4.14.2 Dust Minimisation

As construction activities are likely to generate some dust emissions, particularly during the site clearance and bulk excavation phase, a dust minimisation plan will be prepared and implemented by the contractor during the construction phase of the project.

The following measures will be implemented as part of the dust minimisation plan:

- Limiting vehicle speeds on the construction site;
- During very dry periods, spraying surfaces with water will control dust emissions from heavily trafficked locations;
- All vehicles exiting the site will make use of wheel wash facilities prior to entering onto public roads, to ensure mud and other wastes are not tracked onto public roads. Public roads outside the site will be regularly inspected for cleanliness, and cleaned as necessary. Wheel-washing facilities will be located away from sensitive receptors;
- Topsoil and other dusty material being moved onsite will be transported in covered trucks, where the likelihood of emitting dust is high, and during dry weather conditions the area of removal will be sprayed with water from a mobile tanker on a regular basis to control dust emissions;
- Exhaust emissions from vehicles operating within the site, including trucks, excavators, diesel generators or other plant equipment, will be minimised through regular servicing; and
- Dust monitoring will be carried out at the site boundary throughout the construction phase.

In addition, dust mitigation measures and dust monitoring prescribed in the IE licence for the facility will continue to be implemented.

4.14.3 Site Tidiness

The following are some of the measures that will be taken to ensure that the site and surroundings are maintained to a high standard of cleanliness:

- Daily site inspections will be undertaken to monitor site tidiness;
- A regular programme of site tidying will be established to ensure a safe and orderly site;
- Scaffolding will have debris netting attached to prevent materials and equipment being scattered by the wind;
- Food waste will be strictly controlled on all parts of the site.
- Mud spillages on roads and footpaths outside the site will be cleaned regularly and will not be allowed to accumulate;
- Wheel-wash facilities will be provided for vehicles exiting the site; and
- In the event of any fugitive solid waste escaping the site, it will be collected immediately and removed to storage on site, and subsequently disposed of in the normal manner.

4.14.4 Noise and Vibration

Construction noise will be kept to a minimum in accordance with BS 5228 (2009). Construction-phase noise impacts are addressed in **Chapter 9 Noise and Vibration** of this EIS.

The contract documents will specify that the contractor, undertaking the construction of the works, will be obliged to take specific noise abatement measures and will comply with the best practice outlined in British Standard BS 5228 – 1: 2009 +A1 2014: *Code of Practice for Noise and Vibration Control on Construction and Open Sites – Noise* and the NRA (now TII) guidelines *Good Practice Guideline for the Treatment of Noise during the planning of National Road Schemes* (NRA 2014).

There will be no significant construction noise or vibration impacts on neighbouring residences.

It is anticipated that no significant vibration will be generated during the construction phase of the proposed development.

4.14.5 Biodiversity, Visual and Cultural Heritage and Construction Traffic

Potential impacts of the construction phase on biodiversity, landscape and visual and cultural heritage and construction traffic are addressed in the relevant chapters of this EIS.

4.14.6 Soil, Surface Water and Groundwater

The employment of good construction management practices will minimise the risk of pollution of soil, storm water run-off, seawater or groundwater.

The Construction Industry Research and Information Association (CIRIA) in the UK has issued a guidance note on the control and management of water pollution from construction sites, *Control of Water Pollution from Construction Sites, guidance for consultants and contractors* (Masters-Williams et al 2001). Additional guidance is provided in the CIRIA technical guidance on Control of Water Pollution from Linear Construction Projects (Murnane et al 2006).

The guides are written for project promoters, design engineers and site and construction managers.

They address the main causes of pollution of soil, groundwater and surface waters from construction sites and describes the protection measures required to prevent pollution of groundwater and surface waters and the emergency response procedures to be put in place so that any pollution, which occurs, can be remedied. The guides address developments on green field and potentially contaminated brownfield sites. The construction management of the site will take account of the recommendations of the CIRIA guidance to minimise as far as possible the risk of soil, groundwater and surface water contamination.

Site activities considered in the guidance include the following:

- Excavation;
- Earthmoving;
- concreting operations;
- spreading of topsoil;
- road surfacing;
- site drainage, and the control and discharge of surface water runoff from the site;
- oil and fuel delivery and storage; and
- plant maintenance.

Measures, as recommended in the guidance above, that will be implemented to minimise the risk of spills and contamination of soils and waters, include:

- Training of site managers, foremen and workforce, including all subcontractors, in pollution risks and preventative measures;
- Careful consideration will be given to the location of any fuel storage facilities. These will be designed in accordance with guidelines produced by CIRIA, and will be fully bunded;
- All vehicles and plant will be regularly inspected for fuel, oil and hydraulic fluid leaks. Suitable equipment to deal with spills will be maintained on site;
- Where feasible, soil excavation will be completed during dry periods and undertaken with excavators and dump trucks. Topsoil and subsoil will not be mixed together;

- Ensure that all areas where liquids are stored or cleaning is carried out are in a designated impermeable area that is isolated from the surrounding area, e.g. by a roll-over bund, raised kerb, ramps or stepped access;
- Use collection systems to prevent any contaminated drainage entering surface water drains, watercourses or groundwater, or draining onto the land;
- Wheel wash at site entrance to clean vehicles prior to exiting onto Ballyvryn Road;
- Minimise the use of cleaning chemicals;
- Use trigger-operated spray guns, with automatic water-supply cut-off;
- Use settlement lagoons or suitable absorbent material such as flocculent to remove suspended solids such as mud and silt; and
- Ensure that all staff are trained and follow vehicle cleaning procedures. Post details of the procedures in the work area for easy reference.

The implementation of the above measures will ensure that the risk of pollution of groundwater, soils and surface waters, resulting from the construction activities will be minimised.

4.14.7 Construction Waste Management

4.14.7.1 General

Waste generated during the construction phase will be carefully managed according to the accepted waste hierarchy which gives precedence to prevention, minimisation, reuse and recycling over disposal with energy recovery and finally disposal to landfill.

This hierarchy will be implemented by identifying opportunities to firstly prevent waste from being produced, and secondly minimise the amount of waste produced. Where prevention and minimisation will not be feasible, ways to reuse or recycle waste will be sought, preferably on-site to avoid the impacts arising from transportation. If this is not feasible, opportunities to reuse or recycle the waste off-site will be investigated. If this is not feasible, then waste will be sent to an energy recovery facility, and only where there is no alternative, will waste be disposed of to landfill. To achieve this, existing waste management programmes and networks will be used such as the National Waste Prevention Programme, which is implemented by the Environmental Protection Agency.

All waste removed from the site will be collected only by contractors with valid waste collection permits, under the Waste Management (Collection Permit) Regulations. All facilities to which waste will be taken will have appropriate waste licences or permits, under the Waste Management Act 1996, as amended, and the regulations thereunder, allowing them to accept the type of waste that is to be sent there. Hazardous waste generation will be minimised, and such waste will be recovered where feasible, and only disposed of if recovery is not feasible. Hazardous waste will be managed in accordance with the relevant legislation.

4.14.7.2 Waste Arising

In general, construction waste materials may include general construction debris, scrap timber and steel, machinery oils and chemical cleaning solutions. The practice of excessive purchase of materials and equipment to allow for anticipated wastage will be avoided.

It is anticipated that the majority of the excavated material, which is expected to be uncontaminated soil and stone will be suitable for use as engineering fill. Alternatively, this material will be re-used on site as non-structural fill material, or for landscaping and other uses. It is expected that the waste tarmac (asphalt) will be sent to an approved recycling location. Refer also to section 4.5 above for details.

In the unlikely event of any evidence of soil contamination being found during work on site, the appropriate remediation measures will be employed.

Any work of this nature would be carried out in consultation with, and with the approval of the Environmental Department of Cork County Council. The material would be transported to a permitted site via the national and regional road network.

Timber from trees, felled as part of the site preparation, will be sold to the timber industry.

4.14.7.3 Waste Management Plan

The contractor will be required to develop, implement and maintain a Waste Management Plan during the construction works. A senior manager will be responsible for the waste management plan. The manager will be competent in waste management, and will receive training, where necessary, such as the CIF Site Waste Management and Environmental Awareness course.

The key principles underlying the plan will be to minimise waste generation and to segregate waste at source. The measures to achieve these aims include:

- Ordering of appropriate quantities of materials, with a just-in-time philosophy;
- Immediate and careful storage of materials delivered to the site;
- Storing materials which are vulnerable to damage by rain under cover and raised above the ground;
- Careful handling of materials, using appropriate equipment, to avoid undue damage; and
- Designation of separate storage areas for different types of waste, in order to maximise the reuse and recycling potential of the waste.

The Waste Management Plan will outline how residual waste will be handled as follows:

- The identification of disposal sites;

- The identification of quantities to be excavated and disposed of and classification of this material;
- The identification of measures to prevent nuisance, etc.;
- The identification of the amounts intended to be stored temporarily on site and the location of such storage;
- The contractor's approach to waste management; and
- The names, roles, responsibilities, and authority of the key personnel involved in the waste management.

The Waste Management Plan will include documented procedures for dealing with waste management including liaison with third parties, statutory undertakers and other companies.

The Waste Management Plan will meet the requirements of the guidelines prepared by the National Construction and Demolition Waste Council (NCDWC), Best Practice Guidelines on the Preparation of Waste Management Plans for Construction & Demolition Projects, NCDWC 2006.

The following will also be considered as part of the Waste Management Plan:

- The identification of the amounts of materials intended to be stored temporarily on site and the location of such storage;
- Procedures for controlling sub contracts i.e. for checking waste procedures of subcontractors and ensuring sub-contractors fulfil design teams and contractors obligations in respect of waste management;
- Designation of separate storage areas for different types of waste materials in order to maximise their re-use and recycling potential;
- Procedure for record keeping for waste retained on site;
- Procedure for record keeping for hazardous waste, for example, C1 forms and transfrontier shipment documents; and
- Details of authorised waste hauliers with appropriate and up-to-date Waste Collection Permits. Details of permitted or licensed recovery and/or disposal facilities where waste materials will be sent, including copies of permits and licenses.

4.14.7.4 Waste Minimisation

The main contractor will be required to minimise waste and to segregate waste at source. The possible measures used to achieve these aims will include:

- Ordering of appropriate quantities of materials, with a just-in-time philosophy.
- Immediate and careful storage of materials delivered to the site.
- Storing under cover and raised above ground materials, which are vulnerable to damage by rain.
- Careful handling of materials, using appropriate equipment, to avoid undue damage.

- Designating separate storage areas for different types of waste in order to maximise the re-use and recycling potential of the waste.

Anticipated wastes arising can be summarised as follows:

- Sanitary waste from toilet and washing facilities. These will be routed to the existing sanitary waste infrastructure and treated on site prior to discharge.
- Construction Waste – e.g. packaging, pallets, and metal waste will be disposed off-site at suitably permitted waste facilities.

4.15 Residual Impacts

Every reasonable effort will be made to ensure that negative environmental effects will be minimised during the construction phase of the project. Construction management and the proposed mitigation measures outlined above will ensure there is minimal impact.

It is anticipated that with the proper construction management, there will be no significant long-term negative residual impacts arising from the construction of this development. The residual construction impacts of the construction phase are addressed in various chapters throughout this EIS.

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5 Planning

5.1 Introduction

This chapter outlines the planning and policy context of the proposed Eli Lilly IE43 Biotech Manufacturing Facility Extension.

The proposed development is examined in the context of the policies and objectives of the documents below, which address guidance in relation to economic and planning policy at national, regional and local levels.

5.1.1 National Policy Guidance

- National Development Plan 2007-2013.
- Capital Investment Plan 2016-2021.
- Making Ireland's Development Sustainable, Review, Assessment and Future Action 2002.
- National Spatial Strategy 2002-2020.
- National Climate Change Strategy 2007-2012.
- Climate Action and Low Carbon Development Act 2015
- Building Ireland's Smart Economy: A Framework for Sustainable Economic Renewal 2009-2014.
- Trading and Investing in a Smart Economy: A Strategy and Action Plan for Irish Trade, Tourism and Investment to 2015.
- National Recovery Plan 2011-2014.
- Building on Recovery – Infrastructure and Capital Investment 2016-2021
- Action Plan for Jobs 2015.
- Innovation 2020.
- Enterprise 2025.

5.1.2 Regional Policy Guidance

- Regional Planning Guidelines 2010-2022.
- The Regional Planning Guidelines for the South West Region 2010-2022.
- Southern and Eastern Regional Operational Programme 2014-2020.
- Strategic Environmental Assessment (SEA) SEA Statement for the Southern and Eastern Regional Operational Programme 2014-2020.

5.1.3 Local Policy Guidance

- Cork County Development Plan 2014.
- Bandon Electoral Area Local Area Plan 2015.
- Integrated Strategy for Economic, Social & Cultural Development of County Cork 2002 – 2011.
- Cork Area Strategic Plan 2001-2020.

5.2 Relevant National Policy Guidance

5.2.1 National Development Plan 2007 – 2013

The €184 billion National Development Plan 2007-2013 was launched in January 2007, entitled *Transforming Ireland - A Better Quality of Life for All*.

The main objectives of the Plan included:

- integrated development;
- improved social and economic policies;
- the maintenance of a productive and competitive economy;
- generation of employment; and
- provision of sufficient resources for social and recreational facilities and services.

The key elements of the Plan which supported these objectives included:

- The improvement of structural infrastructure deficits in order to increase competitiveness, regional development and to meet the demands of the growing population;
- The enhancement of enterprise development, science, technology and innovation, working age training and skills provision, in order to create a better economic performance, to be more competitive and to increase the capacity to generate more enterprise from both national and foreign investment;
- The integration of regional development within the National Spatial Strategy framework of gateway cities and hub towns in order to achieve economic growth in the regions and major investment in the rural economy;
- The investment in long-term environmental sustainability to (a) preserve the integrity of our natural environment for future generations, and to (b) meet our climate change commitments;
- The promotion of an all island strengthening in collaboration in areas of infrastructure, research and development, skills and innovation, and the provision of public services;
- The promotion of social inclusion; and
- The provision of value for tax payers' money.

5.2.1.1 Conformance of the Project to the Policy Objectives

The proposed IE43 Extension project will conform to the policy objectives of the National Development Plan by helping to consolidate and build on the southwest region's economic performance.

The proposed facility will be located in the Cork area, thereby contributing to the goal of developing counter-balances to Dublin and distributing growth more widely.

A key element of the overall strategy of social inclusion is the continuation of sustainable economic growth to promote jobs. The proposed facility will help to secure existing employment and create additional employment.

The proposed facility will increase the level of foreign direct investment in the Cork area.

The IE43 Extension project will serve to further embed Lilly in the local community and the region as a whole, and will therefore be in conformance with the policy objectives of the National Development Plan.

5.2.2 Capital Investment Plan 2016-2021

The €27 billion Capital Investment Plan 2016-2021, entitled *Building on Recovery: Infrastructure and Capital Investment 2016 - 2021*, launched in September 2015. The plan prioritised spending on areas of greatest need and was designed to focus on sustainable and long-term investment. At the time of release the then Minister for Public Expenditure and Reform, Mr Brendan Howlin TD, said the Capital Investment Plan 2016-2021 ‘*maps a route to continued economic recovery and will provide the bedrock of future growth*’. The plan set out specific investment policies in the areas of technological infrastructure and transport in order to ‘*consolidate Ireland’s leading position as a destination for foreign direct investment*’.

5.2.2.1 Conformance of the Project to the Policy Objectives

The proposed IE43 Extension supports the objectives of the Capital Investment Plan by providing for further capital investment by Eli Lilly at its Kinsale plant. The proposed development will contribute to economic growth in the region, providing additional long-term employment opportunities in the biotechnology sector and employment in the construction sector in the shorter term.

5.2.3 Making Ireland’s Development Sustainable, Review, Assessment and Future Action 2002

The Department of Environment and Local Government published a national report for Ireland for the World Summit on Sustainable Development in 2002. This presented a review of progress in implementing the 1997 *Sustainable Development: A Strategy for Ireland*, an assessment of that progress, and identified future action.

The assessment acknowledges that multi-national companies represent a considerable proportion of the Irish industrial base. It also states that these companies are required and accustomed, to operate to high environmental standards.

For industry, the overall objective of the assessment is to ensure that development:

- Is environmentally sound, maximising advantage and maintaining quality;
- Optimises the use of natural resources;

- Minimises the production of waste and emissions;
- Uses chemicals and other substances with potentially adverse environmental impacts sparingly and safely;
- Has a strongly defined clean production and clean technology ethos.

In relation to industry's interaction with the environment, the assessment states that it is essential for industry to recognise and address its potential for extensive impacts on the natural environment. However, it acknowledges that industrial emissions are, in general, well regulated. The minimisation of industrial wastes is a major objective of national policy, and the assessment states that measures such as cleaner production processes, life-cycle analysis and other eco-efficient approaches in the industrial sector will contribute to realising this objective.

The assessment says that public regulation and control have an important place in the environmental management of industry, but it also acknowledges that substantial complementary action can, and is, being taken by industry, both to minimise environmental impact and to increase efficiency. Progressive voluntary policies by industry can reduce the need for vigorous regulation, by, for example:

- Participation in environmental management schemes.
- Subscription to international codes of conduct such as the Chemical Industry's Responsible Care Programme.
- The development of dedicated codes of practice to cover, for example, waste prevention and energy saving.

5.2.3.1 Conformance of the Project to the Policy Objectives

The proposed IE43 Extension conforms to the policy objectives of the assessment.

Lilly is committed to the ethos of clean production and clean technology.

Lilly's long established Environmental Management System has been certified to the ISO 14001 Environmental Management System standard.

The plant operation is currently regulated under an Industrial Emissions (IE) Licence (licence number P0009-03) from the EPA. This requires the company to undertake various actions to meet its environmental obligations, including ongoing efforts at waste minimisation and the implementation of clean technology. Eli Lilly is a member of BioPharmChem Ireland and is committed to the principles of the organisation's Responsible Care programme, see details below:

"Responsible Care is the global Chemical industry's environmental, health and safety (EHS) initiative to drive continuous improvement in performance of the pharmaceutical and chemical sector in all aspects, which directly and indirectly impact on the environment, employees or the general public. Responsible Care companies actively strive to maintain leadership in safety and environment performance. The Responsible Care ethic helps chemical companies to operate safely, profitably and with due care for future generations." (BioPharmaChem Ireland 2015).

5.2.4 National Spatial Strategy 2002 – 2020

The National Spatial Strategy (NSS) for Ireland is a twenty-year planning framework designed to achieve a better balance of social, economic and physical development and population growth between regions.

The strategy states that in order to emulate the economic success achieved in Dublin, Ireland needs to strengthen the dynamic, emerging critical mass of the existing gateways in the South East, South and West and develop gateways at other strategic locations. The strategy recognises that of all the regional cities, Cork has the most immediate potential to be developed to the level required to complement Dublin.

With regard to the future trends in enterprise development, the Strategy states that they are likely to include the following:

- Regions with a strong population base that can support high quality business infrastructure, technological development and innovation will continue to be major attractions; and
- To remain competitive and viable, companies will need to increase the technological content of their products and services by allocating additional investment to research, design, innovation and development.

The strategy states that the inherent advantages of the South and East region in its overall contribution to national economic development must be consolidated.

5.2.4.1 Conformance of the Project to the Policy Objectives

The proposed development will be a beneficial element in consolidating the Cork region's contribution to the overall national economic development. Lilly's investment signifies its commitment to developing the technology of its operations to ensure that it remains competitive and continues to meet the highest quality standards.

5.2.5 National Climate Change Strategy 2007-2012

The National Climate Change Strategy, which was produced by the Government in 2007 sets out in a detailed and specific way, the comprehensive measures that the Government has put in place to enable Ireland to meet its target under the Kyoto Protocol.

The strategy brings together the range of actions being taken by the Government to reduce Ireland's greenhouse gas emissions. It provides the necessary whole-of-Government coordination to meet Ireland's Kyoto commitments and builds on progress already made since the original National Climate Change Strategy was published in 2000.

The strategy addresses measures in all sectors of the economy - including energy, transport, agriculture, the residential sector and businesses. It includes existing measures put in place on foot of the 2000 National Climate Change Strategy and, subsequently, through the National Development Plan 2007-2013, Transport 21, the Energy White Paper and the Bioenergy Action Plan.

It also includes a series of additional measures to deliver the overall objective of putting Ireland on a pathway towards a low-carbon economy.

5.2.5.1 Conformance of the Project to the Policy Objectives

The National Climate Change Strategy is relevant to the proposed development in the area of energy usage. The use of clean technologies on site has resulted in improved efficiency in the use of materials and energy.

Lilly employs Best Available Techniques (BAT) air emission abatement systems to control air emissions from the manufacturing process and to minimise energy use.

5.2.6 Climate Action and Low Carbon Development Act 2015

The *Climate Action and Low Carbon Development Act* was published by government in January 2015. The Act sets out the national objective of transitioning to a low carbon, climate resilient and environmentally sustainable economy in the period up to 2050. The Act provides for the preparation of National Mitigation Plans and Sectoral Plans which will specify policies to reduce greenhouse gas emissions for each sector.

5.2.6.1 Conformance of the Project to the Policy Objectives

The Act is relevant to the proposed development in the area of energy usage. The use of clean technologies on site has resulted in improved efficiency in the use of materials and energy. Lilly employs Best Available Techniques (BAT) air emission abatement systems to control air emissions from the manufacturing process and to minimise energy use. Carbon emissions from Lilly are regulated through Greenhouse Gas Emissions Permit, number GHG023-10352-4.

5.2.7 Building Ireland's Smart Economy: A Framework for Sustainable Economic Renewal 2009-2014

Building Ireland's Smart Economy: A Framework for Sustainable Economic Renewal was published in December 2008. The document sets out a framework aimed at addressing the current economic challenges and building a 'Smart Economy' with a thriving enterprise sector, high-quality employment, secure energy supplies, an attractive environment, and first-class infrastructure.

The plan recognises that to support well-paid and quality jobs, Ireland must move up the value chain and assert itself not only as an open enterprise economy with a positive environment for FDI, but also as an open entrepreneurial economy with significant comparative advantages. One of the key actions of the document is to develop a range of measures to make Ireland the innovation and commercialisation capital of Europe – a country that combines the features of an attractive home for innovative multinationals while also being a highly-attractive incubation environment for the best entrepreneurs in Europe and beyond.

Chapter 6 of Building Ireland's Smart Economy states that "the multinational community will be incentivised to intensify innovative, high-value activity and technological convergence which will provide quality jobs".

The document outlines the Government's continued substantial support for the existing multi-nationals by providing significant incentives to business through enhanced R&D incentives for multinationals, tax incentives to those starting a business, capital allowances for energy-efficiency equipment and further pro-enterprise, pro-environment and pro-employment policies.

5.2.7.1 Conformance of the Project to the Policy Objectives

The proposed IE43 extension will conform to the policy objectives set out in the Framework. The proposed development will provide additional high-quality employment for the Cork area. The project also demonstrates Eli Lilly's continued commitment to the research and development of innovative medicines which is in keeping with the Government's goal of intensifying innovative and high-value activities.

5.2.8 Trading and Investing in a Smart Economy: A Strategy and Action Plan for Irish Trade, Tourism and Investment to 2015

Trading and Investing in a Smart Economy: A Strategy and Action Plan for Irish Trade, Tourism and Investment to 2015 was published in 2010 with a primary focus on job creation. The document details plans for programmes and investment to generate trade and tourism with the aim of putting a focused effort into seeking new inward investment and expanding exports of indigenous and foreign-owned businesses.

The life sciences are pinpointed as a significant feature in growing the Irish Economy. The document highlights IDA Ireland focused efforts on high-growth sectors such as information technology companies, life sciences, and financial services. It states that this focus has resulted in almost 1,000 companies – including many of the world's best-known brands - locating their European headquarters in Ireland. Eight of the top ten global pharmaceutical companies are located in Ireland.

The report highlights the value of the chemicals sector, accounting for 56% of Irish goods exported. Organic chemicals and medical and pharmaceutical products account for 80% of chemical exports from Ireland. This strong export trade showed resilience during the downturn where total exports fell by 2.3% in 2009 from 2008, a considerably less dramatic decline than that experienced by other sectors at the time.

Section 2.1 of Building Ireland's Smart Economy highlights "Foreign-owned multinational companies located in Ireland are an important feature of the economy, particularly during the current downturn.

It is clearly a top strategic priority to maintain the existing investments and to continually work to attract new industries and companies.” It specifically outlines strategies to attract an extra 780 foreign investment projects through IDA Ireland by 2015.

5.2.8.1 Conformance of the Project to the Policy Objectives

The proposed IE43 extension will contribute to the government’s strategic priority of maintaining and growing existing investment by foreign-owned multinationals. The proposed manufacturing facility will enable Lilly to expand production capacity and ultimately increase the value of Irish goods exported.

5.2.9 National Recovery Plan 2011-2014 and Building on Recovery – Infrastructure and Capital Investment 2016-2021

The National Recovery Plan was published in 2011. The plan provides a blueprint for a return to sustainable growth in the economy. It sets out in detail the measures to be taken to put Ireland’s public finances in order, with the aim of making a €15 billion adjustment in the public finances. The plan identifies the areas of economic activity which provide growth and employment in the county’s economic development. It specifies the reforms the Government will implement to accelerate growth in those key sectors.

The National Recovery Plan acknowledges in Section 2.5.3, that the life sciences sector was a key driver of Ireland’s positive export performance during the recession. Ireland’s strong reputation in this area is underpinned by core engineering skills and expertise in designing and constructing state-of-the-art manufacturing facilities.

One of the key actions of the document is to develop a range of measures to continue to attract foreign direct investment (FDI) to Ireland. The attraction of FDI is known to have increased growth in the Irish economy in the past and is therefore a key element in the process of driving Ireland’s economic development. Foreign investment in Ireland is substantial in nature: IDA supported companies alone sustain over 135,000 jobs. The document outlines the steps which can be taken to copper-fasten Ireland’s attractiveness as a location for international mobile investment. These steps include “Making Ireland a Global Innovation Hub”, with the aim to make “Ireland the best place in Europe to turn research and knowledge into products and services”; as well as “the best place in Europe for research-intensive multinationals to collaborate with each other and with clusters of small companies.”

The Building on Recovery: Infrastructure and Capital Investment 2016 – 2021 plan is the next phase in capital investment planning, announced by the Minister of Public Expenditure and Reform in September 2015. The aim of the plan, is to *“increase the State’s infrastructure, support economic recovery and jobs, support sustainable communities throughout Ireland and provide modern, fit for purpose buildings to deliver services to our citizens”*.

This report presents a new, €27 billion multi-annual Exchequer Capital Investment Plan, which is supported by a programme of capital investment in the wider State sector, and which over the period 2016 to 2021 will help to lay the foundations for continued growth in Ireland. With the economy recovering and against the backdrop of jobs growth and strengthening public finances, the Government is revising upwards its capital expenditure commitments for the remainder of the decade. This Capital Plan will have a positive impact on job creation across the country and in almost every sector of the economy. It will serve to underpin the Government's commitment to seeing full employment of 2.1 million people in 2018, as set out in its Action Plan for Jobs.

5.2.9.1 Conformance of the Project to the Policy Objectives

The IE43 extension project is entirely in line with the National Recovery Plan (2014) objectives to make Ireland a Global Innovation Hub. The proposed IE43 extension will focus on applying Eli Lilly's research and development to manufacturing innovative medicines, adding to the value of Irish export goods and creating additional employment.

The proposed development will contribute to the government's strategic objectives outlined in Building on Recovery: Infrastructure and Capital Investment Plan 2016 by creating additional fulltime permanent jobs in the Cork area and in reinforcing the biotech/pharmaceutical cluster in the Cork area.

5.2.10 Action Plan for Jobs 2015

The Action Plan for Jobs 2015 was launched in January 2015 and is the fourth annual plan in a multi-year process which started in early 2012. It sets out in detail the actions to be taken by government departments and state agencies during 2015 to support job creation. In its fourth year, the Action Plan for Jobs (APJ) process continues to have an impact. Almost 80,000 more people are at work since the launch of the first Action Plan for Jobs in 2012 and it aimed to raise total employment from 1.8 million to 1.9 million by 2016 and by a further 100,000 by 2020. It is a working document which means subsequent action plans are to be provided annually until these goals are realised. Latest figures suggest that total employment could actually reach 2.0 million in 2016.

The plan has five strategic objectives which include:

- To support 100,000 additional jobs by 2016;
- To get Ireland back to a top-five ranking in international competitiveness;
- To stimulate the domestic economy and generate employment in locally traded Sector;
- To build an indigenous engine of growth that drives up the export market share of Irish companies; and
- To build world-class clusters in key sectors of opportunity.

The plan acknowledges the strength of foreign investment as an important job creator and an important base upon which continued economic growth and sustainable employment creation across the country will be built. IDA Ireland has reported the creation of 15,012 new jobs by IDA client companies during 2014. When job losses were taken into account, the net increase in employment was 7,131, one of the highest net levels of job creation in a decade. The employment growth in these companies is directly linked to their ability to grow sales and exports.

Under objectives detailed in Chapter 6, Enterprise Ireland pledged to “Implement the Enterprise Ireland Strategy to target the creation of 13,000 new fulltime permanent jobs and to support clients to achieve €19 billion in exports in 2015.”

5.2.10.1 Conformance of the Project to the Policy Objectives

This proposed development will contribute to the government’s strategic objective by creating additional fulltime permanent jobs in the Cork area and in reinforcing the biotech/pharmaceutical cluster in the Cork area.

5.2.11 Innovation 2020

Innovation 2020 was published in December 2015 as Ireland’s 5-year strategy for research and development, science and technology. This innovation plan is a key element of the Government’s overall jobs strategy, aimed at building a new economy based on exports and enterprise, and delivering full employment on a sustainable basis. The strategy is aimed at building on the significant successes delivered by the Government’s science strategy over the past decade, which has seen Ireland dramatically improve its performance globally in this area.

A key ambition of the strategy is to increase total investment in R&D in Ireland, led by the private sector, to 2.5% of GNP. On current official projections, this would mean that over €5 billion will be invested per year in R&D by the private and public sectors by 2020. This will represent an almost doubling of 2014 investment levels (€2.9 billion in 2014).

Innovation 2020 highlights the importance of scientific research and innovation to all aspects of Ireland’s future and confirms the Government’s commitment to increase both public and private investment in this area. Science, innovation and technology are considered as driving rapid global changes as the world is continuously becoming more competitive.

Innovation 2020 is a key element in the government’s plan to keep the recovery going by helping to create new jobs and new opportunities for research. It sets out a vision in which Ireland would become a Global Innovation Leader, with research, development, science and technology all contributing to this goal. Ireland’s reputation for research excellence has been a major catalyst in the success in attracting and maintaining foreign direct investment, and this strategy demonstrates that Ireland continues to remain strongly committed to maintaining and improving standards in the excellence of research.

5.2.11.1 Conformance of the Project to the Policy Objectives

The proposed IE43 extension conforms to the ambitions of the strategy. The new facility will expand the production of innovative medicines which will drive the value of Irish goods exports and increase employment.

5.2.12 Enterprise 2025

Enterprise 2025 was launched in November 2015 and is the 10-year jobs and enterprise strategy aimed at ending the cycle of boom-bust and delivering sustainable, enterprise-based jobs growth. The strategy sets a target of having 2.18 million people at work by 2020, the highest in the history of the State, which will require an increase of 266,000 people at work from a 2014 base figure¹. The plan sets an objective of ensuring unemployment in all regions is within 1% of the national average in every region by 2020. It envisages a strong economy with full employment that supports vibrant public services for our people. Innovation, competitiveness and productivity are cornerstones of the strategy in delivering quality employment that is sustainable over the longer term and that delivers a higher standard of living for all of our people.

Key targets in the plan include:

- Stimulate job creation throughout Ireland so that unemployment in each region is within one percent of the national average.
- Restore our competitiveness to rank in the top three of the most competitive small countries in the world.
- Realise long term productivity growth to levels ranking alongside the top 5 EU countries.
- A 60 per cent increase in EI enterprises spending more than €1m on R&D and winning €3.6bn in R&D related FDI.
- An additional 1,080 inward investment projects.
- Export sector to create 47% (105,000) of the new jobs to 2020 (including tourism). During the years of the construction boom, exporting companies accounted for only 19% of jobs. This export-driven strategy will help ensure that the jobs growth is sustainable.

5.2.12.1 Conformance of the Project to the Policy Objectives

The proposed IE43 extension reflects the targets of the Enterprise 2020 report; increasing employment in the export sector.

¹ Annual average employment over four calendar quarters, 2014

5.3 Regional Policy Guidance

5.3.1 Regional Planning Guidelines 2010-2022

The Regional Planning Guidelines for the South West Region were reviewed in 2010 and the review was published as the Regional Planning Guidelines 2010 – 2022. They were published by the South West Regional Authority (SWRA).

The SWRA was one of eight regional authorities which have been consolidated under the Irish Government's regional reform process under the Local Government Reform Act 2014 to form the Southern, the Northern and Western and the Eastern and Midland regions.

The purpose of the document is stated the Preface:

“The Regional Planning Guidelines (RPGs) formulate public policy for the region, covering Cork and Kerry, integrating land-use, transport, economic growth and investment, to enable the region to continue to grow as a sustainable high quality location for investment and one in which to live, work and visit. The RPGs set out a series of recommendations to local authorities, which are clearly linked to and support national investment priorities and are designed to strengthen integrated approaches to policy making and planning at local level, in line with regional and national planning frameworks. Sustainable growth is a key theme of the Guidelines, relating to the development and strengthening of the regional economy; the quantum and location of future housing; environmental improvement and sustainable living with a high level of service integration, all within the context of heightened protection of the region's biodiversity.”

Chapter 1 of the Guidelines sets out the planning context and examines the delivery of the 2004 Guidelines. It notes that:

“1.3.15. The South West Region is the only region in Ireland where output from the manufacturing sector exceeds the value of output from the services sector. Manufacturing accounts for 54% of GVA [Gross Value Added] while services add 44%. It should however be noted that the services sector grew by 70 % between 2000 and 2005 compared to manufacturing growth of 47 % in the same period.”

The economic importance of the pharmaceutical and health care sector to the region is recognised in Chapter 3 of the Guidelines, which presents the economic development strategy for the region.

“3.1.3. The South West has the highest Gross Value Added (GVA) per worker in the State in 2005 and has experienced higher than national average growth rates over the period 1998-2007. There are marked differences however between the counties of Cork and Kerry, with disposable income levels in Cork at 99% of the national average compared with Kerry at 86%. The reason for this is the significant presence of the high value pharma-chem sector, primarily located in the Cork Gateway.”

“3.1.5. The region is unique in that it is the only region where the value of output from industry (manufacturing) exceeds that of services (both traded and non-traded). It has a diverse industry base and well developed geographic clustering of export oriented companies in the Food, Pharmaceuticals and ICT sectors in particular, and to a lesser extent Medical Devices and Engineering.”

Objective RES-01 Production and Knowledge in the Guidelines, in relation to economic development, states:

“It is an objective to promote sustainable growth of indigenous and multinational companies in the economic sectors where the region enjoys competitive advantage and in particular:-

- Knowledge based industry, research and development, with a strong focus on indigenous company growth, supported by the sustainable development of a Regional Science Park in the Gateway.*
- Strategic sites at appropriate locations for large scale developments related to the pharma-chemical, bio-medical, IT and food sciences sectors.*
- Internationally traded services located in high quality sustainable locations, strongly focused on the Gateway and Hub towns, in brown field locations where practicable and within easy access to public transport and support services.*

In order to safeguard the expansion of existing productive industries in the region, it is necessary for local authorities to:

- Ensure adequacy of suitable land for expansion.*
- Identify optimum sustainable locations for large scale production.*
- Where appropriate, facilitate the sustainable generation of renewable energy at source in strategic industrial areas.*
- Encourage the relocation of existing Seveso sites in the Cork Docklands area to facilitate future development of the docklands, in a sustainable manner.*
- Ensure that travel and transport needs are catered for in a sustainable manner.”*

5.3.1.1 Conformance of the Project to Policy Objectives

The proposed IE43 extension project will result in appropriate, sustainable growth of the pharma-chemical sector in Cork, thereby helping to safeguard the economic importance of this sector in the region. The proposed development is within the existing Lilly site, on an area of land which is suitable for the expansion and it continues to be regulated by the EPA, thereby ensuring continuous protection of the environment.

5.3.2 Southern and Eastern Regional Operational Programme 2014-2020

The Southern and Eastern Regional Operational Programme is a document published by the Southern and Eastern Regional Assembly in July 2014 and which was co-funded by the Irish Government and the European Union's Regional Development Fund. A Strategic Environmental Assessment (SEA) was undertaken in parallel with the formulation of the programme, which assessed the likely effects of the operational programme on the environment. The Programme directly supports the South-West Regional Authorities' Regional Planning Guidelines 2010-2022 (2010).

The Assembly was established as part of the Agenda 2000 Agreement which saw the country divided into two regions, for the purpose of structural funds. The designation of regions allows for a more balanced regional development and policies that target region-specific needs. The main objective of the Agreement is to achieve balanced regional development. Under the Local Government Reform Act 2014 the former eight regional authorities and two regional assemblies were consolidated in the Government's regional reform process to form three regions, the Southern, the Northern and Western, and the Eastern and Midland regions.

The Programme recognises the already strong base that the pharma-chemical as well as agri-food, ICT/software and financial services sectors have in the region. Priority number one of the OP Strategy is to "prioritise investment to strengthen research, technological development and innovation (RTDI) to build capacity and contribute to the development of a high-added value and resilient European economy."

5.3.2.1 Conformance of the Project to Policy Objectives

The proposed IE43 extension project will further strengthen the Southern Region's pharma-chemical base. The proposed manufacturing facility is in line with the priorities of the OP. This development will increase Lilly's production capacity and competitiveness by accelerating the development and production of biotechnology products.

5.4 Local Policy Guidance

5.4.1 Cork County Development Plan 2014

The Cork County Development Plan came into effect in March 2015. The Plan acknowledges that generally strategic employment centres are those that are strategic locations for large-scale industry usually associated with FDI (Foreign Direct Investment) companies that require large, stand-alone premises and employ large numbers of employees.

Section 2.1.2 outlines the key aims for the county including "*Sustainable and balanced economic investment, in jobs and services to sustain the future population of the County together with wise management of the County's environmental, heritage and cultural assets*".

Section 6.4.9 states that *“Particularly the ‘Strategic Employment Areas’, Local Area Plans will identify land suitable for large scale industrial development (primarily to meet the needs of chemical, pharmaceutical and energy sectors) and this land will be held in reserve until suitable development opportunities arise.”*

The County Development Plan Objective EE9-1 Business Development in Rural Areas states that:

“The development of appropriate new businesses in rural areas will normally be encouraged where:

- The scale and nature of the proposed new business are appropriate to the rural area, and are in areas of low environmental sensitivity.*
- The development will enhance the strength and diversity of the local rural economy,*
- The proposal will not adversely affect the character and appearance of the landscape,*
- The existing or planned local road network and other essential infrastructure can accommodate extra demand generated by the proposal,*
- The proposal has a mobility plan for employees home to work transportation,*
- Where possible the proposal involves the reuse of redundant or underused buildings that are of value to the rural scene;*
- The provision of adequate water services infrastructure; and*
- Provision of a safe access to the public road network (See Objective TM 31: National Road Network (c) and (d)).”*

5.4.1.1 Conformance of the Project to the Policy Objectives

The Lilly plant has been established in the Kinsale area for more than thirty years and has contributed significantly to the local economy through the provision of employment and use of local services. The expansion of Lilly in a sustainable and balanced manner will help to maintain the rural economy and encourage the development of Kinsale and its hinterlands.

The proposed IE43 extension is in an area that is considered to be of low environmental sensitivity (see Chapter 13 *Biodiversity*). Lilly has confirmed that the water service infrastructure on site is adequate to cater for the proposed expansion. The site has adequate groundwater resources and will not require any additional water from the local municipal water supply mains (current capacity is up to 1000m³/day). Civil infrastructure such as the storm water drainage and on site wastewater plants also have adequate capacity to receive any additional aqueous volumes. Refer to Chapter 14 *Soils, Geology, Hydrogeology and Hydrology*.

It has also been shown that the local road network has sufficient capacity to accommodate the additional volumes of staff and construction traffic during construction, refer to Chapter 8 *Roads and Traffic*.

A mobility management plan (MMP) will be put in place during construction and operation. Refer to **Appendix 8.1**. Previously for the IE43 facility, a construction traffic management plan (CTMP) was agreed with Cork County Council (CCC) prior to construction commencement. A similar CTMP will be put in place for the IE43 extension and agreed with CCC in advance of construction commencement.

The MMP is designed to minimise the impact of any additional traffic volumes to site. Refer to **Appendix 8.1 Mobility Management Plan**.

5.4.2 Cork Area Strategic Plan 2001 - 2020

The Cork Area Strategic Plan is an initiative jointly sponsored by Cork City and County Councils in order to provide a vision and strategy for the development of the Cork City region up to 2020. It was prepared in response to a Government-supported European-wide initiative to create a sustainable approach to social and economic development, which is encouraging Planning Authorities to take a more critical view of settlement patterns, development needs and infrastructure requirements through the preparation of strategic plans.

The Cork Area Strategic Plan study area is determined by a journey time of approximately 45 minutes from Cork City (an area referred to as the Cork City Region). It includes Cork city, satellite towns (including Ballincollig and Carrigaline), the Ring towns (including Bandon and Kinsale) and rural hinterlands. Metropolitan Cork includes Cork City and a number of its surrounding settlements.

Maintaining rural communities and supporting the local economy are important objectives of the Cork Area Strategic Plan but must be seen in the light of the fall in employment in agriculture and forestry and the development of commuter housing in the countryside. The challenge will be to avoid the development of the rural areas as suburbs for Metropolitan Cork and aim for employment-led growth of rural towns and villages. The Ring Towns will become the focus for growth outside the Metropolitan area and new housing provision will be balanced with the provision of new employment opportunities.

Cork has become a location of choice for modern industry and the Cork Area Strategic Plan will promote even stronger ties between inward investors and the educational institutions, to create a future economy, which is knowledge-based, and research led.

A number of key principles were identified, as underpinning the location of future industrial and commercial floor space in the study area. One of these principles was to encourage the location of major foreign direct investment manufacturing plants at large single user sites at key strategically located Ring-towns – Mallow, Fermoy and Midleton with smaller facilities at Bandon, Macroom and Kinsale.

5.4.2.1 Conformance of the Project to the Policy Objectives

The Lilly site is located near the town of Kinsale and has been a key employer in the area as well as supporting the local economy.

The proposed IE43 extension project will sustain existing employment and create additional employment. Furthermore, the expansion of Lilly in a sustainable and balanced manner will help to maintain the rural economy and encourage the development of Kinsale and its hinterlands.

5.4.3 Bandon Electoral Area Local Area Plan 2015

Dunderrow is located within the Bandon Electoral Area. The Bandon Electoral Area Local Area Plan was published in January 2015. The Planning and Development Acts make provision for the LAP to be taken into account as a material consideration in the determination of applications for planning permission either by the County Council or An Bord Pleanála.

The LAP sets out an Employment and Economic strategy for the area in terms of job creation. This is specifically in reference to the predicted population growth that the Plan foresees.

Section 2.2.17 states that *“It is important that this jobs target is achieved in order to help sustain the level of growth in the electoral area and reduce longer distance commuting”*.

Section 2.2.18 of the Plan recognises Eli Lilly as one of the main employers in the electoral area. Section 2.2.9 goes on to say that *“... Kinsale Town needs more jobs to reduce its dependence on commuting to other locations for employment. The Eli Lilly plant in Dunderrow also provides a more local source of employment for people living in Kinsale.”*

Section 15.2.14 of the LAP specifically identifies the role of Lilly within the vision for and context of Dunderrow, with references to further development of the site having direct implications for the proposed extension:

15.2.14. Eli Lilly, a large pharmaceutical firm employing in excess of 450 people has been operating from Dunderrow since 1981. The plant itself is located several hundred metres to the south of the village, and quite distinct from the main body of the village, on the eastern side of the R605. The plant itself is affected by the Seveso II Directive, with a consultation distance of 1,000 meters. Any extension to this existing development will be acceptable in principle subject to the terms of the Directive and the policies and objectives of the County Development Plan.

Zoning

As outlined above, the Lilly Site at Dunderrow is in the Bandon Electoral Area. The Bandon Electoral Area LAP was issued in 2015 however specific zoning relating to Lilly is not included in the LAP.

ZU 2-3 of the 2014 County Development Plan states that “Where lands have not been explicitly zoned, in either the adopted Local Area Plans or the adopted Special Local Area Plans, the specific zoning shall be deemed to be that of the existing use of the lands (if such a use is not an unauthorised use under the Planning Acts) or, if such a use is unauthorised, that of the most recent authorised use of the lands”.

The Lilly site has been operating as a pharmaceutical facility since early 1981 in compliance with its planning permissions. The proposed IE43 extension project conforms to the zoning objective of the Development Plan in that the zoning is that of the existing use of the land, which is industrial. Further, the LAP has stated that further extension at the Lilly facility would be ‘acceptable in principle’, as long as it conforms to Seveso requirements, as well as planning policy and objectives.

5.4.3.1 Conformance of the Project to the Policy Objectives

The Lilly site is located near the towns of Bandon and Kinsale and has been a key employer in the area as well as supporting the local economy.

The proposed IE43 extension project will create additional employment during the construction phase. Under full operation approximately 150 additional full time employees will be required, employed over a two to five year period.

The planning of the proposed IE43 extension has been undertaken in accordance with the Seveso III Directive (2012/18/EU) and the Cork County Development Plan.

The LAP does not specify zoning for the land under Lilly ownership. The proposed development will be constructed within the site boundary and in keeping with the nature and scale of the existing land use.

5.5 Summary

The proposed IE43 extension closely aligns with the national, regional and local policy guidance presented in the preceding sections of this chapter. In respect of national policy, this proposed development consistently fulfils national development policies for high quality employment, innovation, increasing foreign direct investment and exports, as well as innovation. At a regional level, this proposed development is particularly in line with policies that aim to counter balance Dublin centric investments.

On a local level, the proposed development is in line with the policies set by the Cork County Development Plan, Cork Area Strategic Plan and the Bandon Local Area Plan; the proposed IE43 extension brings additional employment to the area; it is located in an area of low environmental sensitivity; and the development is in keeping with the nature of the existing land use.

5.6 References

BioPharmaChem Ireland (2015) *Our Commitment to Sustainability – BioPharmaChem Ireland Responsible Care Report 2015*.
[www.biopharmachemireland.ie/Sectors/PCI/PCI.nsf/vPages/Responsible_Care~2015-responsible-care-report-15-12-2015/\\$file/Responsible+Care+Report+2015.pdf](http://www.biopharmachemireland.ie/Sectors/PCI/PCI.nsf/vPages/Responsible_Care~2015-responsible-care-report-15-12-2015/$file/Responsible+Care+Report+2015.pdf)

Cork City Council & Cork County Council (2002), *Cork Area Strategic Plan (2001-2020)* prepared by WS Atkins.

Cork County Council & Cork City Council (2001) *Cork Area Strategic Plan – Strategy for Additional Economic and Population Growth 2001-2020*.

Cork County Council (201409), *Cork County Development Plan 201409*.

Cork County Council (20150) *Bandon Electoral Area Local Area Plan: Public Consultation Draft November 2010*.

Cork County Development Board (2002), *Integrated Strategy for Economic, Social & Cultural Development of County Cork 2002 – 2011*.

Department of Enterprise, Trade and Innovation (2010) *Trading and Investing in a Smart Economy: A Strategy and Action Plan for Irish Trade, Tourism and Investment to 2015*.

Department of Finance (2010) *National Recovery Plan 2011-2014*.

Department of Finance (2015) *Building on Recovery – Infrastructure and Capital Investment 2016-2021*.

Department of Jobs, Enterprise and Innovation (2015) *Action Plan for Jobs 2015*.

Department of Jobs, Enterprise and Innovation (2015) *Enterprise 2025*.

Department of Public Expenditure and Reform (2015) *Capital Investment Plan, Building on Recovery: Infrastructure and Capital Investment 2016-2021*.

Department of the Environment and Local Government (2002), *National Spatial Strategy 2000–2020*.

Department of the Taoiseach (2008) *Building Ireland's Smart Economy: A Framework for Sustainable Economic Renewal*.

Government Publications Office (1997), *Making Ireland's Development Sustainable, Review, Assessment and Future Action 2002*.

Government Publications Office (2007), *Ireland – National Development Plan 2007-2013*.

Government Publications Office (2007), *National Climate Change Strategy*.

Interdepartmental Committee on Science, Technology and Innovation (2015) *Innovation 2020*.

South West Regional Authority (2010), *Regional Planning Guidelines 2010 – 2022*.

Southern Regional Assembly (2014) *Southern and Eastern Regional Operational Programme 2014-2020*.

6 Population and Human Health

6.1 Introduction

This chapter of the EIS consists of an appraisal of the proposed IE43 Biotech Manufacturing Facility Extension hereafter referred to as the proposed IE43 extension, under the heading of population and human health

This chapter initially sets out the methodology followed (**Section 6.2**) and describes the receiving environment (**Section 6.3**). The main characteristics of the proposed development which are of relevance for human beings are described (**Section 6.4**). The likely significant impacts of the proposed development on human beings are described (**Section 6.5**), measures are proposed to mitigate likely significant impacts (**Section 6.6**), and residual impacts are described (**Section 6.7**). The chapter concludes with a reference section (**Section 6.8**).

6.2 Methodology

6.2.1 Baseline Description

6.2.1.1 Introduction

This assessment was conducted by reviewing the current socio-economic status in the vicinity of the proposed development. The Lilly site is located within the Bandon Electoral Division. Baseline information with respect to the demographic and employment characteristics of the resident population within the catchment area was sourced from the 2006, 2011 and 2016 Censuses (where available). The data included information on population, number of persons at work and unemployment profile. Information was also sourced from the following documents/websites:

- Cork County Development Plan 2014;
- Bandon Electoral Area Local Area Plan 2015; and
- Central Statistics Office (CSO) website www.CSO.ie.

6.2.2 Strategic Context

For 2015, Central Statistics Office (CSO) figures show that the medical and pharmaceutical sector in Ireland exported products to the value of over €30 billion, 27% of the total national exports in 2015. This represents a 36% increase in the sectors export growth over 2014.

The pharmaceutical industry is an important employer in Ireland. In 2012, 21,576 people in Ireland were employed in the sector “*Chemicals and pharmaceuticals*” (AIA35, CSO 2012).

The pharmaceutical sector is a very important employer of third level graduates. BioPharmaChem Ireland (registered partner of Ibec), states that 46% of people employed in the biopharmaceutical sector are third level graduates.

BioPharmaChem Ireland has valued capital investments in the Irish biopharmaceutical sector at €3 billion (BioPharmaChemical, 2015). Lilly has invested €650 million in new facilities in Ireland over the past 8 years (Eli Lilly via BioPharmChem Ireland, 2016).

The existing site employs approximately 600 permanent employees and 200 - 300 contract staff (250 staff averaged over the year), depending on the level of construction and project activity.

The pharmaceutical industry invests heavily in the training and development of its employees at all levels. It has the reputation of being a good employer, paying above average wages and having a good industrial relations record. The pharmaceutical industry can be seen as firmly anchored in the country due to its nature: long lead-in times for research and development and approval of product ranges plus a very high level of capital expenditure and investment in manufacturing plants. Companies are not likely to close down suddenly due to products becoming obsolete or to move elsewhere for marginal savings in labour unit costs.

In addition to being a very important direct employer, the industry is also responsible for a large number of jobs in the sub-supply sectors including the engineering sector. The employment effects from the pharmaceutical industry can be estimated using the “multiplier effect”, that is for every one full-time direct employee, there will be a spin-off of another job (Economic Impact Survey, Cork Pharmaceutical/Chemical Industry Survey on Employment and Expenditure 1983-1992).

6.3 Receiving Environment

6.3.1 Population

The population of Cork (City and County) rose from 519,032 in 2011 to 542,196 in 2016. This represents a total increase in population of 4.6% during this period. The population of Cork City rose during this time by 5.3% (preliminary data from Census 2016).

The Cork South-West Dáil constituency, which includes both Dunderrow and Kinsale, has shown a population increase of 2.5% from 2011 to 2016 (EP003, CSO 2016).

The CSO online population data is provided in the following **Table 6.1**.

The table outlines the population change and growth rate of Kinsale Town between 2002 and 2011 (2016 census data not yet available). The population of the area showed a decrease of 4.4% in the nine year period.

Table 4.6 of the Indecon International Economic Consultants, RPS and Savills HOK publication (July 2008) *Cork Area Strategic Plan – Strategy for Additional Economic and Population Growth - An Update* gives a projected 2020 population for Kinsale town of 2,551 people.

As can be seen from **Table 6.1** however, the population of Bandon (both town and rural area) and Cork County have increased between 2006 and 2011. The Cork South-West Dáil constituency which includes the towns of Kinsale and Bandon also shows a +2.5% population increase from 2011 to 2016.

Table 6.1: Population of Kinsale Town, Bandon, Cork County and Cork South-West Constituency 2006 - 2016

District	2006	2011	2016	Change from 2006-2011 (%)
Kinsale town	2,298	2,197	Data Unavailable	-4.4
Bandon town	1,721	1,913	Data Unavailable	+11.1
Bandon rural area	20,323	22,726	Data Unavailable	+11.8
Cork County	361,877	399,216	Data Unavailable	+10.3
				Change from 2011-2016 (%)
Cork South-West Constituency	N/A	82,952	85,028	+2.5%

(Data source: CSO website)

6.3.2 Trends in Employment

6.3.2.1 Quarterly National Household Survey

The CSO Quarterly National Household Survey, Quarter 2 (Q2) of 2016 states that 2,014,900 persons were in employment in the State in the second quarter (Q2) of 2016, an increase for that quarter of 56,200 or 2.9%. This compares with an increase in employment of 2.4% in the previous quarter (Q1) and an increase of 3.0% in the year to the second quarter of 2016. Unemployment decreased by 23,400 (-11.1%) in the year to Q2 2016 bringing the total number of persons unemployed to 187,800. This is the sixteenth quarter in succession where unemployment has declined on an annual basis. On a seasonally adjusted basis, employment rose by 20,000 (+1.0%) over the previous quarter (Q1). This follows on from a seasonally adjusted increase in employment of 16,100 (+0.8%) in Q1 2016.

The survey states that in Q2 of 2016, there were 187,000 persons unemployed, a decrease of 23,400 (-11.1%) in the year to Q2 2016. This is the sixteenth quarter in succession where unemployment has declined on an annual basis.

6.3.2.2 Cork Area Strategic Plan – Strategy for Additional Economic and Population Growth – An Update

The CASP Update July 2008 outlines the 2020 job target for both Kinsale and Bandon towns and hinterlands. The following table, taken from the CASP, shows the future jobs requirement for both Kinsale town and Kinsale hinterland for 2020 as being 3,641 which is an increase of 400 jobs or 12%. The future jobs requirement for both Bandon town and Bandon hinterland for 2020 is 8,315 which is an increase of 600 jobs, or 8%.

Table 6.2: Future jobs requirement 2006-2020

Settlement	2020 Jobs Target	Growth needed by 2020
Kinsale town	2,308	200
Kinsale hinterland	1,333	200
Bandon town	4,785	500
Bandon hinterland	3,530	100
Cork Total Ring towns & Rural areas	43,186	8,982

Source: Table 3.9 CASP Update July 2008

6.3.3 Land Use and Local Amenities

The land-uses of the proposed site and of the surrounding area are described in Chapter 3 *Description of the Proposed Development* whilst the landscape and visual character of the site are described in Chapter 7 *Landscape and Visual*.

The Lilly site is surrounded by agricultural land with Dunderrow village being located nearby. There are a number of individual road-side houses and farms in the surrounding area. The proposed development will take place on an area of the Lilly site previously disturbed during the construction of IE43. No economic activity will be displaced by the construction of the proposed IE43 extension.

As discussed in Chapter 7 *Landscape and Visual*, the Kinsale to Innishannon road and other roads in the area are designated as scenic roads. The views from these routes which are required to be preserved are of the Bandon River Valley. The new development will not have a significant impact on these views.

The site has no recreational amenity value.

6.4 Characteristics of the Proposed Development

6.4.1 Construction Phase

The proposed development is expected to take approximately 30 – 36 months to construct and it is envisaged that the average number of construction personnel on site will be 450 personnel and that the peak will be in the region of 550 personnel.

There will also be associated off-site secondary employment and economic activity associated with the supply and fabrication of construction materials and services to the site.

The construction of the proposed development will involve significant capital investment at a similar level to the previous IE43 investment which commenced in 2011.

6.4.2 Operational Phase

When the proposed IE43 extension facility is operational, Lilly anticipate that approximately 150 additional staff will be recruited over a two to five year period. It is expected that an additional number of jobs will be generated in the wider economy as a result of these permanent Lilly jobs.

6.5 Identification of Potential Impacts

The proposed development will have a significant positive impact in terms of employment on the area. Initially an average of 450 workers during the construction phase will be required. During operation, approximately 150 additional staff will be required for the proposed development with hiring taking place over a two to five year period. In terms of amenity, it is not envisaged that the proposed development will have a significant negative impact.

Other impacts on human beings are discussed elsewhere in this EIS. For example, landscape and visual impacts are discussed in Chapter 7 *Landscape and Visual*, traffic impacts are assessed in Chapter 8 *Roads and Traffic* whilst noise and air quality impacts during construction are evaluated in Chapters 9 *Noise and Vibration* and Chapter 10 *Air Quality and Climate* respectively.

There will be no impact on recreational amenity. No significant impact on residential amenity is expected. The development will be confined to the existing site.

All emissions will be controlled and there will be no increased emissions locally.

6.6 Proposed Mitigation Measures

It is not anticipated that any mitigation measures will be required in respect of the socio-economic effects discussed in this Chapter. Other relevant mitigation measures associated with human beings are recommended in Chapter 7 of this EIS: *Landscape and Visual Impact*, Chapter 8 *Roads and Traffic*, Chapter 9 *Noise and Vibration* and Chapter 10 *Air Quality and Climate*.

6.7 Residual Impacts

The residual impact of the proposed development on human beings will be a positive economic and employment effect.

6.8 References

BioPharmaChem Ireland (2016) *Molecules make a difference – A Strategy for the Biopharmaceutical Industry in Ireland*.

Central Statistics Office (2002) *Census of Population*.

Central Statistics Office (2006) *Census of Population*.

Central Statistics Office (2011) *Census of Population Preliminary Results*.

Central Statistics Office (2011) *Quarterly National Household Survey, First Quarter 2011*.

Cork County Council (2009) *County Development Plan*.

Cork County Council (2010) *Bandon Electoral Area Local Area Plan: Public Consultation Draft November 2010*.

Indecon International Consultants RPS and Savills HOK (2008) *Cork Area Strategic Plan – Strategy for Additional Economic and Population Growth - An Update*.

PharmaCchemical Ireland (2010) *Innovation and Excellence – Strategic document PharmaChemical Ireland Strategic Plan*.

The Irish Pharmaceutical & Chemical Manufacturers Federation IPPCMF, (1999) *Survey on Expenditure & Human Resources*.

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7 Landscape and Visual

7.1 Introduction

This chapter of the EIS consists of an appraisal of the proposed IE43 Biotech Manufacturing Facility Extension hereafter referred to as the proposed IE43 extension, under the heading of landscape and visual.

This chapter initially sets out the methodology followed (**Section 7.2**) and describes the receiving environment (**Section 7.3**). The main characteristics of the proposed development which are of relevance for landscape and visual are described (**Section 7.4**). The likely significant impacts of the proposed development on landscape and visual are described (**Section 7.5**), measures are proposed to mitigate likely significant impacts (**Section 7.6**), and residual impacts are described (**Section 7.7**).

This appraisal and chapter has been prepared by Brady Shipman Martin.

7.2 Methodology

7.2.1 Introduction

The visual assessment of the site was carried out in July 2016.

The assessment is made with regard to the vulnerability of the landscape to change and to the location of visual receptors relative to the proposed development. The assessment has had regard to, and the methodology is based on, the EPA Guidelines and Advice Notes as listed in Section 7.2.2 below, and entailed:

- A desktop study of the site in relation to its overall context both locally and regionally.
- The use of aerial photography
- Visiting the site and its environs to assess the following:
 - Quality and type of views in the area
 - The extent of the visual envelope, i.e. the potential area of visibility of the site in the surrounding landscape.

The character and quality of the surrounding landscape was assessed in relation to the position of buildings around the site, the proportion of residential and agricultural development, special landscape features, cultural and historical associations and landform.

A number of important vantage points representative of the views of the site from the surrounding landscape were identified. These were photographed and surveyed and accurate, and verifiable photomontages of the proposed development were produced to assist in the landscape and visual assessment process.

7.2.2 Relevant Guidance and Legislation

The landscape and visual impact assessment has had regard to the following legislation, policy documents and reference material:

- Cork County Council, (2007) Cork County Draft Landscape Strategy.
- Cork County Council, Cork Area Strategic Plan (CASP) 2001-2020.
- Cork County Council (2014) Cork County Development Plan 2014.
- Cork County Council, (2015). Bandon Electoral Area Local Area Plan 2011, 2nd Ed.
- Environmental Protection Agency. (2002) Guidelines on the information to be contained in Environmental Impact Statements.
- Environmental Protection Agency. (2003) Advice Notes on current practice in the preparation of Environmental Impact Statements.
- Environmental Protection Agency. (2015) Draft Revised Guidelines on the information to be contained in Environmental Impact Statements.
- Environmental Protection Agency. (2015) Draft Advice Notes on current practice in the preparation of Environmental Impact Statements.
- Government of Ireland. Planning and Development Acts 2000 (as amended).
- Landscape Institute, and Institute of Environmental Management & Assessment (2002) Guidelines for Landscape and Visual Impact Assessment. 3rd Ed. Oxon: Routledge.

7.2.3 Significance Assessment Criteria

The impact significance criteria used in the assessment are based on the EPA Guidelines, 2002 and Advice Notes, 2003 as set out in Table 7.1, with additions from EPA's 2015 revised draft guidelines and notes. The nature of landscape and visual impacts may be positive, neutral or negative/adverse as defined in Table 7.2. The duration of impacts is as described in the EPA Guidelines and as set out in Table 7.3. The terminology used to define impacts is outlined in Table 7.1.

Table 7.1: Significance of Effects Terminology

Impact Level	Definition
Imperceptible	An impact capable of measurement but without noticeable consequences
Not significant	An impact which causes noticeable changes in the character of the environment but without noticeable consequences.
Slight	An impact which causes noticeable changes in the character of the environment without affecting its sensitivities
Moderate	An impact that alters the character of the environment in a manner that is consistent with the existing and emerging trends
Significant	An impact which, by its character, magnitude, duration or intensity alters a sensitive aspect of the environment
Very significant	An impact, which by its character, magnitude duration or intensity, significantly alters the majority of a sensitive aspect of the environment.
Profound	An impact that obliterates sensitive characteristics

*(Guidance on the information to be contained in Environmental Impact Statements, EPA. 2002). Note; 'Not significant' and 'Very significant' definitions introduced in Draft EPA Revised Guidelines on the information to be contained in Environmental Impact Statements, 2015.

As per the EPA Guidelines, landscape and visual impacts (or effects) can be considered to be negative/adverse, neutral or positive in effect. Impacts are considered where they may be direct, indirect and/or cumulative as appropriate. Impact duration is considered as being Momentary (effects lasting seconds to minutes), Brief (less than a day), Temporary (for up to one year), Short-term (from 1 to 7 years), Medium-term (7 to 15 years), Long-term (from 15 to 60 years) or Permanent (in excess of 60 years).

Table 7.2: Nature of Impacts

Nature of Impact	Description
Positive	A change that improves the quality of the environment
Neutral	A change that does not affect the quality of the environment
Negative/adverse	A change that reduces the quality of the environment.

Table 7.3: Duration of Impacts

Nature of Impact	Description
Momentary	Lasting from seconds to minutes
Brief	Lasting less than a day
Temporary	Lasting one year or less
Short-term	Lasting one to seven years
Medium-term	Lasting seven to fifteen years
Long-term	Lasting fifteen to sixty years
Permanent	Lasting over sixty years

There were no limitations or constraints in carrying out the assessment.

7.2.4 Character and Visibility

Effects on character and views are considered separately in the impact assessment. Impacts on character relate to changes in the particular identity of coherent landscape areas. Impacts on views are considered where there are particular or noticeable views, which would be affected by the development.

Impacts on the character of the landscape include responses, which are felt towards the combined effects of the new development. The significance of impacts on the perceived landscape character will depend mainly on the visual experience of the landscape and on the number of people affected, but also on judgements about how much the change will matter. Other factors will also affect the experience, including sounds, smells, feelings, etc., experienced by those concerned.

7.3 Receiving Environment

7.3.1 Site Context

The site is located at the Eli Lilly (Lilly) pharmaceutical facility located at Dunderrow, Co. Cork (see **Figure 7.0**).

Dunderrow is a small village on the R605 road between Innishannon and Kinsale c.5.5km to the northwest of Kinsale and 6.5km southeast of Innishannon. The surrounding environment is characterised by rolling, agricultural landscape with elevated land to the north and south. The R605 is a scenic route along the Bandon River Valley, with the river lying c.1.5km to the southwest.

The Lilly plant directly adjoins Dunderrow which lies to the north. Over the past 30 years the facilities have expanded and now much of the site is occupied by a mixture of production, production support and administration facilities.

The general level of the site is c. 29.7 site Datum The main entrance to the site is via the R605 road, which runs along the south western boundary of the site and from a local road (Ballyvrin Road) to the north of the site. There are large employee/visitor car parks at the entrances. The main and large construction entrance is situated on the third class road along the northern boundary. The plant covers a wide area and comprises a wide variety of building types and tanks.

Considering the size of the site and the buildings and structures at the plant, the levels of landscape and visual impact of the existing plant on the surrounding landscape are generally slight. This has been achieved through the utilisation of topography, hedgerows, new tree and hedgerow screening which, when seen against the backdrop of the surrounding elevated landscape, help to incorporate the buildings into the landscape. From much of the surrounding landscape the Lilly plant is relatively well screened by existing vegetation and topography.

The north eastern portion of the site is currently occupied by the existing IE43 Biotech Manufacturing Facility. The proposed IE43 extension will be adjacent to this.

The northern boundary of the site adjoins a small country road (Ballyvryn Road) (L3211) and is heavily planted with an evergreen hedge and tree screening along much of its length, breaking at the point of entrance to the existing IE42 and IE43 buildings. The eastern boundary adjoins a small third class road (L7241), extending south from Ballyvryn Cross Roads, with traditional rural hedging along this undeveloped section of the site.

The south western boundary adjoins the R605 road where the main entrance lies, and is planted with a mixture of ornamental evergreen hedges (*Leylandii* and *Grisellinia*) and deciduous Ash (*Fraxinus excelsior*) trees. Above the southern boundary, the site is intersected by a small stream which physically divides the existing developed and undeveloped sections of the site. Small bridges are used as access between the two sections. A thin wooded corridor with a mixture of indigenous hedgerow species, including Hawthorn (*Crataegus*), Ash (*Fraxinus excelsior*) and Alder (*Alnus*), covers the stream along the western portion of the site.

A section of the stream at the eastern part of the site was diverted in 2016 as part of the IE43 development, with the channel now extending further south near the proposed extension area before returning to the original route. There is a large earthen and planted berm to the south of the stream.

The surrounding landscape is very much rural in character, with pastoral and arable agriculture the predominant landuse. There are dispersed rural dwellings throughout the surrounding rolling countryside, together with the linear settlement pattern defining the small village of Dunderrow. The topography of the wider landscape is consistent with the east-west grain of the south Cork region, enclosed by ridges to the north and south. Dunderrow and the Lilly plant are located in a broad undulating valley at the c. 30m OD contour. The northern horizon is defined by a ridgeline running in a general east-west orientation. The ridge to the north has an elevation of over 100m OD (Malin) at a distance of c.1km. The southern horizon is defined by the east-west ridgeline at Tisaxon, 1.5km to the south, and the elevated ridgeline, c.3.5km to the south, from Ringrone to Ballinadee on the southern shore of the Bandon River.

There is a network of regional and third class roads throughout the surrounding landscape. The R605 road leads from Kinsale Town in a northwest direction towards Dunderrow. The R606 follows the Bandon River from Archdeacon Duggan Bridge at Kinsale and joins the R605 at Ballythomas Cross Roads 500m southeast of Dunderrow. A third class road (Ballyvryn Road) (L3211) runs along the northern boundary of the site linking Dunderrow to the townland of Ballyvryn. There is a disused schoolhouse along this road. Opposite the school, there is a site entrance (Ballyvryn Road entrance) into the Lilly plant, currently used by Lilly staff. Some 500m to the east, there is another third class road (L7241) running along the eastern boundary linking the townland of Ballyvryn to Millwater Cross Roads.

7.3.2 Planning Context and Site Significance

Dunderrow is designated in the Cork County Development Plan 2014 and the Bandon Electoral Area Local Area Plan 2011 as a “*Village Nucleus*” with a vision to “*encourage development within the village and restore a village core for local services*” (BEALAP, 2011). The CDP outlines the strategic aim for such settlements to “*Preserve the rural character of village nuclei and encourage small scale expansion at a scale, layout and design that reflects the character of each village ...*”

Most of the Bandon Electoral Area is covered by the Cork Area Strategic Plan (CASP) – a large-scale framework to guide growth at a sub-regional scale within Metropolitan Cork. The CASP includes strategic policy objectives to “*enhance the environmental quality and landscape setting of the Cork sub-region, minimise impacts on ecologically sensitive areas and on built heritage and cultural landscapes*” and “*minimise the effects on rural landscape character*”.

Section 15.3.1 of the BEALAP recognised that “*Dunderrow’s attractive rural setting, ease of access to Innishannon and Kinsale and existing industry has made it an attractive location for development in recent years*”.

Section 15.2.14 of the BEALAP specifically identifies the role of Lilly within the vision for and context of Dunderrow, with references to further development of the site having direct implications for the proposed extension:

“Eli Lilly, a large pharmaceutical firm employing in excess of 450 people has been operating from Dunderrow since 1981. The plant itself is located several hundred metres to the south of the village, and quite distinct from the main body of the village, on the eastern side of the R605. The plant itself is affected by the Seveso II Directive, with a consultation distance of 1,000 meters. Any extension to this existing development will be acceptable in principle subject to the terms of the Directive and the policies and objectives of the County Development Plan.”

With regard to further development of Dunderrow, the BEALAP states the following objective which has implications for the landscape context of the site:

Objective DB-01 (e):

“It is important that any proposed development would not be over-dominant in views of the village when approaching from the east thereby detracting from the attractive character, appearance and setting of Dunderrow.”

7.3.3 Landscape Character and Significance

The character of the landscape is intensively agricultural in nature with rolling, east-west oriented, valley/ridge topography, with a patchwork of various field sizes, typical of the south Cork coastline, bounded by mature but relatively low broadleaf hedgerows with some coniferous plantations on slopes and higher ground.

The site is situated within the landscape character type 7(b): Rolling Patchwork Farmland as identified in the Cork County Draft Landscape Strategy, 2007, and further recognised in the County Development Plan 2014¹. The Strategy lists the landscape as having **medium** value and sensitivity, and as being of **local** importance. The site lies in close proximity (c.1.5km west) to the neighbouring landscape character type 3: Indented Estuarine Coast, largely defined by landscape of and around the Bandon River valley and Kinsale Harbour, with its incised patchwork valley and wooded estuary landscape character. This landscape type is identified as having a very high value and sensitivity, and is of national importance. The site itself and associated landscape type have a more inland landscape setting contributing to its lower levels of value and sensitivity.

Historically, the wider landscape was the setting for the Battle of Kinsale in 1601, although there is no above ground traces of the event or geographical certainty as to its precise location. This is elaborated on with regard to cultural heritage in Chapter 15 *Archaeological, Architectural and Cultural Heritage*.

The Strategy describes Dunderrow as having experienced a significant growth in residential development in recent years. It includes specific reference to Lilly's socio economic role in the area and how the factory "*fits relatively well into the landscape*" – referenced with regard to its appearance at the time of the Strategy in 2008, and in advance of the more recent IE43 building, to which is attached the proposed extension of this study.

Today the existing Lilly plant with its subsequent developments and expansions is generally well screened due to its nestled location and intervening topography, as well as from mature hedgerows and tree lines around the site and within the wider landscape. Only a small number of open views exist of the site, yet the visual impact is slight. For the most part its impact on the rural character of the area is generally neutral.

Overall the environs of the site hold particular landscape values and associated sensitivities, with certain areas and routes designated within the CDP as elaborated in the following sections. Along with ecological value, as evident by the Proposed Natural Heritage Area along a section of the Bandon River c.2.5km west of the site, the wider landscape possesses a rich built heritage, with a number of protected structures including castles, estate houses and churches situated on the slopes of the Bandon River Valley. There is also a large collection of national monuments in the form of archaeological features (e.g. ring fort remains, souterrains, fulacht fias) scattered around the site.

7.3.4 Landscape Designations

The entire neighbouring landscape character type (type 3) corresponds to a '*High Value Landscape*'.

This includes the Bandon River Valley lying immediately south and west of the site.

A number of scenic routes run through this valley in a northwest – southeast orientation, two of which lie close to the site (S62 and S63). The S63 is located along the R605 which borders the southwest boundary of the site. The policies relating to these areas (Volume 1, Chapter 13 of the Cork County Development Plan 2014) read:

“G1 6-2: Draft Landscape Strategy

Ensure that the management of development throughout the County will have regard for the value of the landscape, its character, distinctiveness and sensitivity as recognised in the Cork County Draft Landscape Strategy and its recommendations, in order to minimize the visual and environmental impact of development, particularly in areas designated as High Value Landscapes where higher development standards (layout, design, landscaping, materials used) will be required.”

“GI 7-1: General Views and Prospects

Preserve the character of all important views and prospects, particularly sea views, river or lake views, views of unspoilt mountains, upland or coastal landscapes, views of historical or cultural significance (including buildings and townscapes) and views of natural beauty as recognized in the Draft Landscape Strategy.”

Where a particular area of zoned land has High Value Landscape designation or adjoins a scenic route, this does not mean that development is automatically prohibited. Section 13.7.3 of the CDP states that:

“Whilst advocating the protection of such scenic resources the plan also recognises the fact that all landscapes are living and changing, and therefore in principle it is not proposed that this should give rise to the prohibition of development along these routes, but development, where permitted, should not hinder or obstruct these views and prospects and should be designed and located to minimise their impact. This principle will encourage appropriate landscaping and screen planting of developments along scenic routes.”

7.3.4.1 Designated Scenic Routes

There are a number of designated scenic routes in close proximity to the site (**Figure 7.0**). The policies read:

“GI 7-2: Scenic Routes

Protect the character of those views and prospects obtainable from scenic routes and in particular stretches of scenic routes that have very special views and prospects identified in this plan. The scenic routes identified in this plan are shown on the scenic amenity maps in the CDP Map Browser and are listed in Volume 2 Chapter 5 Scenic Routes of this plan.”

“GI 7-3: Development on Scenic Routes

a) Require those seeking to carry out development in the environs of a scenic route and/or an area with important views and prospects, to demonstrate that there will be no adverse obstruction or degradation of the views towards and from vulnerable landscape features. In such areas, the appropriateness of the design, site layout, and landscaping of the proposed development must be demonstrated along with mitigation measures to prevent significant alterations to the appearance or character of the area.

b) Encourage appropriate landscaping and screen planting of developments along scenic routes which provides guidance in relation to landscaping. (See CDP Chapter 12 Heritage Objective HE 46).”

The S62 ‘R606 & R600 Regional Roads between Kinsale and Ballythomas (Coast Road)’ joins the R605 at Ballythomas Cross Roads c.200m to the southwest of the site. There are glimpsed views of the tops of the existing buildings and structures in the Lilly complex from these cross roads.

The S63 “R605 Regional Road and Local Road between Innishannon and Kinsale via Shippool” runs from Kinsale to Innishannon and also adjoins the south western boundary of the site. There are a number of viewpoints of the Lilly Plant along this road to the southeast at Ardmartin and northwest of the plant at Knocksmall/ Horsehill.

The S65 “Local Roads from Innishannon to Ballinadee to Kinsale Western Bridge” runs along the top of the Bandon River Valley affording views over the Bandon River Estuary and to the wider landscape to the north in which the Lilly plant is located. Due to the intervening distance and vegetation, the Lilly Plant when seen against the backdrop of the elevated hills to the north has a slight visual impact.

7.3.5 Visual Envelope

The visual envelope of the site is indicated in **Figure 7.0**. The visual envelope, i.e. the extent of potential visibility of the site to or from a specific area or feature in the landscape, is defined by the topography and vegetation in the area.

The ridgelines to the north and southeast form the visual envelope. There are views to the elevated ridges to the north at Horsehill and to the northeast at Ballyregan. To the south east, there are views of the ridgeline at Ardmartin to the back of Kinsale. To the south, there are views of the ridgeline at Tisaxon and beyond to the ridgelines at Ringrone. To the west, there are views of the ridgelines at Ballinadee on the western side of the Bandon River.

There are views of the site from a number of adjoining residential properties and roads. For descriptive purposes the residential properties have been amalgamated into groups.

7.3.5.1 Residential properties in the vicinity of the site

Residential Area RA01 (Dunderrow)

The residential properties in this area are clustered around Dunderrow to the northwest of the Lilly plant.

They are generally at a slightly higher elevation and there are views into the Lilly plant. Overall, when viewed against the surrounding agricultural landscape and the ridgelines at Ardmartin, the buildings are generally well absorbed into the surrounding landscape, with particular integration achieved due to the utilisation of intervening topography, vegetation and the green colour of some of the buildings. **Figures 7.1.1, 7.2.1 and 7.3.1.**

Residential Area RA02 (Ballyvrin)

The residential properties in this area to the northeast of the site are at a slightly higher elevation affording some views of the existing plant, particular the more recent IE43 building. However, the plant is seen against the backdrop of the surrounding landscape which helps to reduce the impact of the buildings on the landscape. **Figures 7.4.1**

Residential Area RA04 (Ballyvrin/Ballynamona)

The residential properties in this area to the northeast of the site are at approximately the same elevation as the plant. There are views of some of the higher structures in the plant; however, the impact is slight due to the intermittent nature of the views through the intervening hedgerows and the existing building colours. **Figure 7.6.1.**

Residential Area RA05 (Kilary/Ballywilliam)

The residential properties in this area to the south of Dunderrow have views of the tops of the existing buildings at the Lilly plant. With the topography rising to the south, the views into the site increases further south. The ridgeline at Ballywilliam /Tisaxon forms the visual ridgeline. **Figure 7.5.1.**

Residential Area RA06 (Ardmartin)

A number of dispersed properties in the Ardmartin area are at a relatively high elevation (60-70m contour) and have long range views (c.2.5km) of the existing Lilly plant. The plant is viewed against the backdrop of the clusters of housing in Dunderrow and against the agricultural areas to the north of site, and has a slight impact on views from this area. The openness of the views along this road determine them as the most sensitive in this study.

On the Kinsale to Innishannon Road via Ballinadee, on the south side of the River there are numerous dispersed rural dwellings with views over the Bandon River and to the broad valley in which the Lilly plant is situated. There are long-range views of the plant; however, the visual impact is slight due to the intervening distance. **Figures 7.7.1 and 7.8.1.**

7.3.5.2 Roads

The extents of the views of the existing Lilly plant from surrounding roads are illustrated in **Figure 7.0**. The roads include;

R605 Road between Kinsale and Innishannon via Shippool

When approaching Dunderrow from Kinsale to the southeast, there are vantage points with intermittently open views of the existing site. There are long range views (c.2.5km) from the elevated ridge at Ardmartin. The existing buildings are visible, but are viewed against the backdrop of the clusters of housing in Dunderrow and against the agricultural land to the north of site, which substantially reduces the visual impact of the plant. **Figure 7.8.1**.

When approaching Dunderrow from Innishannon to the northwest, there are views of the existing plant, particularly the western section yet where the green colour of the buildings assists their integration into the landscape. Most of the buildings are screened by the evergreen hedge along the northern boundary of the site; however, some of the larger buildings and structures are visible above the hedge. **Figure 7.2.1**.

The main entrance to the plant is on the R605 close to Dunderrow Cross Roads, through which there are limited views of the buildings due to planted trees and berms. Approximately 100m southeast of this and along the same boundary, there are a number of intermittent glimpsed views of some of the larger buildings through a second smaller entrance. **Figure 7.2.1**

This road is a designated scenic route (S63) in the CDP.

R606 Coast Road between Kinsale and Ballythomas Cross Roads

The R606 joins the R605 road at Ballythomas Cross Roads. Some 200m to the southeast of the cross roads, there is a straight section of road which is directly on the alignment of the Lilly Plant. Previous views of the tops of the buildings have since been closed in due to maturing vegetation and trees, while a small, intervening hill also screens the lower buildings of the site.

This road is a designated scenic route (S62) in the CDP.

Ballyvrin Road along the Northern Boundary of the Site

Views from the road adjoining the northern boundary into the site are limited by the heavily planted evergreen hedge along the boundary. There are occasional, open views of the northern section of the site and buildings from the main entrance to the IE43 building, which is opposite the disused school. There are views of the building above the boundary hedge at Ballyvrin.

Roads to the East of the Site

There are open views of the site from Ballyvrin Cross Roads, especially of the eastern elevation of the IE43 building. The cross roads are at a higher elevation than the site and are located c.750m from the eastern boundary of the site.

The existing buildings are seen against the backdrop of the ridgelines on the western side of the Bandon River at Ballinadee. **Figure 7.4.1.**

There is a small country road (L7241) running north/south and along the eastern boundary of the plant, through the townland of Ballynamona.

This links Ballyvrin Cross Roads to the R605. Due to the hedgerows running along much of the road, there are only a small number of sporadic vantage points of the site through gaps in the hedgerows. **Figure 7.6.1.**

Roads to the South of the Site

South of the R605 road that runs along the southern boundary of the site, there are a number of small third class roads with glimpsed and views of the site and in particular the taller buildings in the plant. **Figure 7.5.1.**

Roads to the South and West of the Bandon River

The road from Kinsale to Innishannon via Ballinadee to the south and west of the Bandon River is generally at a high level (varying between the 50 and 100m contour). There are views over the Bandon River and to the landscape beyond to the north in which the Lilly plant is situated. The extent of the roads in the area that have views of the site are indicated on **Figure 7.6.**

The viewing distance varies from c. 2.5km to 5.5km. Most views of the existing buildings of the site have a backdrop of elevated ridgelines, which combined with the dark colour of the buildings and intervening distance, visually recedes the buildings into the landscape.

At Kilmacsimon, to the north of Ballinadee, there are occasional views in which some of the existing buildings break the skyline, however due to the intervening distance (c.2.5km), the visual impact is slight.

This road ("Road between Innishannon to Ballinadee to Kinsale Western Bridge") is a designated scenic route (S65) in the CDP.

7.4 Characteristics of the Proposed Development

7.4.1 Construction Phase

Construction activities which are of relevance for landscape and visual include excavations, changes to entrances (i.e. temporary use of existing entrance for construction and creating new temporary staff entrance), construction equipment such as cranes, general construction activities and movement of construction staff and vehicles on and off site during construction. Separate carparking and access/egress points will be provided for Lilly staff and construction staff. A temporary entrance will be located to the west of the existing Ballyvrin road entrance. This will be used by Lilly staff during the construction phase whereas the existing Ballyvrin Road entrance will be used for construction traffic only. The temporary entrance will be closed once the construction phase is complete.

7.4.2 Operational Phase

The extension to the existing IE43 biotech manufacturing facility will include administration and manufacturing accommodation over three floors with intermediate service platforms.

The manufacturing element of the IE43 extension (referred to as process block extension) will extend outwards from the southern façade of the existing IE43 facility. The administration element of the IE43 extension (referred to as headblock extension) will extend outwards from the north eastern façade of the existing IE43 administration block. Additional staff car parking will be provided via new car parks. Internal site roads, services, hard standing and landscaping are also proposed as part of the development.

Elevations and colour of the proposed extension will be generally in keeping with those of the existing IE43 building. External cladding colour will include a continuation of a combination of moss green and pinewood green, while the louvres on the extension will use anthracite grey.

A full description of all components is provided in Chapter 3.

7.5 Evaluation of Potential Impacts

7.5.1 Construction Impacts

Construction staff and vehicles will enter and leave the site from the existing Ballyvtrin Road entrance which will give rise to landscape and visual impacts upon the local road network (R605 and the Ballyvtrin road along the northern boundary) with construction traffic going to and from the construction site. A temporary staff entrance/exit will be constructed further west along the Ballyvtrin Road. This will lead to a slight to moderate, negative impact on both views and character of these local roads.

Due to previous excavations in association with the IE43 building, altering the ground level to approximately 29m (local bench mark level), excavations will be limited to those required for foundations and services. The earthworks associated with the proposed extension will lead to temporary negative visual impacts from the surrounding landscape arising from the excavation process and earth moving machinery. Any material which is excavated will be reused as engineering fill or for landscaping on the existing berm to the south east or on the proposed berm along the eastern boundary adjacent to the extension. This will result in an increase in land elevation directly to the south and immediate east of the extension.

These impacts however will be short term, and once these works are completed the site will present an ever-improving appearance as internal site landscaping at the construction entrance establishes and matures.

Cranes will be utilised during the construction of the building, and will be visible from much of the surrounding landscape. However, the visual impact will be short term in nature and will cease when construction is complete.

7.5.2 Operational Impacts

Considering the scale of the existing Lilly plant, the overall landscape and visual impacts of the buildings on the surrounding landscape are generally slight. This is achieved by siting the plant at the base of the broad valley at Dunderrow, the provision of a mature evergreen screen around the perimeter of the site and utilisation of a darker colours, particularly the dark green natural cladding of the more western buildings, which help to visually recede some of the larger buildings into the surrounding landscape.

The proposed IE43 extension is a large addition to the site, and once constructed, will lead to some increased levels of cumulative impact on the character of the landscape, albeit to a slight degree in this context, in spite of the overall scale of the entire Lilly site. Its location is such that the building will be nestled into the low ground at this eastern part of the site, and will therefore be largely screened from all but a few locations. It will be most visible from the eastern and northeast locations mentioned.

The design details including setting, elevations, cladding colour and landscaping additionally assist the integration of the extension into the existing landscape, contributing to the generally slight impacts, with only a few viewpoints presenting localised moderate impacts (detailed in the following sections). In this respect the proposal does not detract from the wider character and significance of the receiving landscape.

Visual impact on the designated scenic landscape along the Bandon River will not be significant due to the intervening distance and topography. There may be some long distance glimpse views of the proposed extension between existing buildings on site from the western site of the Bandon River at Kilmacsimon.

Views of the proposed extension from the R605 (S63) and R606 (S62) designated scenic routes should largely comprise intermittent glimpsed views through breaks in hedgerows, and at that will only be of the upper elements of the proposed IE43 extension as it will be nestled into the lower elevations of the eastern part of the site and largely screened from these locations by the higher ground to the south. Glimpsed impacts from these locations will range from none to imperceptible. Notable open views are located on the R605 in Ardmartin where the entire site is clearly visible from elevated land. Again the low-lying setting of the site assists in integration into the landscape, determining slight visual impacts from this vantage point. **Figure 7.7.2 and 7.8.2.**

From the entrance to the site on the R605 at Dunderrow, the proposed extension will not be visible as it will be screened behind the foreground buildings. On the approach into Dunderrow from Innishannon, there will be glimpsed views of the upper elements of the proposed building but for the most part, the proposals will be screened by existing buildings and/or existing trees. Impacts will range from none to slight. **Figures 7.1.2, 7.2.2 and 7.3.2.**

7.5.3 Impacts on Residential Areas

Residential Area RA01 (Dunderrow)

The residential properties in this area clustered around Dunderrow are generally at a slightly higher elevation and have views into the Lilly plant. The proposed extension may be visible in glimpses between the existing buildings, but will be viewed against the backdrop of the elevated ridgeline at Ardmartin. This will lead to a slight, negative visual impact. **Figure 7.1.2, 7.2.2 and 7.3.2.**

Residential Area RA02 (Ballyvrin)

The residential properties in this area to the northeast of the site are at a higher elevation affording views of the existing IE43 building. The proposed extension will be a continuation of the existing built form and will be seen against the backdrop of the rolling agricultural topography to the south. It is worth noting that the building will not break the skyline. Given these factors, the resulting visual impact is deemed to vary from slight to moderate, negative visual impact. **Figure 7.4.2**

Residential Area RA03 (Ballyvrin/Ballynamona)

The residential properties in this area to the east of the site are at approximately the same elevation as the plant. There will be views of the upper parts of the proposed extension behind the existing tree boundaries, resulting in a moderate, negative visual impact. The development from this direction will be set against a backdrop of hills to the south and west with a number of intervening hedgerows. **Figure 7.6.1** represents the most open view of the proposed development from this area. In most other locations in this area the proposed development is largely screened, with impacts therefore varying from imperceptible to moderate negative.

Residential Area RA04 (Kilany/Ballywilliam)

The residential properties in this area to the south of Dunderrow have views of the tops of the existing buildings at the plant. The upper elements of the proposed extension will be partly visible behind the existing buildings on site from some locations in this area leading to a slight, negative visual impact. **Figure 7.5.2.**

Residential Area RA05 (Ardmartin)

A number of dispersed properties in the Ardmartin area are at a relatively high elevation (60-70m contour) and have long range views (c.2.5km) of the Lilly plant. There will be views of the upper parts of proposed extension, but these will be seen in amongst the existing trees and buildings, and always against a backdrop of the clusters of housing in Dunderrow and the agricultural areas to the north of site. Visual impact will be slight and negative. **Figure 7.8.2.**

There will be long-range glimpsed views of the upper elements of the proposed extension from the dispersed rural dwellings on the Ballinadee Road. These will be between the existing buildings on site and against the backdrop of the surrounding landscape. Visual impacts will be slight to imperceptible. **Figure 7.7.2.**

7.5.4 Impact on Roads

R605 Road between Kinsale and Innishannon via Shippool

When approaching Dunderrow from Kinsale to the southeast, there are a number of vantage points of the existing site. There will be long-range glimpse views of the proposed extension from the elevated ridge at Ardmartin, but it will be viewed against the backdrop of the clusters of housing in Dunderrow and against the agricultural areas to the north of the site.

The resulting visual impact will be slight and neutral. **Figure 7.8.2.**

When approaching Dunderrow from Innishannon to the northwest, there are views of the plant. The proposed extension may be partially visible behind the existing buildings on site from the higher elevations of these approach routes, with a resulting visual impact varying from imperceptible to slight, negative. **Figure 7.2.2.**

The entrance to the plant is on the R605 close to Dunderrow Cross Roads. The proposed extension will not be visible from this location. **Figure 7.2.1.**

Figures 7.4.2, 7.5.2, 7.6.2, 7.7.2 illustrate the levels of visual impact experienced from the other third class roads in the Dunderrow area, and while there may be occasional and limited glimpses in the direction of the proposed extension, in general the building will not be visible beyond these viewpoints in such locations.

R606 Coast Road between Kinsale and Ballythomas Cross Roads

The R606 joins the R605 road at Ballythomas Cross Roads. This road is a designated scenic route (S62) in the CDP.

The building will not be visible from this location due to the roadside planting and the intervening topography.

Ballyvrin Road along the Northern Boundary of the Site

Views of the proposed development will be generally limited due to the evergreen planting along the northern boundary of the site, apart from a potential glimpse of the extension at the construction entrance (at present existing staff entrance) and through trees and hedgerows. These will be slight to imperceptible and neutral due to the setting of the extension behind the existing of the IE43 building from this point. Views from the temporary staff entrance will eventually be re-screened once the entrance is closed up and proposed planting is implemented and matures, at which point views will be slight to imperceptible and neutral in terms of visual impact.

Roads to the East of the Site

There are a number of open views of the site from Ballyvrin Cross Roads. The cross roads are at a higher elevation than the site and are located c.750m from the eastern boundary of the site. The upper section of the proposed extension will be visible over the roadside hedgerows, but always against a backdrop of existing vegetation and existing buildings on site, leading to slight, negative visual impact. **Figure 7.4.2.**

A local road runs south from the Ballyvtrin Cross Roads and rises to c.45m OD at a point due east of the site. From here, occasional breaks in the hedgerows will permit views through to the upper portions of the proposed extension, with the lower portions being screened behind existing vegetation. The visual impact from these views is moderate and negative yet very momentarily and locally experienced through narrow glimpsed views through these breaks in mature hedgerows. **Figure 7.6.2.**

Roads to the South of the Site

South of the R605 road that runs along the southern boundary of the site, there are a number of small third class roads with views of the site and in particular the taller buildings in the plant. There may be glimpsed views of the upper parts of the proposed extension leading to a slight, negative visual impact. **Figure 7.5.2.**

Roads to the South and West of the Bandon River

There will be long range glimpsed views of the top of the proposed extension from a number of the roads on the southern side of the Bandon River. Most views of the proposed building will have a backdrop of elevated ridgelines to the north of the site, which combined with the dark colour of the buildings, will visually recede the building into the landscape. Considering the distance of the views, the visual impact will be negligible.

At Kilmacsimon, to the north of Ballinadea, the proposed extension may be partially visible between the existing buildings, however due to the intervening distance (c.2.5km), it is considered that the visual impact will be imperceptible.

7.5.5 Lighting Impacts

There is potential for visual impact to arise due to the requirement to maintain adequate internal lighting levels. To achieve these required levels, lighting will be provided by a combination of low pole and bollard light fittings. The pole fittings will be specified and selected to achieve compliance with dark-sky criteria (i.e. no upward lighting), with precise light control capability. The lamps will be low-impact LED with an anti-glare and cut-off facility. There will be no illuminated building-mounted signage, or flood-lighting of the building facades. Visual impact of the lighting will be slight negative to imperceptible.

7.6 Proposed Mitigation Measures

The primary objective of the proposed mitigation measures will be to minimise negative impacts on the character and views from adjoining residential properties, roads and other public areas. As outlined in the BEALAP 2011, “it is important that new development is provided at a scale, layout and design that reflects the character of the village”.

The Lilly site is a well-established pharmaceutical plant. The boundaries of the site have been planted in the past with an evergreen screen. This has established and grown into an effective visual screen for much of the existing development on the site.

Due to the scale of the proposed building, only the lower portions of the structure will be screened by the existing planting. Soil from the construction site will be used for landscaping and provision of berms to the south and east of the building which will be planted with a mixture of native deciduous and evergreen trees. This will also contribute to a reduction in the visual impact of the building.

As such the primary methods of reducing the visual impact of the building will be through the adoption of simple shapes of varying colours selected from prominent colours within the landscape.

The building will primarily be viewed against a background of elevated hills in tillage and pasture. A mixture of profiled and smooth cladding will be utilised on the exterior of the building. Local natural colour tones will be utilised. The green colours of the existing buildings have been and continue to be effective colours in the rolling landscape of Dunderrow. It is therefore proposed to continue this colour and texture theme with the proposed buildings.

7.7 Residual Impacts

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 impact 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 cumulative landscape and visual impacts will generally range from none to slight. From the north eastern locations, the proximity of some public vantage points will result in an increased degree of impact, as well as from Residential Areas RA02 and RA03 where moderate negative yet very localised impacts are predicted. The buildings will however be set into the landscape, will display colours / textures that assist its blending into the landscape, will be mitigated by tree screening, and only the upper parts will be visible and always against a backdrop of existing vegetation or buildings.

8 Roads and Traffic

8.1 Introduction

This chapter of the EIS consists of an appraisal of the proposed development under the heading of roads and traffic. This chapter initially sets out the methodology followed, describes the receiving environment and summarises the main characteristics of the proposed development which are of relevance for roads and traffic. The likely significant impacts of the proposed development on roads and traffic are described. Measures are proposed, where necessary to mitigate likely significant impacts and residual impacts are described.

8.2 Methodology

This Roads and Traffic assessment has been developed utilising standard industry practices and guidance. A brief description of the methodology behind this assessment is presented below:

- Section 8.3 of this assessment describes the '*Existing Receiving Environment*'. It describes the location of the proposed development in its context to Dunderrow and the surrounding area and gives a detailed description of the local road network, in respect of the proposed development. It also sets out the existing traffic patterns on the local road network.
- Section 8.4 of this assessment sets out the '*Characteristics of the Proposed Development*'. Within this section, the nature of the proposed development is set out, in terms of the traffic anticipated to be generated by the development. It also details the projected trip distribution on the local road network. This section identifies the traffic anticipated to be generated during both the operational stage and construction stages of the development, and sets out the proposed parking provision during both scenarios.
- Section 8.5 of this assessment sets out the '*Evaluation of Impacts*'. This section details the expected background traffic during the opening year of the development, taking into account the approved future year growth rates in accordance with the TII's '*Project Appraisal Guidelines*' Unit 5.5 (*Link-Based Traffic Growth*). The projected traffic generated by the proposed development is then applied to the local road network. This enables an assessment to be carried out on the local road network, and a comparison between the 'without' and 'with' development scenarios both for the opening year and peak construction year. This section also sets out the critical junctions and provides an assessment of each with a summary of the findings in terms of the 'Ratio of Flow to Capacity' and mean maximum queuing. An examination of the potential cumulative impact of the development in conjunction with other proposed developments in the vicinity is also discussed in this section.

- Section 8.6 of this assessment describes the ‘*Mitigation Measures*’ proposed to reduce the impact of the proposed development on the receiving environment.
- Section 8.7 of this assessment identifies any residual impact associated with this proposed development.

8.3 Receiving Environment

8.3.1 Site Location

Dunderrow is located approximately 32 kilometres south west of Cork City and 5 kilometres north-west of Kinsale. The site is bounded by the R605 to the south and west, by the Ballyvryn Road to the north and by agricultural land to the east. Refer to **Figure 8.1**.

8.3.2 Local Road Network

The local road network can be seen in **Figure 8.1** and shows the three primary routes serving Lilly. The first is the R605 serving Kinsale; the second is also via the R605 serving Innishannon and West Cork. The third route is via L3205 (Ballydonagh Road) onto the R607 serving Cork City. The L3205 links the R605 and R607. In addition, the Lilly site is served by the Ballyvryn Road, which is very lightly trafficked. A section of the Ballyvryn Road (between the R605 and the car park entrance located on the Ballyvryn Road) was previously widened by Lilly in advance of the construction of the IE43 Biotech Manufacturing facility.

The R605 is a regional road linking Innishannon and Kinsale. It is a two-lane, single carriageway road of approximate width of 6.0m in the vicinity of the Lilly plant, with no hard shoulders or verges along the majority of the route.

The speed limit along the R605 is 80 km/h for the most part, however this reduces to 50 km/h in the vicinity of the Lilly facility, through the R605 / Ballyvryn Road signalised junction.

The horizontal profile of the R605 is varied, with numerous tight bends and smaller curve radii. The width of the R605 reduces to approximately 5.0m to the north between Dunderrow and Innishannon.

The L3205 is a local road linking the R605 and R607. It is a two-lane, single carriageway road along most of its length, albeit with no road markings in sections.

The L3205 has similar characteristics to the R605 in terms of road width and horizontal alignment. The speed limit along the L3205 is 80 km/hr.

The junction of the R605 and Ballyvryn Road is a traffic signal controlled junction. This junction was upgraded to a signalised junction in advance of the construction of the Lilly IE30 facility. This junction is a 3-arm junction operating on a 2 stage configuration. No pedestrian facilities are present at this junction.

The junction of the R605 and L3205 is a 3-arm priority junction with the L3205 (Ballydonaghy Road) being the minor arm of the junction. This junction is skewed, with the minor arm approaching the R605 at an angle.

As a result, visibility to the right of the minor arm is restricted on approach to the junction, however this improves significantly at the stop line.

8.3.3 Access to Lilly

The Lilly site is currently served by three access junctions, as shown in **Figure 8.2**. The Lilly Main Access Junction (Entrance 1) is located off the R605 at the western end of the site, closest to the Ballyvryn Road junction, and serves staff and deliveries to the site. The Lilly Secondary Access Junction (Entrance 2) is located off the R605, to the south of Entrance 1, and serves staff and contractor traffic. The Lilly Third Access Junction to the existing IE43 facility (Entrance 3) is located off the Ballyvryn Road at the northern end of the site. Entrance 3 currently acts as the access point for staff in the IE43, IE42 and IE30 buildings.

8.3.4 Existing Traffic Patterns

In order to assess the impact of the generated traffic on the surrounding road network, an examination of existing traffic flows was necessary. Traffic counts were carried out on Tuesday 12th of July 2016 between 07:00 – 10:00 and 16:00 – 19:00 at key junctions in the vicinity of the site. These time periods are typically the busiest in terms of traffic generation. The network morning peak hour was identified as being from 07:15 – 08:15 at the R605 / Ballyvryn Road junction and 07:00-08:00 at the R605 / L3205 junction. The network evening peak hour was identified as being from 16:00 – 17:00. The development morning peak (this is the time period when the existing Lilly facility generates most traffic) was identified as 07:15 – 08:15. The development evening peak period aligns with the network peak period (16:00 – 17:00).

Traffic counts were carried out at the following junctions:

1. R605/ Ballydonaghy Road (L3205) Junction;
2. R605/ Ballyvryn Road Junction;
3. R605/ Lilly Main Access Junction (Entrance 1);
4. R605/ Lilly Secondary Access Junction (Entrance 2); and
5. Ballyvryn Road/ Lilly Third Access Junction (Entrance 3).

The locations of each of the traffic counts undertaken are shown below in **Figure 8.3**.

The peak hour link counts on the surrounding road network can be seen in **Table 8.1** below.

Table 8.1: Existing Two-Way Traffic Flows

Link	AM Peak (07:15 – 08:15)	PM Peak (16:00 – 17:00)
R605 (North of Ballydonaghy Road)	209	215
Ballydonaghy Road (L3205)	175	175
R605 (South of Ballydonaghy Road)	380	382
R605 (North of Ballyvryn Road)	402	393
Ballyvryn Road (West of Entrance 3)	116	79
Ballyvryn Road (East of Entrance 3)	30	30
R605 (North of Entrance 1)	362	343
R605 (North of Entrance 2)	276	215
R605 (South of Entrance 2)	190	146
Entrance 1	136	84
Entrance 2	220	201
Entrance 3	112	77

All results are in Vehicles per hour

From **Table 8.1**, it can be seen that the busiest road link is the R605 north of the Ballyvryn Road junction for both the AM and PM peak hours. It can also be seen that the majority of existing traffic on the road network is generated by Lilly indicating that the background traffic, not associated with the Lilly plant, on the road network is very low.

8.4 Characteristics of Proposed Development

8.4.1 Nature of IE43 Extension Development

The proposed development will involve the construction of an extension to the existing biotech manufacturing facility, IE43, within the existing site boundary, along with modifications to the existing car-park. The existing site employs approximately 600 permanent employees and 200 - 300 contract staff (250 staff averaged over the year). The proposed development is anticipated to create in excess of 150 permanent jobs created over a 2 – 5 year period. The maximum anticipated additional staff is 190 and for the purposes of a robust assessment of transport impacts, this figure has been used for examination and analysis. Of these it is anticipated that 70 staff will be day staff working Monday – Friday while the remaining 120 staff will be shift staff, working in 4 rotating shifts. These shifts are proposed to operate 06:00-18:00, 12:00-00:00. The proposed extension will operate on a 24 hour a day, 7 days a week basis.

The additional 190 staff are anticipated to access the Lilly plant via the existing access on the Ballyvrrin road once the plant becomes operational.

During the construction phase of the proposed development, it is proposed that the existing Ballyvrrin access junction (Entrance 3) will be utilised by construction staff and deliveries. A new temporary access junction (Temporary Entrance 4) on the Ballyvrrin Road shall be constructed to the south-west of Entrance 3 to accommodate existing staff for the duration of the construction period. Upon completion of construction, Temporary Entrance 4 will be closed off and existing and new staff will use Entrance 3 from the Ballyvrrin Road.

8.4.2 Projected Traffic Generation

The projected AM and PM peak traffic generation at the Ballyvrrin Road entrance (Entrance 3) has been calculated from comparing the volume of traffic generated by the existing Day Staff at the facility with the existing number of total staff. Table 8.2 outlines the volume of traffic generation associated with the existing 900 staff (600 permanent and 300 contract) based on the recent traffic count data. There are 205 shift staff at the Lilly facility, with the majority arriving and departing outside of the AM and the PM peak traffic periods. Only 20 shift staff arrive and depart during peak hours, and this occurs during the AM peak traffic period, either side of the 8am shift change. For the purposes of trip rate calculation, the existing 185 shift staff at the Lilly plant who currently do not arrive during peak hours, were excluded from peak hour trip rate calculation.

Table 8.2: Traffic Generation - Existing Lilly complex

	In	Out	Total
AM Peak (07:15 – 08:15)	423 vph	5 vph	428 vph
PM Peak (16:00 – 17:00)	16 vph	346 vph	362 vph

Table 8.3 outlines the trip rate calculated for the proposed Day staff at the proposed IE43 extension, based on the current arrivals and departures profile for Day (non-shift) staff at the Lilly facility.

Table 8.3: Trip Rate - Existing Lilly Day Staff

	In	Out	Total
AM Peak (07:15 – 08:15)	0.609	0.007	0.616
PM Peak (16:00 – 17:00)	0.023	0.498	0.521

Based on the projected increase in staff associated with the proposed IE43 extension development during peak hours (70 personnel), the following increase in traffic is expected at the Ballyvrrin Road access junction (Entrance 3) during the AM and PM peak hours during the operational phase. Note, that the additional 120 shift staff anticipated to be generated by the proposed development will not arrive at or depart from the site during the AM or PM peak hours and as such have not been included in the proposed peak hour traffic generation.

Table 8.4: Traffic Generation – IE43 Extension Operational Traffic

	In	Out	Total
AM Peak (07:15 – 08:15)	43 vph	1 vph	44 vph
PM Peak (16:00 – 17:00)	2 vph	35 vph	37 vph

Due to flexi-time, currently in operation at the Lilly plant, it can be seen above that not all 70 day staff are anticipated to arrive during the AM peak hour or depart during the PM peak hour. In addition to staff traffic, the development of the IE43 extension will generate some additional movements associated with the production process. However, it is envisaged that any increase in production traffic will occur outside of the AM and PM peak hours in line with current patterns.

8.4.3 Trip Distribution – Operational Phase

As stated previously, employee traffic associated with the IE43 extension will use the entrance to the site from Ballyvrin Road (Entrance 3). It is anticipated that operational traffic generated by the proposed development will mirror the distribution of existing traffic generated by the existing development.

In line with Lilly policy, all traffic accessing the Ballyvrin Road entrance, except for local traffic, is instructed to utilise the R605. This has been demonstrated in the traffic surveys undertaken, which identified that only 2.9% of traffic arriving at the Lilly site turned left into Entrance 3 from the Ballyvrin Road during the AM peak hour, while 3.5% of traffic leaving Lilly in the PM peak turned right out of entrance 3 onto the Ballyvrin Road.

Currently during the AM peak hour, 38.8% of arrivals originate along the R605 north of the Ballydonaghy Road junction, 35.1% originate from the Ballydonaghy Road, and 23.2% of arrivals originate along the R605 south from the direction of Kinsale.

It is anticipated that all traffic generated by the proposed development will access the Lilly site via Entrance 3 on the Ballyvrin Road. It is therefore expected that 73.9% of arrivals shall travel along the R605 north and turn left onto the Ballyvrin Road while 23.2% of arrivals will travel along the R605 south and turn right onto the Ballyvrin Road. The remaining 2.9% are anticipated to be local arrivals via the Ballyvrin Road north.

Currently during the PM peak hour, 96.5% of departures traffic turns left out of Entrance 3 and travels along the Ballyvrin Road to the R605. At this junction 25.3% turns left onto the R605 towards Kinsale, while 71.3% turns right onto the R605 towards Innishannon. At the Ballydonaghy Road junction, 35.4% of departures turn right onto the Ballydonaghy Road while the remaining 35.9% continue along the R605 towards Innishannon. It is anticipated that additional operational traffic for the proposed development will mirror this distribution.

8.4.4 Traffic Assignment – Operational Phase

Using the traffic generation outlined in **Table 8.4**, traffic from the proposed development was assigned to the surrounding road network links. The results of this exercise can be viewed in **Table 8.5**.

Table 8.5: Projected Two Way Traffic Flows

Link	AM Peak (07:15 – 08:15)	PM Peak (16:00 – 17:00)
R605 (North of Ballydonaghy Road)	237 vph	239 vph
Ballydonaghy Road (L3025)	199 vph	197 vph
R605 (South of Ballydonaghy Road)	432 vph	428 vph
R605 (North of Ballyvrrin Road)	455 vph	440 vph
Ballyvrrin Road (West of Entrance)	164 vph	118 vph
Ballyvrrin Road (East of Entrance)	33 vph	33 vph
R605 (North of Entrance 1)	391 vph	370 vph
R605 (North of Entrance 2)	301 vph	320 vph
R605 (South of Entrance 2)	210 vph	247 vph
Entrance 1	143 vph	88 vph
Entrance 2	232 vph	212 vph
Entrance 3	167 vph	118 vph

8.4.5 Car Parking – Operational Phase

Currently there are 389 parking spaces provided at the car-park located adjacent to the IE43 building, serving the IE43, IE42 and IE30 buildings. Upon completion of construction, it is proposed to increase this existing car-park by 136 spaces to accommodate the maximum of 190 additional staff. Due to the shift times envisaged, it is anticipated that at peak time for parking demand (between 12:00 – 16:00 Mon-Fri) there will be up to 130 additional staff on site. These comprise the 70 no. day staff, 30 no. 12:00-00:00 shift workers and 30 no. 06:00-18:00 staff. Additionally parking spaces are necessary to accommodate the overlap at shift change times. The proposed provision of 136 additional parking spaces is considered satisfactory to accommodate the anticipated maximum 190 additional staff associated with the proposed IE43 extension.

The existing Cork County Development Plan would permit a maximum of 605 additional spaces for the proposed IE43 extension based on the following information:

Table 8.6: Proposed Car Parking Assessment

	Proposed Area of land use / m ²	Development Plan Parking Standard Allowance	Total Parking Spaces Permitted
Office	2,000	1 space per 17m ²	117
Industrial	24,400	1 space per 50m ²	488
Total			605

As can be seen, under the current development plan, 605 spaces could be permitted, therefore, the proposed additional car parking provision of 136 car park spaces complies with the current Cork County Development Plan.

8.4.6 Construction Generated Traffic

8.4.6.1 Construction Staff

The proposed development is expected to take approximately 30 – 36 months to construct and it is envisaged that the average number of construction personnel on site will be 450 personnel and that the peak will be in the region of 550 personnel. The peak construction period in relation to construction staff presence on site is anticipated to occur in 2018. The estimated number of cars/vans entering/leaving the site on a daily basis is shown in **Table 8.7**, based on the following assumptions:

- 100% of construction workers will arrive on site by car / van;
- On average there will be 1.25 construction workers per car / van;
- 80% of construction staff will arrive/depart during the peak hour periods; and
- On average each construction staff vehicle will carry out 3 trips per day.

Table 8.7: Estimated Construction Staff Traffic

	Construction Staff	Daily Traffic	Peak Hour Traffic
Average	450	1,080 trips	288 trips
Peak	550	1,320 trips	352 trips

It should be noted that the above assumptions are considered conservative and are intended to assess the worst case scenario. During the construction of the IE43 facility, Lilly developed a “Road Safety and Car Pooling Strategy” for all IE43 project personnel and construction personnel working for the various construction companies employed at the IE43 project including delivery drivers. Within this strategy Lilly set a target occupancy of 1.8 persons per car. This target was achieved during the construction of the IE43 facility and it is proposed that this strategy will be replicated during the construction of the IE43 extension. However, as stated above, in order to carry out a robust assessment of the road capacity a car occupancy of 1.25 was used for the purposes of analysis.

8.4.6.2 Construction Deliveries

The estimated number of construction delivery trucks/vans entering/leaving the site on a daily basis is shown below in **Table 8.8** and is based on an average 12 hour working day (07:00 -19:00) and has been estimated based on the number of HGV trips generated by the previous construction of the existing IE43 facility. This includes all anticipated construction related deliveries such as those associated with the import and export of materials.

Table 8.8: Estimated Construction Deliveries Traffic

	Duration	Daily Traffic	Peak Hour Traffic
General Construction Deliveries	30 - 36 months	120 trips	10 trips

From **Table 8.8**, it can be seen that the volume of traffic associated with the delivery of construction material is significantly less than the construction personnel traffic during the peak hour periods with only an average of 5 arrivals and 5 departures per hour. It should be noted that a significant volume of the earthworks necessary to accommodate the proposed extension was completed during the construction of the IE43 project and as such the stated volume of construction deliveries can be considered conservative.

8.4.6.3 Total Construction Related Traffic

Table 8.9 presents the total expected volume of traffic associated with the peak construction activities.

Table 8.9: Total Construction Deliveries Traffic

	Daily Traffic	Peak Hour Traffic
Peak	1,320 trips	352 trips
General Construction Deliveries	120 trips	10 trips
TOTAL	1,440 trips	362 trips

8.4.7 Trip Distribution - Construction Phase

During the construction phase of the proposed development, it is proposed that the existing Ballyvrin access junction (Entrance 3) will be utilised by construction staff and deliveries. Construction related traffic will not be permitted to travel on the Ballyvrin Road north east of the site. Therefore construction related traffic will be instructed to access Entrance 3 on Ballyvrin Road, only coming from the R605. This was identified in the Lilly Road Safety and Car Pooling Strategy developed and executed for the previous IE43 construction stage. Signage is currently in-situ at this entrance informing staff of this restriction.

In addition to the restrictions to traffic associated with the proposed development, HGV traffic associated with the proposed development will be contractually instructed to approach the site via the R605. HGV traffic will be instructed not to use the Ballydonaghy Road (L3025). This restriction was also included in the Road Safety and Car Pooling Strategy for the previous IE43 construction stage.

Table 8.10 demonstrates the projected distribution of trips associated with the construction of the proposed extension.

Table 8.10: Traffic Distribution Construction Phase

Link	Trip Distribution	
	Personnel	Deliveries
R605 (North of Ballydonaghy)	40%	70%
Ballydonaghy Road (L3025)	36%	0%
R605 (South of Entrance 2)	24%	30%

8.4.8 Traffic Assignment - Construction Phase

Using the traffic distribution profile outlined in **Table 8.10** above, traffic from the construction phase of the proposed development was assigned to the surrounding road network links. The results of this exercise can be viewed in **Table 8.11**. For the purposed of assessment, the anticipated peak of the construction period has been presented. Throughout the construction period the average traffic volumes anticipated to be generated are approximately 20% lower than the peak traffic.

Table 8.11: Projected Two Way Traffic Flows

Link	AM Peak (07:15 – 08:15)	PM Peak (16:00 – 17:00)
R605 (North of Ballydonaghy Road)	148 vph	148 vph
Ballydonaghy Road (L3025)	127 vph	127 vph
R605 (South of Ballydonaghy Road)	275 vph	275 vph
R605 (North of Ballyvrrin Road)	275 vph	275 vph
Ballyvrrin Road (West of Entrance)	362 vph	362 vph
Ballyvrrin Road (East of Entrance)	0 vph	0 vph
R605 (North of Entrance 1)	87 vph	87 vph
R605 (North of Entrance 2)	87 vph	87 vph
R605 (South of Entrance 2)	87 vph	87 vph
Entrance 1	0 vph	0 vph
Entrance 2	0 vph	0 vph
Entrance 3	362 vph	362 vph

8.4.9 Car Parking –Construction Phase

During the construction stage, it is proposed to temporarily create a new access junction from the Ballyvrrin Road to the Lilly plant at a location south-west of the existing car park access junction. It is proposed to segregate part of the existing car-park and extend both sides in order to provide a separate car park for Lilly staff and construction staff during the construction of the IE43 extension.

It is proposed that this staff car-park will have 400 parking spaces and the construction car-park will have 450 parking spaces. These 450 spaces are to serve a maximum demand of 550 construction workers during the construction period, which will require a minimum car occupancy of 1.25 for construction staff. Lilly has previously developed a Road Safety and Car Pooling Strategy for the construction of the IE43 building. This document aimed to achieve an average car occupancy of 1.8 for construction staff for the duration of the works which was achieved. This document shall be utilised for the construction of the IE43 extension and shall similarly aim to achieve an average car occupancy of 1.8 persons per car for all construction staff on site during the construction period.

Upon completion of the works it is anticipated that up to an additional 190 staff will be employed due to the IE43 extension. It is proposed that the temporary construction car-park will be reconfigured to a more permanent arrangement. This proposal includes the closure of the temporary access onto the Ballyvrin Road and the reconfiguration of the two segregated car-parks into a single car-park comprising 525 parking spaces.

8.5 Evaluation of Impacts

8.5.1 General

The potential impact on the local road network has been assessed by examining the projected traffic flows on the local road network both with and without the proposed IE43 extension development.

The peak periods, AM peak (07:15 – 08:15) and PM peak (16:00 – 17:00) have been examined in order to assess the busiest case in terms of traffic generated by the proposed development.

It is assumed that the proposed development will be operational by 2020. It is anticipated that the peak construction period will occur in 2018. Therefore the 'with construction' scenario has been examined for 2018 and the 'with development' scenario has been examined for the year 2020. Traffic on the existing road network has been increased by 1.3% per annum for cars / LGV's and 0.9% for HGV's in order to establish the base flows for each scenario. This is to account for the growth in background traffic and is in accordance with the NRA's Project Appraisal Guidelines Unit 5.5 Link Based Traffic Growth Forecasting.

8.5.2 Link Flows

The traffic flows for both the 'with' and 'without' development scenario in 2020 are quoted in **Table 8.12** below.

Table 8.12: 2020 Link Flows with and without Proposed Development

Link	Year 2020 without Development		Year 2020 with Development	
	07:15 - 08:15	16:00 – 17:00	07:15 - 08:15	16:00 – 17:00
R605 (North of Ballydonaghy)	220vph	226 vph	237 vph (+8%)	239 vph (+6%)
Ballydonaghy Road (L3025)	184 vph	184 vph	199 vph (+8%)	197 vph (+7%)
R605 (South of Ballydonaghy)	400 vph	402 vph	432 vph (+8%)	428 vph (+6%)
R605 (North of Ballyvrrin Road)	423 vph	414 vph	455 vph (+8%)	440 vph (+6%)
Ballyvrrin Road (West of Entrance)	122 vph	83 vph	164 vph (+34%)	118 vph (+42%)
Ballyvrrin Road (East of Entrance)	32 vph	32 vph	33 vph (+4%)	33 vph (+4%)
R605 (North of Entrance 1)	381 vph	361 vph	391 vph (+3%)	370 vph (+3%)
R605 (North of Entrance 2)	291 vph	311 vph	301 vph (+3%)	320 vph (+3%)
R605 (South of Entrance 2)	200 vph	238 vph	210 vph (+5%)	247 vph (+4%)

It can be seen from **Table 8.12** above, that following the completion of the proposed development it is envisaged that the highest increase in traffic will occur along the Ballyvrrin Road, between the R605 and the site access junction (Entrance 3). This link will experience a percentage increase of 42% during the PM peak hour, however this only equates to an increase of 35 vehicles. Assuming that the peak PM departures are spread out evenly over a 1 hour period, this would equate to approximately 0.6 vehicles per minute or 1 vehicle every 103 seconds. The Ballyvrrin Road was recently widened by Lilly in advance of the construction of IE43 and has been demonstrated to have sufficient capacity to cater for this increase in traffic volumes. The highest total traffic volume is expected to occur on the R605 north of the Ballyvrrin Road junction which is anticipated to experience a two-way flow of 455 vehicles per hour during the AM peak traffic period. The R605 has sufficient capacity to comfortably accommodate a link flow of 455 vehicles per hour.

8.5.3 Junction Analysis

As stated above, the largest increase in traffic associated with the development proposals will be along the Ballyvrrin Road between the R605 and the Entrance 3 to the Lilly site.

Therefore the junctions on the public road network which will experience the largest increase in traffic volumes are the existing Lilly site access junction on the Ballyvrin Road (Entrance 3), the R605 / Ballyvrin Road junction and the R605 / Ballydonaghy Road junction. These junctions have been analysed and the results are presented below.

8.5.3.1 Site Access on Ballyvrin Road

The proposed development, when operational will utilise the existing site access junction on the Ballyvrin Road. This is a standard priority T-junction on a rural road. The junction has been modelled utilising **Junctions 9** software, which is a dedicated software package for the analysis of standard priority junctions (containing the PICADY and ARCADY analysis packages). The 2020 opening year of operation results for the AM and PM peak hours are shown below in **Table 8.13** and **Table 8.14** indicating the 'Queue', 'Delay' and Ratio of Flow to Capacity 'RFC' values for the respective arms of the junction for both the 'with development' and 'without development' scenarios.

Table 8.13: 2020 without Development – Site Access (Entrance 3) / Ballyvrin Road

Approach Arm	AM Peak (07:15 – 08:15)			PM Peak (16:00-17:00)		
	Queue (PCU)	Delay (sec)	RFC (%)	Queue (PCU)	Delay (sec)	RFC (%)
Arm A – Ballyvrin Rd North	-	-	-	-	-	-
Arm B - Site Access (Entrance 3)	0	0	0	0.1	6	13
Arm C – Ballyvrin Rd South	0.2	7	18	0	6	0

It can be seen from the above table that the existing site access junction (Entrance 3) will operate well below capacity in the year 2020 without the proposed development.

Table 8.14: 2020 with Development – Site Access (Entrance 3) / Ballyvrin Road

Approach Arm	AM Peak (07:15 – 08:15)			PM Peak (16:00-17:00)		
	Queue (PCU)	Delay (sec)	RFC (%)	Queue (PCU)	Delay (sec)	RFC (%)
Arm A – Ballyvrin Rd North	-	-	-	-	-	-
Arm B - Site Access (Entrance 3)	0	0	0	0.2	6	18
Arm C – Ballyvrin Rd South	0.3	7	25	0	6	1

It can be seen from the table above that the site access junction (Entrance 3) will operate below capacity in the year 2020 even with the inclusion of the proposed development. This is demonstrated by its maximum RFC value of 25% which is significantly below the desirable maximum RFC value for priority junction of 85%.

8.5.3.2 R605/ Ballyvrin Road Junction

The junction of the R605/ Ballyvrin Road was modelled using LINSIG which is a UK Department of Transport software application designed to model traffic signal controlled junctions. This junction has been modelled as a three arm signalised junction. The results of the analysis can be seen in **Table 8.15** and **Table 8.16** below for the ‘without development’ and ‘with development’ scenarios respectively.

Table 8.15: 2020 without Development – R605/ Ballyvrin Road

Approach Arm	AM Peak (07:15 – 08:15)			PM Peak (16:00-17:00)		
	Queue (PCU)	Delay (sec)	RFC (%)	Queue (PCU)	Delay (sec)	RFC (%)
Arm A- R605 from Innishannon	2	5	28	0.5	5	6
Arm B – Ballyvrin Road	0.3	31	8	1	25	22
Arm C – Arm C – R605 from Kinsale	0.4	4	5	2	6	23

Table 8.16: 2020 with Development – R605/ Ballyvrin Road

Approach Arm	AM Peak (07:15 – 08:15)			PM Peak (16:00-17:00)		
	Queue (PCU)	Delay (sec)	RFC (%)	Queue (PCU)	Delay (sec)	RFC (%)
Arm A- R605 from Innishannon	3	5	30	0.6	7	7
Arm B – Ballyvrin Road	0.3	31	9	2	22	25
Arm C – Arm C – R605 from Kinsale	0.4	4	6	2	8	25

It can be seen from **Table 8.16** above that the junction is expected to have sufficient capacity to accommodate the traffic associated with the proposed development during its operational phase. This is demonstrated by its maximum RFC value of 30% which is below the desirable maximum RFC of 90% for traffic signal controlled junctions.

8.5.3.3 R605 / Ballydonaghy Road Junction

The junction of the R605 and Ballydonaghy Road (L3205) is a 3-arm priority controlled junction. The Ballydonaghy Road has a skewed approach. The junction has been modelled utilising **Junctions 9** software.

The results of the analysis can be seen in **Table 8.17** and **Table 8.18** below for the ‘without development’ and ‘with development’ scenarios respectively:

Table 8.17: 2020 without Development – R605 / Ballydonaghy Road

Approach Arm	AM Peak (07:15 – 08:15)			PM Peak (16:00-17:00)		
	Queue (PCU)	Delay (sec)	RFC (%)	Queue (PCU)	Delay (sec)	RFC (%)
Arm A – R605 North	-	-	-	-	-	-
Arm B – Ballydonaghy Road	0.5	10	33	0	8	3
Arm C – R605 South	0	6	3	0.6	7	34

Table 8.18: 2020 with Development – R605 / Ballydonaghy Road

Approach Arm	AM Peak (07:15 – 08:15)			PM Peak (16:00-17:00)		
	Queue (PCU)	Delay (sec)	RFC (%)	Queue (PCU)	Delay (sec)	RFC (%)
Arm A – R605 North	-	-	-	-	-	-
Arm B – Ballydonaghy Road	0.6	10	36	0	8	3
Arm C – R605 South	0	6	3	0.7	8	37

It can be seen from the table above that the R605 / Ballydonaghy Road junction will operate below capacity in the year 2020 even with the inclusion of the proposed development. This is demonstrated by its maximum RFC value of 37% which is significantly below the desirable maximum RFC value for priority junction of 85%.

8.5.4 Potential Impact of Construction Traffic

During the construction phase of the proposed development, it is proposed that the existing Ballyvrin access junction (Entrance 3) will be utilised by construction staff and deliveries. A new temporary access junction (Temporary Entrance 4) on the Ballyvrin Road shall be constructed to the south-west of Entrance 3 to accommodate existing staff for the duration of the construction period. This entrance will be used by staff who currently use the Ballyvrin Road access.

Upon completion of construction, Temporary Entrance 4 will be closed off and existing and new staff will use Entrance 3 from the Ballyvrin Road.

The Ballyvrin Road was widened previously to accommodate the construction of IE30, IE 42 and IE43 and has been demonstrated to be adequate to accommodate construction traffic.

It is expected that construction traffic will have a more pronounced impact on local traffic volumes compared to the operational phase of the development. However, this impact will be temporary in nature and will cease following completion of the development. It is worth noting that the level of construction traffic associated with the proposed development is of a similar level as the IE43 project, which was completed within the Lilly facility in recent years. During the construction phase of the IE43 project, construction traffic was well managed and there was limited impact on traffic conditions on the surrounding road network.

As with the operational traffic; the peak periods, AM peak (07:15 – 08:15), and PM peak (16:00 – 17:00) have been examined in order to assess the impact of the construction traffic on the local road network. The proposed development is expected to experience the peak of construction activity in 2018. Traffic on the existing road network has been increased by 1.3% per annum for cars / LGV's and 0.9% for HGV's in order to establish the base flows for 2018. This is to account for the growth in background traffic and is in accordance with the NRA's Project Appraisal Guidelines Unit 5.5 Link Based Traffic Growth Forecasting.

8.5.4.1 Link Flows

The traffic flows for the construction phase of the works are quoted below in the **Table 8.19**.

Table 8.19: 2018 Link Flows during the Construction Phase

Link	Year 2018 without Construction		Year 2020 with Construction	
	07:15 - 08:15	16:00 – 17:00	07:15 - 08:15	16:00 – 17:00
R605 (North of Ballydonaghy)	214vph	221 vph	362 vph (+69%)	367 vph (+67%)
Ballydonaghy Road (L3025)	180 vph	180 vph	306 vph (+71%)	308 vph (+72%)
R605 (South of Ballydonaghy)	390 vph	392 vph	664 vph (+70%)	667 vph (+70%)
R605 (North of Ballyvrin Road)	412 vph	403 vph	687 vph (+67%)	679 vph (+68%)
Ballyvrin Road (West of Entrance)	119 vph	81 vph	481 vph (+304%)	443 vph (+447%)
Ballyvrin Road (East of Entrance)	31 vph	31 vph	31 vph (0%)	31 vph (+0%)
R605 (North of Entrance 1)	371 vph	352 vph	459 vph (+24%)	438 vph (+25%)
R605 (North of Entrance 2)	283 vph	303 vph	371 vph (+31%)	389 vph (+29%)
R605 (South of Entrance 2)	195 vph	232 vph	282 vph (+45%)	318 vph (+37%)

It can be seen from **Table 8.19** that during the construction phase the road network in and around the Lilly complex will experience a temporary increase in traffic. As the increase in traffic associated with the construction phase is greater than the volume of operational traffic, an assessment of the operation of the site access junctions and the junctions of the R605/ Ballyvrin Road and the R605 / Ballydonaghy Road has been carried out to include the additional traffic associated with the construction traffic.

8.5.4.2 Junction Analysis – Construction Phase

The proposed development, during construction, will utilise the existing site access junction on the Ballyvrrin Road (Entrance 3) for construction generated traffic and utilise a temporary access junction (Entrance 4) for existing staff. These are both standard priority T-junctions on a rural road. These junctions have again been modelled utilising **Junctions 9** software. The 2018 peak construction year for the AM and PM peak hours are shown below in **Table 8.20** and **Table 8.21** indicating the 'Queue', 'Delay' and Ratio of Flow to Capacity 'RFC' values for the respective arms of the junctions for the 'with construction' scenario.

Table 8.20: 2018 with Construction – Site Access (Entrance 3) / Ballyvrrin Road

Approach Arm	AM Peak (07:15 – 08:15)			PM Peak (16:00-17:00)		
	Queue (PCU)	Delay (sec)	RFC (%)	Queue (PCU)	Delay (sec)	RFC (%)
Arm A – Ballyvrrin Rd North	-	-	-	-	-	-
Arm B - Site Access (Entrance 3)	0	10	2	1.3	12	56
Arm C – Ballyvrrin Rd South	1.7	15	63	0.6	11	2

It can be seen from the above table that the existing site access junction (Entrance 3) will operate below capacity in the year 2018 during the construction period.

Table 8.21: 2018 with Construction – Temporary Site Access (Entrance 4) / Ballyvrrin Road

Approach Arm	AM Peak (07:15 – 08:15)			PM Peak (16:00-17:00)		
	Queue (PCU)	Delay (sec)	RFC (%)	Queue (PCU)	Delay (sec)	RFC (%)
Arm A – Ballyvrrin Rd North	-	-	-	-	-	-
Arm B - Site Access (Entrance 3)	0	0	0	0.2	7	15
Arm C – Ballyvrrin Rd South	0.4	5	22	0	7	0

It can be seen from the above table that the proposed temporary site access junction (Entrance 4) will operate below capacity in the year 2018 during the construction period.

The junction of the R605/ Ballyvrrin Road was again modelled using LINSIG and the results of the analysis can be seen in **Table 8.22** and **Table 8.23** below.

Table 8.22: 2018 without Construction – R605/ Ballyvrin Road

Approach Arm	AM Peak (07:15 – 08:15)			PM Peak (16:00-17:00)		
	Queue (PCU)	Delay (sec)	RFC (%)	Queue (PCU)	Delay (sec)	RFC (%)
Arm A- R605 from Innishannon	2	4	27	0.5	5	6
Arm B – Ballyvrin Road	0.3	31	8	1	25	21
Arm C – Arm C – R605 from Kinsale	0.3	4	5	2	6	23

Table 8.23: 2018 with Construction – R605/ Ballyvrin Road

Approach Arm	AM Peak (07:15 – 08:15)			PM Peak (16:00-17:00)		
	Queue (PCU)	Delay (sec)	RFC (%)	Queue (PCU)	Delay (sec)	RFC (%)
Arm A- R605 from Innishannon	5	6	49	1	18	14
Arm B – Ballyvrin Road	0.5	32	13	5	12	46
Arm C – Arm C – R605 from Kinsale	0.9	8	22	4	22	47

It can be seen **Table 8.23** above that the traffic signal controlled junction is expected to have sufficient capacity to accommodate the traffic associated with the proposed extension during its construction phase. As stated previously, this can be considered a robust assessment of the impact of construction traffic, as it examines the peak anticipated construction traffic, and has assumed a conservative vehicle occupancy of 1.25 persons per vehicle. It is proposed that Lilly will apply a Road Safety and Car Pooling Strategy to the construction of the IE43 extension and a target occupancy of 1.8 persons per vehicle for construction workers is anticipated.

In addition to the operation of the above junction, the junction of the R605/ Ballydonaghy Road has also been assessed for construction phase traffic to ensure that this priority controlled junction has sufficient capacity to accommodate the projected increase in traffic associated with the development proposals. The junction of the R605/ Ballydonaghy Road has been assessed using Junctions 9 (PICADY) which is a UK Department of Transport software application designed to model priority controlled junctions. The results of this analysis are shown below in **Table 8.24** and **Table 8.25**.

Table 8.24: 2018 without Construction – R605 / Ballydonaghy Road

Approach Arm	AM Peak (07:15 – 08:15)			PM Peak (16:00-17:00)		
	Queue (PCU)	Delay (sec)	RFC (%)	Queue (PCU)	Delay (sec)	RFC (%)
Arm A – R605 North	-	-	-	-	-	-
Arm B – Ballydonaghy Road	0.5	9	32	0	8	3
Arm C – R605 South	0	6	3	0.6	7	33

Table 8.25: 2018 with Construction – R605 / Ballydonaghy Road

Approach Arm	AM Peak (07:15 – 08:15)			PM Peak (16:00-17:00)		
	Queue (PCU)	Delay (sec)	RFC (%)	Queue (PCU)	Delay (sec)	RFC (%)
Arm A – R605 North	-	-	-	-	-	-
Arm B – Ballydonaghy Road	2	18	61	0	9	3
Arm C – R605 South	0	7	3	2	12	65

It can be seen from **Table 8.25** above that the junction is expected to have sufficient capacity to accommodate the traffic associated with the proposed extension during its construction phase.

8.5.5 Cumulative Impact

While the proposed IE43 extension is a stand-alone project in its own right, an investigation into additional potential developments which could have an impact on the surrounding road network was carried out. There are no defined projects in the immediate term which would have a cumulative impact on traffic. However, it is anticipated that in the medium term there will be upgrades of existing facilities and potentially construction of an additional warehousing facility. There are currently no details of these future site developments and these would be subject to a separate traffic impact assessment prior to planning consent. The analysis of the road network has identified that there is spare capacity at present at each of the junctions with the IE43 extension in place.

8.6 Mitigation Measures

8.6.1 Road Safety and Car Pooling Strategy

In advance of the construction of the existing IE43 facility, Lilly prepared a Car Pooling and Road Safety Strategy which was applicable to all IE43 project personnel and construction personnel working for the various construction companies employed at the IE43 project.

This document set out procedures which all IE43 personnel were obliged to adhere to, including use of permissible routes only to and from the plant, 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.

In addition to this, the strategy identified a mechanism to reduce the volume of traffic entering the Lilly plant through the use of car-pooling. The document identified a target occupancy of 1.8 persons per car entering the site which was monitored by Lilly during the course of construction.

It was found that this target was achieved, thereby significantly reducing the potential number of vehicles on the local road network.

Lilly intends to adopt a similar approach to the construction of the IE43 extension. The Road Safety and Car-Pooling Strategy will be updated and appointed contractors will be obliged to adhere to the policies and procedures contained within the document.

8.6.2 Construction Traffic Management Plan

A construction traffic management plan will be prepared as part of the construction activities on site and will be subject to agreement with Cork County Council. The plan will need to implement all relevant mitigation measures identified in this EIS and the updated Road Safety and Car Pooling Strategy will form an integral part of the plan. The construction traffic management plan will include travel restrictions on all Lilly traffic using Ballyvrin Road to the east of the existing construction entrances.

In addition, HGVs associated with the construction works will be instructed not to use the Ballydonaghy Road (L3025) and all heavy construction traffic will be instructed to use the R605 route only to access the site.

The construction traffic management plan 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.

8.6.3 Temporary Site Access

In order to segregate construction traffic from operational traffic a temporary site access to Lilly will be constructed on the Ballyvrin (Temporary Entrance 4). Lilly staff will utilise this access for the duration of the construction period. Turning movements of Heavy Goods Vehicles and Lilly staff therefore will not occur at the same junction reducing the potential for conflict.

8.6.4 Mobility Management Plan

Lilly has developed a Mobility Management Plan (MMP) for the Dunderrow site, which accompanies this planning application. Refer to **Appendix 8.1** of this EIS. Due to the rural nature of the existing plant, public transport is not readily accessible for Lilly staff. Therefore this MMP focuses on utilising car-pooling in order to reduce the number of vehicles generated by the plant. Lilly has targeted a mode share of 7.5% of staff arriving to work as a passenger with another staff-member in the short term. Should this target be met, it will result in a reduction in the number of vehicles currently accessing the site.

8.6.5 Shift Patterns and Flexi-Time

Lilly currently operates a number of operational shifts at the plant. These shift times are 8am-8pm and 8pm-8am on the western side of the site (accessed from the R605) and 6am-6pm and 12pm-12am on the eastern side of the site (accessed via the Ballyvrin Road).

These current shift patterns do not coincide with the traditional road network peak hours of 8am-9am and 5pm-6pm, or school opening or closing times.

Lilly anticipate that the shift times that will be associated with the IE43 extension will also be 6am-6pm and 12pm-12am. This will reduce the potential impact the proposed development would have on the road network.

In addition to shift patterns, Lilly has a flexi-time policy for non-shift staff. The start time for flexi time staff varies between 07:15 – 09:30 and finish times between 16:00 – 18:15. The results of the traffic count surveys and staff travel survey undertaken as part of the Lilly Mobility Management Plan identified that the peak hours for staff travelling to and from work are currently 07:15-08:15 and 16:00-17:00 which also do not coincide with traditional road network peaks or school opening or closing times.

Lilly proposes to continue this flexi-time policy for non-shift staff anticipated to be employed in the IE43 extension, thereby reducing the impact on the surrounding road network.

8.7 Residual Impacts

The proposed development is expected to generate increased traffic during the construction phase of the IE43 extension. However, all junctions in the vicinity of the proposed development are expected to operate within capacity. The construction period anticipated for the IE43 extension is 30 – 36 months, at which point the proposed temporary access (Temporary Entrance 4) to the Lilly facility from the Ballyvrin Road will be closed off.

Following the construction of IE43 extension there will be an increase in operational traffic generated by the Lilly facility. The results of the junction modelling undertaken on the surrounding road network have indicated that there will be sufficient capacity to comfortably accommodate this additional traffic with no discernible increase in queuing or delay envisaged.

8.8 References

Project Appraisal Guidelines - Unit 5.5 Link Based Traffic Growth Forecasting – National Roads Authority – January 2011.

Road Safety and Car Pooling Strategy –Lilly – July 2012.

Lilly Mobility Management Plan – Arup – August 2016.

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9 Noise and Vibration

9.1 Introduction

This chapter of the EIS addresses noise and vibration in the existing environment, assesses the impact of the proposed IE43 biotech manufacturing facility extension on the ambient environment, proposes mitigation measures where necessary, and considers the residual impact.

This chapter of the EIS consists of an appraisal of the proposed IE43 Biotech Manufacturing Facility Extension hereafter referred to as the proposed IE43 extension, under the heading of noise and vibration.

This chapter initially sets out the methodology followed (**Section 9.2**) and describes the receiving environment (**Section 9.3**). The main characteristics of the proposed development which are of relevance for noise and vibration are described (**Section 9.4**). The likely significant impacts of the proposed development on noise and vibration are described (**Section 9.5**), measures are proposed to mitigate likely significant impacts (**Section 9.6**), and residual impacts are described (**Section 9.7**). The chapter concludes with a reference section (**Section 9.8**).

9.2 Methodology

9.2.1 Modelling Software

Calculations have been completed using SoundPLAN noise modelling software, Version 7.0. The following input data was used to develop the noise model:

- Details of ground topography and ground conditions.
- Noise data from typical plant during construction and operational phases
- Location and height of the nearest sensitive receptors.
- Location and height of on-site buildings

Noise predictions were made using this software according to guidelines specified in ISO 9613-2: Attenuation of Sound Propagation Outdoors: General Method of Calculation, International Organisation for Standardisation, 1996.

9.2.2 Construction phase methodology

Noise levels have been predicted using guidance set out in BS 5228: Code of Practice for Noise and Vibration Control on Construction and Open Sites (Part 1: Noise) (BSI, 2009). The assessment has been conducted to be representative of a worst case scenario. However, it should be noted that the predicted noise levels for construction activities are indicative only and are intended for comparison with the construction noise criteria. If additional noise sources are introduced, noise levels may be higher than those stated and additional noise control measures may be deemed necessary.

The following assumptions have also been made in the preparation of these construction noise prediction calculations:

- A 75% utilisation of equipment over a working day;
- plant and equipment will be located at the north eastern boundary of the site; closest to the nearest noise sensitive locations.

Table 9.1 outlines the typical plant likely to be in use during the construction phase of the development.

Table 9.1: Typical construction noise levels from proposed plant (dB L_{Aeq,1hr})

Phase	Plant Item	Maximum Plant Noise Level at 10m Distance (dB L _{Aeq,1hr}) ¹
Site Clearance & Preparation	Pneumatic breaker	83
	Wheeled loader	79
	Tracked excavator	79
	Dozer	80
	Dump truck	76
General Construction	Circular Saw	84
	Diesel Hoist	78
	Compressor	75
	Generator	74
	Crane	78
	Hydraulic Hammer Piling Rig	83

¹: BS 5228-1 Code of practice for noise and vibration control on construction and open sites.
Noise

9.2.3 Operational Phase Methodology

The noise prediction modelling assessment undertaken for this report considers the impact of operations of the facility on surrounding noise sensitive locations. Jacobs Engineering Ltd provided details of the noise sources and locations.

There are a number of internal noise sources proposed as part of the IE43 extension. These sources will be contained within the building and breakout noise will be minimal.

Details of the noise sources modelled are presented in **Table 9.2**.

Table 9.2: Details of Noise Sources Modelled

Source	Location	Comments	Sound Power Level (dB) of each Source
Sanitary Centrifugal Pumps	Lower ground floor – Room L281	6 No.	97
Vapor Compression WFI Still	Lower ground floor – Room L285	1 No.	100

It is assumed that all sources are operating 24 hours per day.

9.2.4 Limits and Significance Criteria

9.2.4.1 Construction Phase

There is currently no published statutory Irish guidance relating to the maximum allowable noise level that may be generated during the construction phase of a project.

BS 5228-1:2009+A1:2014 Code of Practice for Noise and Vibration Control on Construction and Open Sites - Noise, sets relative construction noise criteria with reference to the existing noise environment. These limits are considered the most appropriate noise limits to apply in this instance as they consider the existing baseline noise environment. The significance criteria are the recommended range of 'total noise' (i.e. the ambient combined with the construction noise) which should not be exceeded for each assigned category. **Table 9.3** sets out construction noise criteria presented in BS5228.

Table 9.3: BS5228 (Part 1) ABC Assessment Categories and Thresholds (BSI, 2014)

Assessment Category and Threshold Value Period L_{Aeq}	Threshold Value in Decibels (dB)		
	A ^{A)}	B ^{B)}	C ^{C)}
Night (23:00-07:00hrs)	45	50	55
Evening ^{D)}	55	60	65
Day (07:00-19:00hrs)	65	70	75

A) Category A: threshold values to use when ambient noise levels (when rounded to the nearest 5dB) are less than these values

B) Category B: threshold values to use when ambient noise levels (when rounded to the nearest 5dB) are the same as category A values

C) Category C: threshold values to use when ambient noise levels (when rounded to the nearest 5dB) are higher than category A

D) 19:00 – 23:00hrs weekdays, 13:00-23:00hrs Saturdays and 07:00-23:00hrs Sundays

As the ambient day-time L_{Aeq} noise levels recorded at the site boundary range from 43 to 60dB, (refer to **Table 9.5**) the A category limits are applicable as specified in **Table 9.3**. Therefore the limits outlined in **Table 9.4** will be applied at the nearest sensitive receptor to the construction works.

Sensitive receptors are defined in BS5228 as any occupied premises outside a site used as a dwelling, place of worship, educational establishment, hospital or similar institution or any other property likely to be adversely affected by an increase in noise level.

Table 9.4: Noise Limits to be applied based on BS5228 Criteria

Assessment Category and Threshold Value Period L_{Aeq}	A
Night (23:00-07:00hrs)	45
Evening (19:00-23:00hrs)	55
Day (07:00-19:00hrs)	65

The total noise (L_{Aeq}) which should not be exceeded during daytime is therefore 65dB. . Working outside normal hours may be necessitated through consideration of safety or 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 strictly controlled. Lilly will notify Cork County Council if works outside normal working hours are required. It should be noted that a significant portion of the work will take place indoors, once the IE43 extension building is constructed.

Continuous Flight Auger (CFA) piling may be used during the construction phase. This is the quietest form of piling and is a fast and very economical technique. In accordance with the TII guidelines, a vibration limit for human tolerance of 2.5mm/s will be implemented at the nearest sensitive receptor. Limits of 8mm/s at a frequency of less than 10Hz, 12.5mm/s at a frequency of between 10 and 50Hz and 20mm/s at a frequency of greater than 50Hz will be applied to avoid the risk of cosmetic damage to buildings. Table 9.5 outlines the significance criteria for increases in noise due to traffic as provided by the Design Manual for Roads and Bridges (DMRB, Volume 11, Section 3, Part 11) based on a change in L_{A10} . Link roads where an increase in AADT of greater than 25% occurs are considered in the assessment, in accordance with TII guidance. No links are predicted to experience traffic increases greater than 25% during the operational phase of the development. Refer to Chapter 8 *Roads and Traffic* for further details.

Table 9.5: Classification of magnitude of noise impacts in the short term (DMRB, 2011)

Noise Change $L_{A10,18hr}$	Magnitude of impact
0	No change
0.1-0.9	Negligible
1-2.9	Minor
3-4.9	Moderate
5+	Major

9.2.4.2 Operational Phase

During the operational phase of the development, the noise from the facility must comply with the Industrial Emissions Licence Limits. Schedule B.4 of the current IE licence (P0009-003) specifies limits of 45 dB(A) and 55 dB(A) L_{Aeq} (30 mins) for night and daytime operations at noise sensitive locations, respectively. It is expected that a new evening time limit of 50dB L_{Aeq} will be introduced as part of the IE licence review for the site in accordance with the EPA Guidance Note for Noise, Licence Applications, Surveys and Assessments in Relation to Licensed Sites (NG4).

It was also deemed appropriate to apply significance criteria through consideration of predicted changes in noise level due to the proposed development. This was done by calculating the change in L_{Aeq} and categorising the significance (refer to **Table 9.6**).

Table 9.6 Changes in Noise Level – Significance Criteria

Change in Sound Level (dB)	Subjective Reaction	Significance Level
<3	Inaudible	Imperceptible
4-5	Perceptible	Slight
6-10	Up to doubling of loudness	Moderate
11-15 >16	Over a doubling of loudness	Significant Profound

Source: Based on a number of noise documents including EPA Guidelines, BS4142 and PPG24

9.3 Receiving Environment

9.3.1 Annual noise monitoring

Lilly personnel currently conduct annual noise monitoring at a number of locations in the vicinity of the site. Monitoring is carried out in accordance with the current IE licence requirements (P0009-03), ISO 1996 Part 1 and 2 Description and Measurement of Environmental Noise (1996 and 2007) and with BS 4142: Method for Rating Industrial Noise Affecting Mixed Residential and Industrial Areas.

Triplicate samples are measured at each location over 30 minute durations. Monitoring is carried out using a Cirrus Data Logging Integrating Sound Level Meter with external condenser microphone cartridge mounted on a tripod at a height of 1.8 m above ground. The system is calibrated using the Cirrus calibrator.

Schedule B.4 of the IE licence specifies limits of 45 dB(A) and 55 dB(A) L_{Aeq} (30 mins) for night and daytime operations at noise sensitive locations respectively.

The noise monitoring locations are shown in **Figure 9.1**. The noise levels shown in **Table 9.7** are ranges of triplicate samples taken during the 2015 noise survey.

Table 9.7: Noise Monitoring Results (2015)

Name	Location	L _{A90} (30 mins) Noise Level (dB)	
		Daytime	Night-time
M1	Disused National School	42	43
M2	Behind the security building	44	40
M3	Soccer pitches	44	36
M4	Car park at the south west of the main facility	36	31
M5	South of containment pond adjacent to TOC hut	40	*45

*A fast flowing stream dominated the night-time results.

The 2015 monitoring results are within the licensed noise daytime and night-time limits. Therefore, the impact of noise from the facility on the nearest residences which are located further from the facility than the monitoring points is currently not significant.

9.3.2 Vibration

No vibration monitoring is conducted to determine the existing vibration environment as there are no current activities on site which give rise to vibration to any appreciable degree.

9.4 Characteristics of the Proposed Development

9.4.1 Construction Phase

Construction activities which are of relevance for noise and vibration include excavations, piling, general construction activities and movement of vehicles on site during construction. Refer to Section 9.5 below for details on potential impacts.

9.4.2 Operational Phase

The extension to the existing IE43 biotech manufacturing facility will include administration and manufacturing accommodation over three floors with intermediate service platforms. The manufacturing element of the IE43 extension (referred to as process block extension) will extend outwards from the southern façade of the existing IE43 facility. The administration element of the IE43 extension (referred to as headblock extension) will extend outwards from the north eastern façade of the existing IE43 administration block. Additional staff car parking will be provided via new car parks. Internal site roads, services, hard standing and landscaping are also proposed as part of the development. Activities which are of relevance for noise and vibration during the operational phase include noise emissions arising from the buildings and noise emissions arising from additional traffic. Refer to Section 9.5 below for details on potential impacts.

9.5 Evaluation of Impacts

9.5.1 Construction Phase Impact Assessment

The proposed construction works are expected to take approximately 30 months with hours of construction from 08:00-19:00 Monday to Friday and 09:00 to 16:00 Saturdays. Although there may occasionally be the need to work outside the normal hours of construction, heavy or noisy construction activities will be minimised during these periods.

A variety of items of plant will be in use for the purposes of site clearance, preparation and construction activities. Due to the nature of these activities, there is potential for the generation of noise.

Table 9.8 details the results from the modelling of noise emissions during the construction phase. Levels are provided at the façade of the worst-case sensitive receptor, N1. The locations N1, N2, N3 and N4 were considered in the assessment, refer to Figure 9.2.

Table 9.8: Construction Noise Modelling Results

Construction Phase	Predicted $L_{Aeq,1hr}$ at worst-case sensitive receptor - N1 (dB)
Site clearance and preparation	50
General Construction (including piling)	55

During site construction works, the maximum predicted total noise level due to the construction phase of the IE43 extension of 50dB is predicted to comply with the BS5228 daytime limit of 65dB. 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 impact on the local environment is not considered to be significant.

An assessment of the changes in traffic volumes due to the construction phase of the IE43 extension was also undertaken based on traffic information provided in **Chapter 8 Roads and Traffic**.

Sensitive receptors that are adjacent to link roads where construction traffic is predicted to increase by more than 25% were assessed and impacts associated with the increase are rated in accordance with **Table 9.5**. **Table 9.9** presents the receptors assessed, see **Figure 9.2** for sensitive receptor locations.

Table 9.9: Construction Traffic Modelling Results

Receptor Location (see Figure 9.2)	Do Nothing Value (without proposed development) (dB)	Do Something Value (with proposed development) (dB)	Increase (dB)	Significance Rating
R01	59	61	1.8	Minor
R02	57	59	2.2	Minor
R03	62	64	1.9	Minor
R04	66	68	1.8	Minor

Construction works are not anticipated to give rise to any appreciable vibration.

9.5.2 Operation Phase Noise Assessment

The impact of noise from the proposed facility was determined by comparing the existing baseline noise environment to the proposed situation with the proposed noise sources in operation, refer to Table 9.2. The baseline levels used in the assessment for sensitive receptors were based on the nearest monitoring points to the receptors. Predicted values are compared to the baseline level for daytime and night-time in **Tables 9.9** and **9.10** respectively.

Table 9.9 Summary of Daytime Noise Level Model Outputs at Sensitive Receptors during operational phase

Receptor Location (see Figure 9.2)	Existing Measured Noise level at nearest monitoring locations	Predicted Noise levels with IE43 extension	Increase in Predicted Noise Level	Impact
	dB(A) L _{A90}	dB(A) L _{Aeq}	dB(A) L _{Aeq}	
N1	42	42	0	No impact
N2	44	44	0	No impact
N3	40	41	1	Imperceptible
N4	42	42	0	No impact

Table 9.10 Summary of Night-time Noise Level Model Outputs at Sensitive Receptors during operational phase

Receptor Location (see Figure 9.2)	Existing Measured Noise level at nearest monitoring locations	Predicted Noise levels with IE43 extension	Increase in Predicted Noise Level	Impact
	dB(A) L _{A90}	dB(A) L _{Aeq}	dB(A) L _{Aeq}	
N1	43	43	0	No impact
N2	36	36	0	No impact
N3	45*	45	0	No impact
N4	43	43	0	No impact

*Noise from a nearby flowing stream dominated the night-time noise survey.

There is no significant increase in noise levels predicted at the noise sensitive locations due to the operation of IE43 extension and levels will continue to comply with IE licence limits. Based on the predicted noise levels, values will also comply with a likely evening time limit of 50dB_{L_{Aeq}}.

9.6 Mitigation Measures

Whilst the construction phase is not expected to give rise to noise impacts, as a matter of good practice, reference will be made to BS5228 (BSI, 2014) which offers detailed guidance on the control of noise and vibration from demolition and construction activities. However as mentioned earlier, the predicted noise levels during the construction phase are also within the IE licence daytime limit.

In general BS5228 advises the following, where necessary:

- Avoid unnecessary revving of engines and switch off equipment when not required;
- Keep internal haul routes well maintained and avoid steep gradients;
- Use rubber linings in, for example, chutes and dumpers to reduce impact noise;
- Minimize drop height of materials, and
- Start-up plant and vehicles sequentially rather than all together.

The following more specific measures are also advised:

- In accordance with best practicable means, plant and activities to be employed on site will be reviewed to ensure that they are the quietest available for the required purpose;
- Where required, improved sound reduction methods, e.g. enclosures should be used;
- Site equipment should be located away from noise sensitive areas, as much as is feasible;
- Regular and effective maintenance by trained personnel should be carried out to reduce noise and/or vibration from plant and machinery;
- Limiting the hours during which site activities likely to create high levels of noise or vibration are carried out;
- Establish channels of communication between the contractor/developer, Local Authority and residents;
- Appointing of a site representative responsible for matters relating to noise and vibration; and
- Monitoring typical levels of noise and vibration during critical periods and at sensitive locations for comparison with limits and background levels.

No mitigation measures are required during the operational phase of the development as no impacts are predicted to occur.

9.7 Residual Impacts

No significant residual effects are envisaged during the construction phase following the implementation of mitigation measures outlined above.

The operational phase of the development is not likely to generate significant residual effects.

9.8 References

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British Standards Institution (BSI), 2009. BS 5228-2: 2009 Code of Practice for Noise and Vibration Control on Construction and Open Sites - Vibration. British Standards Institution, United Kingdom.

EPA, 2012. Guidance Note for Noise: Licence Applications, Surveys and Assessments in relation to Scheduled Activities (NG4). Environmental Protection Agency, Wexford, Ireland.

International Electrotechnical Commission (IEC), 2002. IEC 61672-1: Electroacoustics – Sound Level Meters – Part 1: Specifications. IEC, Geneva, Switzerland.

International Standards Organisation (ISO), 2003. ISO 1996-1: Acoustics – Description, measurement and assessment of environmental noise - Part 1: Basic Quantities and Assessment Procedures. ISO, Geneva, Switzerland (2nd edition).

ISO, 2007. ISO 1996-2: Acoustics – Description, measurement and assessment of environmental noise - Part 2: Determination of environmental noise levels. ISO, Geneva, Switzerland (2nd edition)

TII, 2014. Guidance for the Treatment of Noise during the Planning of National Road Schemes. National; Roads Authority, March 2014

10 Air Quality and Climate

10.1 Introduction

This chapter of the EIS consists of an appraisal of the proposed IE43 Biotech Manufacturing Facility Extension hereafter referred to as the proposed IE43 extension, under the heading of air quality and climate.

This chapter initially sets out the methodology followed (**Section 10.2**) and describes the receiving environment (**Section 10.3**) and existing emissions (**Section 10.4**). The main characteristics of the proposed development which are of relevance for air quality and climate are described (**Section 10.5** (air) and **Section 10.9.2** (climate)). The likely significant impacts of the proposed development on air quality are described (**Section 10.6**), measures are proposed to mitigate likely significant impacts (**Section 10.7**), and residual impacts are described (**Section 10.8**). Potential climate impacts are addressed in **Section 10.9**. The chapter concludes with a reference section (**Section 10.11**).

10.2 Methodology

10.2.1 Introduction

This chapter has been prepared having regard to relevant guidance. The air quality standards that regulate ambient air levels in Ireland are described. Existing air quality in the vicinity of Lilly has been assessed against these standards.

10.2.2 Ambient Air Quality Standards

In order to reduce the risk of poor air quality, national and European statutory bodies have set limit values in ambient air for a range of air pollutants. These limit values are set for the protection of human health and ecosystems.

The Air Quality Standards Regulations 2011 (S.I. No. 180 of 2011) transposed EU Directive 2008/50/EC into Irish law. The 2011 Regulations revoked the relevant previous Regulations.

The purpose of the 2011 Regulations is to establish limit values and alert thresholds for concentrations of certain pollutants, to provide for the assessment of certain pollutants using methods and criteria common to other European Member States, to ensure that adequate information on certain pollutant concentrations is obtained and made publically available and to provide for the maintenance and improvement of ambient air quality where necessary.

The limit values established under the 2011 Regulations are included in **Table 10.1** below.

Table 10.1: Air Quality Standards (AQS) from the Air Quality Standards Regulations 2011 (S.I. No. 180 of 2011)

Pollutant	Limit value for the protection of:	Averaging period	Limit value ($\mu\text{g}/\text{m}^3$)	Basis of application of limit value	Limit value attainment date
NO ₂	Human Health	1-hour	200	≤ 18 exceedances p.a. (99.79 %ile)	1 January 2010
		Calendar year	40	Annual mean	1 January 2010
NO _x	Vegetation	Calendar year	30	Annual mean	1 January 2010
PM ₁₀	Human Health	24-hours	50	≤ 35 exceedances p.a. (90%ile)	1 January 2005
		Calendar year	40	Annual mean	1 January 2005
PM _{2.5}	Human Health	Calendar year	25	Annual mean	1 January 2010
		Calendar year	20	Annual mean	1 January 2020

10.2.3 Construction and operational phase impact methodology

10.2.3.1 Significance Criteria

Significance criteria was adopted from the TII air quality guidelines.

Table 10.2 includes significance criteria for the assessment of the potential impact of construction dust off site. Tables 10.3 to Table 10.5 provide a basis for assessing the level of potential air quality impact due to the additional traffic accessing the proposed development during the construction and operational phases.

Table 10.2: Assessment criteria for the impact of dust emissions from construction activities with standard mitigation in place

Source		Potential distance for Significant Effects (Distance from Source)		
Scale	Description	Soiling	PM _{10a}	Vegetation Effects
Major	Large construction sites, with high use of haul routes	100 m	25 m	25 m
Moderate	Moderate sized construction sites, with moderate use of haul routes	50 m	15 m	15 m
Minor	Minor construction sites, with limited use of haul routes	25 m	10 m	10 m

Note: ^a Significance based on the PM₁₀ Limit Values specified in SI No. 180 of 2011, which allows 35 daily exceedances/year of 50 $\mu\text{g}/\text{m}^3$

Table 10.3: Definition of impact magnitude for changes in ambient pollutant concentrations

Magnitude of Change	Annual Mean NO ₂ /PM ₁₀	No. days with PM ₁₀ concentration greater than 50 µg/m ³	Annual Mean PM _{2.5}
Large	Increase/decrease ≥ µg/m ³	Increase/decrease >4 days	Increase/decrease ≥2.5 µg/m ³
Medium	Increase/decrease 2-<4µg/m ³	Increase/decrease 3 or 4 days	Increase/decrease 1.25 -<2.5µg/m ³
Small	Increase/decrease 0.4-<2µg/m ³	Increase/decrease 1 or 2 days	Increase/decrease 0.25-<1.25µg/m ³
Imperceptible	Increase/decrease <0.4µg/m ³	Increase/decrease <1 day	Increase/decrease <0.25µg/m ³

Table 10.4: Air quality impact descriptors for changes to annual mean nitrogen dioxide and PM10 and PM2.5 concentrations at a receptor

Absolute Concentration in Relation to Objective/Limit Value	Change in Concentration ¹		
	Small	Medium	Large
Increase with Scheme			
Above Objective/Limit Value With Scheme (≥40 µg/m ³ of NO ₂ or PM ₁₀) (≥25µg/m ³ of PM _{2.5})	Slight Adverse	Moderate Adverse	Substantial Adverse
Just Below Objective/Limit Value With Scheme (36≤40 µg/m ³ of NO ₂ or PM ₁₀) (22.5≤25µg/m ³ of PM _{2.5})	Slight Adverse	Moderate Adverse	Moderate Adverse
Below Objective/Limit Value With Scheme (30≤36 µg/m ³ of NO ₂ or PM ₁₀) (18.75≤22.5 µg/m ³ of PM _{2.5})	Negligible	Slight Adverse	Slight Adverse
Well Below Objective/Limit Value With Scheme (<30 µg/m ³ of NO ₂ or PM ₁₀) (<18.75µg/m ³ of PM _{2.5})	Negligible	Negligible	Slight Adverse
Decrease with Scheme			
Above Objective/Limit Value Without Scheme (≥40 µg/m ³ of NO ₂ or PM ₁₀) (≥25µg/m ³ of PM _{2.5})	Sight Beneficial	Moderate Beneficial	Substantial Beneficial
Just Below Objective/Limit Value Without Scheme (36-<40 µg/m ³ of NO ₂ or PM ₁₀) (22.5-<25µg/m ³ of PM _{2.5})	Sight Beneficial	Moderate Beneficial	Moderate Beneficial
Below Objective/Limit Value Without Scheme (30-<36 µg/m ³ of NO ₂ or PM ₁₀) (18.75-<22.5 µg/m ³ of PM _{2.5})	Negligible	Slight Beneficial	Slight Beneficial
Well Below Objective/Limit Value Without Scheme (<30 µg/m ³ of NO ₂ or PM ₁₀) (<18.75µg/m ³ of PM _{2.5})	Negligible	Negligible	Slight Beneficial

¹ Where the impact magnitude is imperceptible, then the impact description is negligible.

The scenarios modelled for the purpose of the air quality assessment are as follows:

- The 'Do-Nothing' (DN) Scenario assumes that the proposed development is not constructed with traffic scenarios for the year of construction, 2016, and the year of operation 2018; and
- The 'Do-Something' (DS) Scenario assumes that the proposed development is constructed with traffic scenarios for the year of construction, 2016 and the year of operation, 2018.

The TII Guidelines state that increases in Annual Average Daily Traffic (AADT) flows during the operational and construction phases of less than 5% and 10% respectively are unlikely to result in significant air quality impacts.

The UK Design Manual for Roads and Bridges (DMRB) Screening Method (Version 1.03c) spreadsheet (DMRB, 2007) is used in this assessment. This spreadsheet calculates annual average concentrations of NO₂, PM₁₀ and PM_{2.5}.

The DMRB spreadsheet method computes concentrations of pollutants based on factors including:

- Location and distance of sensitive receptors to road;
- AADT flows;
- Average speed of traffic;
- Traffic composition;
- Road type; and
- Background pollutant concentrations.

Annual average concentrations for the traffic related pollutants NO₂, PM₁₀, and PM_{2.5} were modelled at each receptor located adjacent to roads where changes in AADT of greater than 10% are predicted to occur during the construction phase and greater than 5% occur during the operational phase. The predicted concentrations were compared to the relevant air quality standards.

Background concentrations were taken from EPA background air quality monitoring data for the years 2012, 2013 and 2014 (refer to Section 10.3).

Table 10.6 and Figure 10.2 presents the receptors considered in the assessment. As stated earlier, where changes in AADT of greater than 10% are predicted to occur during the construction phase and greater than 5% occur during the operational phase. In some cases, increases in AADT occur where no sensitive receptors are located. These locations are omitted from the assessment.

Table 10.6: Details of individual receptor locations used in the DMRB model

Receptor Location Reference (see Figure 10.2)	Link Road
R01	R605 (West of Ballydonaghy Road)
R02	Ballydonaghy Road (L3205)
R03	R605 (North of Dunderrow village)
R04	R605 (East of Dunderrow village)
R05	R605 (South of Entrance 2)

10.3 Receiving Environment

Lilly is located in a rural area, in a zone referred to by the Environmental Protection Agency (EPA) as Zone D – Rural Ireland. Air quality is measured by monitoring the levels of various pollutants. This monitoring checks whether air quality meets standards that are considered adequate for the protection of human health and environment.

Table 10.7 outlines the monitoring data provided by the EPA for Zone D for pollutants relevant to the Lilly facility. Where no data is available for Zone D, Zone C or Zone B data is used.

Table 10.7: Baseline monitoring data

Pollutant	Annual mean 2014	Annual mean 2013	Annual mean 2012	Average annual mean (2012-2014)
NO ₂	4.6 µg/m ³	6.3 µg/m ³	6 µg/m ³	5.6 µg/m ³
NO _x	7.5 µg/m ³	8.7 µg/m ³	9.3 µg/m ³	8.5 µg/m ³
SO ₂	2.5 µg/m ³	2.5 µg/m ³	3 µg/m ³	2.6 µg/m ³
CO	450 µg/m ³	300 µg/m ³	200 µg/m ³ ²	316 µg/m ³ ¹
PM ₁₀	10.3 µg/m ³	13 µg/m ³	10.3 µg/m ³	11.2 µg/m ³
PM _{2.5}	9 µg/m ³	12.5 µg/m ³	7.5 µg/m ³	9.7 µg/m ³
Lead ³	1.5 ng/m ³	1.8 ng/m ³	5.5 ng/m ³	2.9 ng/m ³
Arsenic ³	0.3 ng/m ³	0.3 ng/m ³	0.6 ng/m ³	0.4 ng/m ³
Cadmium ³	0.2 ng/m ³	0.2 ng/m ³	0.2 ng/m ³	0.2 ng/m ³
Nickel ³	0.7 ng/m ³	0.4 ng/m ³	0.9 ng/m ³	0.7 ng/m ³
Mercury	No data	1.5 ng/m ³	1.5 ng/m ³	1.5 ng/m ³

¹ EPA Zone B averages, as insufficient data or no data for Zone D

² EPA Zone C averages, as insufficient data or no data for Zone D

³ Monthly levels

All baseline levels measure in Zone D are in compliance with air quality standards.

10.4 Existing Emissions

There are a number of licensed (Industrial Emissions licence, P0009-03) emission points on the site, both main and minor. Main emissions points are listed below in **Table 10.8** below and shown on **Figure 10.1**. Both the existing licence (P0009-003) labels and proposed licence (P0009-04) labels as part of the current licence review are provided.

Table 10.8: Main licensed emission points to air

Proposed Licensed Ref. No. (P009-004)	Existing Licence Ref. (P009-003)	Description
A1-1	4-1	Boiler stack
A1-2	n/a	Proposed additional boiler
A2-1	7-1(a)	Reeco Regenerative Thermal Oxidiser Incinerator
A2-2	7-1 (b)	John Zink (KEU) Thermal oxidiser
A2-3	7-1 (c)	Thermall Thermal Oxidiser*
A2-4	A3-24	Proposed carbon absorber
A2-5	A3-30	Proposed Carbon absorber IE16
A2-6	n/a	CHP unit

* Thermall Unit demolished but emission point retained in the EPA IE licence for possible replacement unit in the future

Emission limit values are set by the licence, limiting the emissions of various parameters. Lilly is required to monitor these parameters in accordance with the requirements of the licence and submit the measurements to the EPA on an annual basis. There were no exceedances of emission limit values for any licenced parameters in 2015.

Other emissions to air associated with the operations at Lilly arise from traffic movements around the site and traffic travelling to and from the site.

None of the solvents used at the Lilly site are malodorous. A potential source of odour emissions is the biological waste water treatment plant. However, the air from the primary settlement tanks and aeration tanks is ducted to a biofilter for treatment. Under normal operation there are no odours from the operation of the existing plant.

10.5 Characteristics of the Proposed Development

10.5.1 Construction Phase

Construction activities which are of relevance for air quality include excavations, general construction activities and movement of vehicles on site during construction. Refer to Section 10.6 below for details on potential impacts.

10.5.2 Operational Phase

The extension to the existing IE43 biotech manufacturing facility will include administration and manufacturing accommodation over three floors with intermediate service platforms. The manufacturing element of the IE43 extension (referred to as process block extension) will extend outwards from the southern façade of the existing IE43 facility. The administration element of the IE43 extension (referred to as headblock extension) will extend outwards from the north eastern façade of the existing IE43 administration block. Additional staff car parking will be provided via new car parks. Internal site roads, services, hard standing and landscaping are also proposed as part of the development. Activities which are of relevance for air quality during the operational phase include air emissions arising from new sources and air emissions arising from additional traffic. Refer to Section 10.6 below for details on potential impacts.

10.6 Evaluation of Impacts

10.6.1 Construction Activities

The construction phase of the development may have a short-term impact on air quality in the immediate vicinity of the site due to activities including:

- Excavations;
- general construction activities;
- movement of vehicles on the site during construction.

The potential for dust emissions will only arise during site clearance 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 TII guidance outlined in Table 10.2, the impact of the proposed development is deemed to be of a moderate scale, with soiling impacts predicted at distances up to 50m from the site works and potential for PM₁₀ and vegetation effects within 15m. As there are no sensitive receptors within 50m of the works, no construction dust impacts are likely.

10.6.2 Construction Traffic

The potential impact on air quality is assessed below for the construction year (2016) under the 'Do Nothing' (DN) and 'Do Something' (DS) scenarios is presented in Table 10.9.

R04 is predicted to be the worst-case receptor in terms of predicted concentration increases due to worst-case construction traffic. At this receptor, annual average concentrations of NO₂ are predicted to be 7.5µg/m³, which complies with the AQS of 40µg/m³; annual average concentrations of PM_{2.5} are predicted to be 10.1µg/m³, which complies with the proposed limit value of 20µg/m³ and the annual average concentrations of PM₁₀ are predicted to be 11.6µg/m³ which complies with the limit value of 40 µg/m³.

All predicted increases in pollutant concentrations presented in Table 10.9 are considered negligible, refer to Tables 10.3 to 10.5. All predicted concentrations are in compliance with air quality standards.

Table 10.9: Predicted pollutant concentrations including background concentrations 2016 – Construction Phase

Receptor	Scenario	NO ₂ (µg/m ³)	PM ₁₀ (µg/m ³)	PM _{2.5} (µg/m ³)
	Limit Values	40	40	25
R01	DN	6.1	11.3	9.8
	DS	6.4	11.4	9.8
	Increase/Decrease DS- DN	0.3	0.0	0.0
R02	DN	6.0	11.3	9.8
	DS	6.2	11.3	9.8
	Increase/Decrease DS- DN	0.3	0.0	0.0
R03	DN	6.5	11.4	9.9
	DS	7.1	11.5	10.0
	Increase/Decrease DS- DN	0.6	0.1	0.1
R04	DN	6.8	11.5	10.0
	DS	7.5	11.6	10.1
	Increase/Decrease DS- DN	0.7	0.1	0.1
R05	DN	6.3	11.4	9.8
	DS	6.6	11.4	9.9
	Increase/Decrease DS- DN	0.3	0.0	0.0

10.6.3 Operational Activities

The products, which will be manufactured in the proposed IE43 biotech manufacturing facility extension will be aqueous based and will not contribute to any significant increase in air emissions.

All process waste gas streams from the proposed development will be discharged directly to atmosphere via filters as there will be no new main emission points as part of the development. Solid wastes will be treated in the existing incinerator. It is proposed to provide minor emission points in the form of emergency relief vents and building air extracts. It is envisaged that there will be no drying operations in the proposed IE43 extension and therefore there will no associated dust emissions from the facility.

The only solvents expected to be used in the proposed facility will be an aqueous ethyl alcohol buffer for resin and Glacial Acetic Acid for buffer makeup. The small volumes of solvent from these operations will be segregated, recovered or sent to the wastewater treatment plant along with other liquid wastes from the facility. Refer to Chapter 11 *Effluent Generation and Treatment* for further detail.

The process air emissions from the building will be classified as minor emission points and will be discharged directly to atmosphere.

The limits on emission to air from the plant, set out in the future IE Licence (P0009-04) will be required to continue to be met when this facility is commissioned. Monitoring will be carried out to confirm compliance. It is not envisaged that the proposed IE43 extension will result in the generation of odours.

10.6.4 Operational Traffic

The potential impact on air quality due to potential traffic emissions was assessed for the opening year (2018) under the 'Do Nothing' (DN) and 'Do Something' (DS) scenarios; results are presented in Table 10.10.

R04 is predicted to be the worst-case receptor in terms of predicted pollutant concentration increases. , Annual average concentrations of NO₂ are predicted to be 6.6µg/m³, which complies with the AQS of 40µg/m³; annual average concentrations of PM_{2.5} are predicted to be 9.7µg/m³, which complies with the proposed limit value of 20µg/m³ and the annual average concentrations of PM₁₀ are predicted to be 11.3µg/m³ which complies with the limit value of 40 µg/m³.

All predicted increases in concentrations presented in Table 10.10 are considered negligible, refer to Tables 10.3 and 10.4. All predicted concentrations are in compliance with air quality standards.

Table 10.10: Predicted pollutant concentrations including background concentrations 2018 – Operational Phase

Receptor	Scenario	NO ₂ (µg/m ³)	PM ₁₀ (µg/m ³)	PM _{2.5} (µg/m ³)
	Limit Values	40	40	25
R02	DN	5.1	11.0	9.4
	DS	5.3	11.0	9.4
	Increase/Decrease DS- DN	0.3	0.0	0.0
R03	DN	5.6	11.1	9.5
	DS	6.2	11.2	9.6
	Increase/Decrease DS- DN	0.6	0.1	0.1
R04	DN	5.9	11.2	9.6
	DS	6.6	11.3	9.7
	Increase/Decrease DS- DN	0.7	0.1	0.1

10.7 Mitigations Measures

10.7.1 Construction Phase

Dust control measures will be implemented during the construction phase as follows:

- Vehicle speeds in the construction site will be strictly limited.
- During very dry periods, dust emissions from heavily trafficked locations will be controlled by spraying surfaces with water.
- A mechanical road sweeper will be used to control mud on roads as required.
- Potentially dusty material being removed from the site will be transported in covered trucks, where the likelihood of emitting dust is high, and during dry weather conditions the area of removal will be sprayed with a mobile tanker on a regular basis to control dust emissions.
- Exhaust emissions from construction plant and equipment operating within the site, including trucks, excavators, diesel generators and compressors, will be controlled by the contractor by insuring that the equipment is well maintained and is operated in accordance to normal good practice.
- If cement is stored in a silo on site, a filter will be fitted to the silo; alternatively ready-mix concrete might be supplied by truck.
- Refer to Chapter 4 *Construction Activities* for further details of dust mitigation measures.

10.7.2 Operational Phase

Proposed emissions from the IE43 biotech manufacturing facility extension will be filtered as appropriate and will be discharged directly to atmosphere. There will be no further abatement required.

No mitigating measures are deemed necessary to minimise odours as the generation of odours on site is not expected to occur.

10.8 Residual Impacts

If the construction mitigation measures outlined above are implemented, the effect of construction on air quality will not be significant. No residual operational impacts are envisaged.

10.9 Climate

Carbon emissions from Lilly are regulated through Greenhouse Gas Emissions Permit, number GHG023-10352-4. This permit allocates 24,650.2 tonnes of CO₂ to Lilly annually.

No significant carbon emissions are likely as a result of the development of the IE43 biotech manufacturing facility extension.

10.10 References

Air Quality Standards Regulations 2011 (S.I. No. 180 of 2011) *Government Publications*, Dublin, Ireland.

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11 Effluent Generation and Treatment

11.1 Introduction

This chapter of the EIS details the wastewater which will be generated and the wastewater management systems which will be utilised by the proposed IE43 Biotech Manufacturing Facility Extension, referred to as the IE43 extension. This section also details the capacity of the system and its regulatory status. The impact of the emissions of treated wastewater (effluent) on the receiving waters is also addressed. The site has considerable wastewater treatment capacity available for the project which is compliant with EU and National requirements.

11.2 Methodology

This chapter has been prepared with information in consultation with Eli Lilly's environmental engineering team at Dunderrow and Jacobs engineering consultants who carried out the proposed IE43 extension design.

11.2.1 Industrial Emissions Licensing

The Eli Lilly site at Dunderrow has operated under an EPA licence since 1994 when such industrial activities were required to be licensed under the Environmental Protection Agency Act 1992 as amended. The EU Industrial Emissions (IE) Directive was transposed into Irish law in 2013. It amended the EPA Act (1992-2013) to incorporate the activities listed in Annex 1 of the Directive. Sites carrying out these listed industrial activities must operate under an IE licence. The Eli Lilly site is subject to Industrial Emissions (IE) licensing, licence number P0009-03. A revised IE licence (P0009-04) is currently in the proposed determination stage and is expected to be in place by year end. IE43 extension will be included in this revised licence. Lilly have assessed the proposed development against the conditions of P0009-04 which are in line with current regulatory requirements

Full details of the conditions of this licence are available on the EPA website, www.epa.ie.

Under the IE licence the EPA sets emission discharge limits. The wastewater discharges within the parameters of the existing licence have been adjudicated upon by the EPA to ensure that no significant adverse environmental impact will or can arise from such discharges.

The IE43 extension project falls within the same category of licensable activity under IE licensing, and has been accommodated within the scope of the current IE licence.

The company is required to ensure that the combination of onsite and (where relevant) off-site treatment facilities combine to conform with best available techniques (BAT), taking into account the BAT Reference (BREF) note for the

Organic Fine Chemical Sector produced by the EU Joint Research – European IPPC Bureau in Seville, Spain, and the relevant Irish BAT Guidance Note.

This project is also required to comply with the relevant wastewater pre-treatment requirements for thermal or chemical inactivation of biotic material appropriate to a Class 1 activity under the Genetically Modified Microorganisms (GMM) Regulations.

There is already sufficient organic and hydraulic treatment capacity available in the Lilly wastewater treatment plant to accommodate the project and to ensure that the wastes receive the necessary treatment to conform to BAT and that there will be no significant residual environmental impact.

11.3 Existing Wastewater Sources and Characteristics

11.3.1 Origin of Wastewater Arising

The existing organic chemical synthesis processes on site give rise to wastewaters which may be characterised as:

- Process wastewater – arising directly and indirectly from manufacturing
- Utility wastewater – steam and hot water generation, purified water production and cooling systems
- Sanitary/foul wastewater – canteen, washrooms and toilets (similar in composition to normal domestic sewage)
- Surface water
- Incinerator quench water

11.3.2 Process Wastewater

Process wastewater arising from the Lilly facility is categorised into either direct or indirect wastewater. Direct wastewater arises directly from the manufacturing process, while indirect wastewater arises from equipment cleaning, floor washing and abatement systems. The direct and indirect wastewater streams generated at Lilly currently, are described below.

11.3.2.1 Direct Process Wastewater

In the case of IE2, IE8, IE16 and IE30, wastewater arises directly from reaction vessels due to a number of processing operations, which are mainly concerned with isolation and purification of products. These wastewater streams are typically characterised by (i) inorganic dissolved solids such as sodium, sulphate, chloride and ammonium contributed by the use of acids, alkalis and inorganic salts in the processes and (ii) degradable organic substances, mainly common organic solvents, with traces of products. The high organic load waste waters are segregated on the basis of their solvent and active pharmaceutical ingredient (API) content and are then appropriately routed to incineration or biological treatment based on the characterisation.

Biowaste (from IE42 & IE43) arises from the direct cellular mass and growth media after the product has been recovered and the entire content is then thermally inactivated prior to discharge to the conventional biological wastewater treatment system. This is a very small fraction of the total wastewater load arising from the process.

11.3.2.2 Indirect Process Wastewater

The sources of indirect process wastewater include equipment cleaning, floor washing and some of the abatement systems employed to control emissions to the atmosphere such as scrubbers. These wastewater streams contain traces of products and organic solvents. Laboratory wastewater is also included in this category.

Rainwater run-off, which is potentially at risk of contamination by process or utility materials (such as from bunds), is also directed to the indirect process wastewater system rather than to the storm water system.

Only wastewaters proven to be biodegradable are directed to the biological wastewater treatment plant (WWTP) as described in Section 11.3.2, refer to **Figure 11.2**.

11.3.3 Utility Wastewater

The 'clean' utility wastewater includes water from steam and hot water generation, purified water production and cooling systems. The wastewater streams arising from these activities are characterised mainly by inorganic dissolved solids as well as residues of proprietary chemical formulations used to treat boiler and cooling water. In the case of boilers and cooling towers, the wastewater is the blowdown, which is necessary to prevent excessive concentrations of dissolved solids, which would give rise to scale formation on heat exchanger surfaces. The wastewater from water purification is the wastewater that arises from regeneration of ion exchange resins and filter back-washing.

Utility wastewater is combined with treated incinerator wastewater in the cooling ponds. A portion of this is recycled back through clarifiers and sand filters to act as make up water for the inorganic wastewater system. The remaining water is discharged with the treated wastewater wastewater to the sea outfall off Sandy Cove in the outer Kinsale Harbour.

11.3.4 Sanitary Wastewater

Sanitary wastewater arises from the canteen, washrooms and toilets and is similar in composition to normal domestic sewage. Sanitary wastewaters are directed to a separate foul sewer system, which terminates at a sanitary inlet sump adjacent to the aeration tanks of the biological wastewater treatment plant. This wastewater is discharged directly to the aeration tanks. The micronutrient content is of benefit to the treatment of the process wastewater. This wastewater is collected in the sanitary sump, T6, and is pumped directly to the aeration basins.

11.3.5 Incinerator Quench Water

The site's incinerator and thermal oxidisers generate scrubber waters and quench waters, which are made up from the utility, groundwater and mains water intake. These quenches typically contain inorganic salts but no organic load. This waste water is sent to the inorganic WWTP.

11.3.6 Storm Water

The existing and proposed storm water drainage systems are described in Chapter 14 *Soils, Geology, Hydrology and Hydrogeology*, of this EIS.

11.3.7 Wastewater Source Segregation

Process and utility wastewater are initially screened for the Best Practicable Environmental Option solution for reuse, recovery and recycling or pre-treatment prior to disposal. Such screening is carried out at various levels to ensure that appropriate decisions can be made from the process design level through to ultimate reuse or disposal. This process can include material substitution or other modifications to make a by-product stream more amenable to or for a treatment process.

As a start point in this process, liquors containing process materials and wastes are classified into:

- Primary liquids (solvent content normally greater than 80% or primary mother liquors).
- Secondary liquids (solvent content less than 20%).
- Aqueous wastewater (solvent content less than 2%).

This initial classification is used primarily to determine the most likely processing route, which might be followed.

Primary Liquids

Primary liquids are most likely to be candidates for solvent recovery, for inter or intra product use where permitted by Food and Drugs Administration /Irish Medicines Board manufacturing licensing or for incineration for calorific recovery where solvent recovery is not desirable or possible.

Secondary Liquids

Secondary liquids are those, which are worthy of consideration for recovery for reuse or for calorific recovery depending on the characterisation of the materials and the energy and cost benefit. Some streams are incinerated for calorific recovery or for simple disposal where other options are precluded by the manufacturing licence or on environmental benefit grounds.

Aqueous Wastewater

Aqueous wastewater are those waste waters from processes and utilities with a solvent content less than 2%.

This wastewater is currently treated on-site in a purpose designed biological WWTP, subject to compliance with the waste acceptance criteria. The operation of the biological WWTP is described in Section 11.5.3 below. Given that the aqueous wastewaters are much lower in terms of organic load, figures in respect of these wastewaters are presented separately from other direct process wastewaters in **Table 11.2**.

The quench water from the incinerators is treated in the inorganic WWTP, refer to **Figure 11.1**.

11.3.8 Wastewater Acceptance Criteria

The choice of aqueous streams for biological treatment is based on a set of acceptance criteria comprising considerations such as:

- Biodegradation
- Presence of active pharmaceutical ingredients
- Recalcitrant COD content
- Inhibition tests
- Osmotic pressure (high mobility ions content)
- Chemical characterisation
- Microtoxicity
- Respirometry/specific oxygen uptake rate
- Pilot trials at representative F/M ratios
- Residual toxicity

Not all of these tests are necessary in all cases but the objective is to ensure that the material is biodegradable and the treatment process or final wastewater is not impaired.

This screening and assessment procedure optimises the use and reuse of resources, water and energy in particular. As will be seen from the description of the biological wastewater treatment plant in section 11.5.3 below, the plant has an inherent capacity and flexibility to handle a wide variety of hydraulic and organic wastewater loads. The utilisation of that treatment capacity and of the subsequent discharge allowances and receiving environment assimilative capacity is dependent on the campaign product mix from time to time.

This flexibility is important both for environmental sustainable performance and for the site's ability to compete for products within the group.

For example, the existing mix of process derived streams gives rise to an organic loading which only utilises some 14.6% of organic design treatment capacity and some 41-50% of hydraulic capacity of the biological treatment plant.

Opportunities to utilise this capacity efficiently by diverting streams from other endpoints are constantly reviewed against the relevant acceptance criteria.

The main existing chemical components, which contribute to the degradable COD load, are typically methanol, ethanol, acetone, glycol and acetates. Of these methanol is a major constituent. The primary alcohols are highly biodegradable but do not contribute much usable carbon for bacterial replication, consequently in this plant the excess sludge generation rate is low.

11.3.9 Aqueous Wastewater Hydraulic and Organic Load

The individual contribution, which each site activity makes to the total volume of aqueous wastewater varies from day-to-day, because of the batch nature of the Lilly operation.

Table 11.1 gives an indication of where this wastewater arises. **Table 11.1** excludes the site sanitary waste at 75m³/day and biowaste.

Table 11.1: Aqueous Wastewater Sources

Source	Aqueous Waste (m ³ /day)	COD Range (mg/litre)	COD Kg	BOD Kg (Note 1)
IE30	115	500-1000	115	57.5
IE34	0	100-150	0	0
IE2	5	2000-5000	10	5
IE8	40	2000-5000	200	100
IE16	20	2000-5000	100	50
IE42	40	500-1000	40	20
IE43	170	500-1000	170	82
IE28	40	100-150	6	3
IE5	5	100-150	0.75	0.4
Cooling Towers	15	100-200	3	1.5
Bunds/Sumps	5	100-150	0.75	0.4
Others	5	100-150	0.75	0.4
Total	460	16,700-38,900	646.25	320.2

Note 1: Estimate

At present the biological wastewater plant is under-loaded and the potential increase in the hydraulic and biodegradable organic load would be both a beneficial, and a more energy effective treatment mechanism than incineration, for appropriate streams.

11.4 Characteristics of Wastewater from the Proposed IE43 Facility Extension

As with the existing IE43 facility, the proposed IE43 extension will generate:

- Direct process wastewater (biowaste)
- Indirect secondary process wastewater
- Indirect aqueous process wastewater
- Utility wastewater ('clean')

The direct 'biowaste' wastewater will primarily be from highly biodegradable growth media for mammalian cells and waste from purification operations (which contains mainly inorganic chromatography buffers) materials. The main wastewaters will be accompanied by cleaning solutions using acidic, caustic and degradable detergents.

The secondary indirect process wastewater contains 20% solvent. This indirect wastewater is sent to the John Zinc (KEU) incinerator on-site for solvent recovery. Refer to Chapter 12 *Waste*.

Indirect aqueous process wastewater from the proposed IE43 extension contains less than 2% solvent. This wastewater stream will contain CIP solutions and the chromatography waste which comprises the bulk of the organic load. The main constituents of this wastewater stream are shown below in **Table 11.2**. These wastewaters will not contain active cellular material as precautionary cellular inactivation is to be performed on the waste streams prior to discharge from the facility. The proposed IE43 extension will add a maximum of 95.28 m³/day of indirect aqueous process wastewater at peak production.

The 'clean' utility waste water from the IE43 extension can be accommodated in the existing water management systems associated with IE43 and IE30. Waste water will be discharged via those systems for recovery and reuse where possible. Any surplus clean water will bypass the biological treatment plant as no organic load is present and will be monitored prior to final discharge in the existing system.

Table 11.2 presents estimated constituents of the biowaste stream and indirect process wastewater or aqueous wastewater stream will be generated by the proposed IE43 extension.

Table 11.2: Constituents of the direct process waste (biowaste) and indirect aqueous process wastewater stream for the proposed IE43 extension

Component	Direct Process Waste (Biowaste)		Indirect Aqueous Process Waste	
	Average kg/day for proposed IE43 T2	Worst Case kg/day proposed IE43 T2	Average kg/day for proposed IE43 T2	Worst Case kg/day proposed IE43 T2
Total dissolved solids	6.64	50.78	372.5	1095.25
Total suspended solids	7.30	58.1	1.66	4.64
Total solids	13.94	108.9	373.82	1099.91
Chemical Oxygen Demand (COD:mg O ₂ /L)	15.27	120.51	241.02	709.48
Total Kjeldahl Nitrogen (TKN:mg/L)	1.32	9.96	10.28	30.54
Ammonia Nitrogen (NH ₃ -N: mg/L)	0.65	4.98	10.62	30.87
Phosphorous-ortho	0.17	0.98	3.31	9.95
Chloride	0.32	2.32	83.98	247.34
Sulfate	0.17	1.32	41.17	121.18
Sodium	0.32	1.32	80	235.05
Potassium	0.32	1.65	2.32	6.31

The above rates are plant generation rates and calculated based on the existing IE43 operations. The wastewater will be routed to the existing IE43 aqueous waste tank and pumped out to the biological wastewater treatment plant at an average rate of 350 litres per minute.

The direct process wastewater from the IE43 extension, or biowaste as it is called, will have similar characteristics to that arising currently in IE42 and existing IE43 (T1) in that the growth media and chromatography elution materials are essentially compatible with mammalian cells, are highly biodegradable and are akin to domestic wastewater. The proposed IE43 extension will add an estimated 3.4m³/day of biowaste at peak production (values estimated based on IE43 T1). The main constituents of the biowaste stream are shown in **Table 11.2**. The above rates are plant generation rates. These will be routed to the IE43 biowaste tank and pumped out to the biological wastewater treatment plant at average rate of 100 litres per minute. The IE43 extension wastewater which will be similar to the existing wastewater streams from IE42 and existing IE43 will beneficially add to the existing load and provide the treatment bacteria with a wide range of nutrients which will enhance stability and treatment performance for the total wastewater mix. The addition of the proposed IE43 extension will be accommodated without causing any net increase in organic wastewater emissions from those already licensed.

11.5 Wastewater Treatment On Site

11.5.1 Overview

The Lilly site has a very wide range of technologies available for the recovery, reuse and treatment prior to disposal of all process wastewater.

These include:

- Inorganic wastewater treatment plant
- Biological wastewater treatment - activated sludge with air stripping, aerosol and off-gas management.
- On-site biosolids dewatering and incineration.

These give a great degree of flexibility and modular response for a multi-product organic synthesis site.

11.5.2 Inorganic Wastewater Treatment Plant

The inorganic WWTP treats the quench water and scrubber blow down from the incineration process. Refer to **Figure 11.1 Inorganic Treatment Plant**.

The treated wastewater is combined with the treated utility wastewater and treated wastewater from the biological WWTP in the cooling ponds before being discharged to the sea outfall off Sandy Cove in the outer Kinsale Harbour.

11.5.3 Biological Wastewater Treatment Plant

The biological WWTP treats the inactivated biowaste (direct process wastewater), indirect aqueous process wastewater, sanitary wastewater and rainwater runoff from bunds.

11.5.3.1 Design Capability and Loadings

The primary design parameters and system configuration of the biological treatment plant are aimed at maintaining:

- a stable Food: Microbes Ratio (F/M) and mean cell age,
- an adequate oxygen supply,
- a viable bacterial population with good settlement characteristics (SSVI),
- avoidance of pH, temperature, osmotic, organic, or hydraulic shocks by proper stream selection and equalisation,
- appropriate bacterial population by sludge wasting.

The current hydraulic load is approximately 500-600m³/day, containing 490kg COD. This equates to approximately 41-50% of the Maximum Design Hydraulic Loading of 1200m³/day for the site biological WWTP with IE43 (T1).

The plant can conservatively cater for the anticipated expanded hydraulic load of 340m³/day and organic loading of 256 kg/COD /day when all current projects are

commissioned. The existing items of plant can be configured to provide an organic loading capacity of 3,360 kg COD/day.

Therefore, the current loads only utilise approximately 14.6% of total available biological capacity and this uptake will only increase to 22% of organic capacity and 78% hydraulic capacity when the IE43 extension facility is operating at peak capacity.

11.5.3.2 Plant Process Configuration

Figure 11.2 is a process flow schematic showing the current equipment trains and capabilities of the biological WWTP. The biological WWTP is described below.

11.5.3.3 Equalisation , pH Correction and Emergency Dump Tank Capacity

Tank 14 (TK -14 in **Figure 11.2**) is the balancing / pH correction system. This has a working volume of 1200m³, which provides >2 days hydraulic balancing at present and will still provide approximately 1 day balancing when the proposed IE43 development has been completed. Emergency dump tank capacity is also provided for off line diversion of unsuitable materials or excess loads.

The normal pH correction is between 6.5 - 8.5 as registered in the aeration basins. Correction in both directions is undertaken by addition of 96% Sulphuric acid or 25% caustic.

11.5.3.4 Aeration Tanks, Contact Tank and Pre-denitrification

The forward feed system allows very fine control of both hydraulic and organic loading to the activated sludge system.

This system comprises four interlinked tanks, T-12, T-9, T-10 and T-11, which provide in excess of 1800m³ of available aeration volume. The tank configuration is multi-purpose and can be used to provide classical aeration, contact tanks or pre-denitrification by selectively routing return activated sludge, forward feed and recycle flows to whichever configuration is required.

11.5.3.5 Off- Gas Management

The aeration tanks are roofed and the off-gases are routed to a biofilter. The biofilter has a capacity of greater than 190,000 Nm³/day air and services both aeration duties and sludge holding tank off-gases.

11.5.3.6 Oxygenation

Oxygenation is provided by subsurface jet aeration and ancillary blowers. At depth this system gives a high level of oxygen transfer efficiency. Dissolved oxygen is monitored in the relevant tankage.

The system is serviced by 57 kW of installed blower capacity and 76 kW jet aeration pump capacity. This has a demonstrated oxygen transfer capacity of 136

kg O₂/hour at an efficiency of 1.02 kg O₂ transferred per kWh absorbed. This provides a very high level of mixing and agitation in addition to oxygen transfer. The efficiency would increase at higher organic loadings.

The capacity at the current efficiency is conservatively estimated at 1600 kg BOD /day or 3360 kg COD /day and with a modest increase in efficiency would increase to 4000 kg COD /day. With the aeration system operating at an MLSS concentration of 5000 mg/l and a COD F/M ratio of 0.1-0.2 kg COD /kg MLSS/day, the BOD and COD removal performance would be in excess of the licence requirements and in excess of BAT. Therefore, in all respects the organic capacity of the plant is conservatively designed.

11.5.3.7 Clarifiers

Two 8m diameter clarifiers are available (T-124 and T- 125). With an effective surface area of 50m², each of the clarifiers are capable of operating at an upward flow rate of 0.25m /hour giving a hydraulic capacity to the system of 25m³ /hour or 600m³/day. The current and proposed hydraulic capacity uptake is approximately 76% average and 90% peak respectively of the available capacity.

Variable sludge return and sludge wastage is possible via the return activated sludge (RAS) pumps.

A scum skimmer separately collects floatables and discharges them to the centrate (centrifuge supernatant) collection system and to the sludge management system.

11.5.3.8 Excess Sludge Management

The excess activated sludge, is directed to and stored in two of the four tanks T-29, T-30, T-25, and T-24. Two tanks are usually devoted to sludge from the biological treatment plant and two to inorganics from the quench water treatment system. These provide aerated storage for up to 40 days depending on excess activated sludge generation rate and loadings. Any excess supernatant liquid can be decanted back to the biological treatment plant via the centrate sump. The sludge is dewatered to 15% solids in a centrifuge via an Indag polymer dosing system and the centrate returned to the biological treatment plant via the centrate sump. The dewatered biosolids are discharged to a skip and transported offsite for incineration.

11.5.3.9 Final Biological Treatment Plant Wastewater Discharge

The wastewater from the clarifiers is discharged to T-37. This is the last chamber of the cooling pond set upstream of the entry to the wet well, T-36, for discharge via the pipeline and sea outfall to the seaward side of Sandycove in Kinsale Harbour.

It is at this point in the system that any unused waters from clean water sources that are routed through the IE30 system and which bypass the biological treatment plant enter the final discharge system.

This chamber, T-36, provides a final pH safeguard with in situ measurement and correction. This chamber also receives the overflow from the incinerator quench system, which has been through a clarification and sand filtration process.

The discharge is provided with flow measurement and flow proportional composite sampling prior to discharge.

11.5.3.10 Treatment of Sanitary Waste

From the sanitary inlet sump T6, the sanitary waste is macerated, screened and pumped to the activated sludge system. The sanitary waste provides essential trace nutrients and cofactors to the treatment heterotrophic bacteria, which are primarily using / degrading process wastewater. This maintains a healthy sludge population, and greatly aids the treatment process.

11.5.3.11 Summary of Biological Treatment Capacity

Table 11.4: Summary of Biological Treatment Capacity

The treatment capacity of the biological treatment plant is summarised in Table 11.4.Type:	Activated Sludge	
Aeration Tank Capacity:	1800 m ³	
Average Daily Operation Capacity:	1200m ³ /day	
Licensed Flow:	3000 m ³ /day	125 m ³ /hour
Average BOD	1600kg/day	
Average COD	3360 kg/day	
Capacity Uptake Projected	22% organically 78% hydraulically	
% Removal Efficiency:	> 98 % BOD Removal > 93 % COD Removal	

11.5.3.12 Cooling Ponds (with prior Filtration)

The clarified or filtered wastewater from the quench system is discharged to the cooling ponds. The overflow from the cooling ponds discharges, via further flow proportional sampling and continuous pH checking and back correction if necessary, to the wet well T-36. In T-36 it is combined with the biological treatment plant final wastewater and discharged to the Sandy Cove outfall.

11.5.3.13 Modifications to the Biological Treatment Plant

As has been demonstrated above, the hydraulic and organic capacities of the biological treatment plant are very conservative for the current organic loads and no physical modifications are necessary to accommodate the IE43 extension.

11.5.3.14 Completed Upgrades

To meet the requirements of the Waste Incineration Directive 2000/76/EC, the incineration process waste water plant was upgraded in 2005. Management of the hydraulic loads associated with the inorganic treatment system was streamlined and enhanced by the addition of an extra clarifier and additional solids removal capability was enhanced by the addition of sand filters. In 2009, the following aspects of the wastewater treatment plant were upgraded:

- Improved WWTP off-gas capture and biofilter upgrade.
- Improved final discharge tank mixing and aeration.
- Ground water protection improvements including double walled underground tanks and piping, hard surfacing under all high risk pipe arbour, relining of WWTP final discharge tanks.

11.5.3.15 Process Control

Process control for both treatment plants is achieved using the plant wide Fox I/A Distributed Control System. This means that the wastewater plant is an integral part of the process reporting and control on site.

11.5.3.16 IE Licence Wastewater Emission Requirements and Compliance

The monitoring point for the discharge from the biological treatment plant is designated emission point 6-1 in the IE licence. The licensed limits for 6-1 are shown in **Table 11.5**.

Table 11.5: IE Licence Emission Limit Values for the Discharge from the Biological Treatment Plant under Licence Ref. P0009-04

Schedule 2(i)	Emissions to Water
Emission Point Reference No:	6-1
Name of Receiving Waters:	Outer Kinsale Harbour
Location: Volume to be emitted:	East of Sandy Cove Island Maximum in any one day: 3000m ³ Maximum rate per hour: 125m ³
Parameter	Emission Limit Value
pH	6-9
Toxicity	10TU
	mg/l
BOD	20
COD	250
Suspended solids	105kg per day
Total Nitrogen	25
Total Ammonia (as N)	10
Total Phosphorous (as P)	150kg per day
Tin	100
Copper	0.5
Zinc	0.6
Benzene Toluene and Xylene	0.1

As can be gauged by the low uptake of treatment capacity, the annual mass emissions are substantially less than the licensed mass emissions.

The biological treatment plant discharges less than the licensed values due to the current site portfolio of products. Although the volume of discharge will rise, it will remain well below the biological treatment plant capacity and the discharge limit. The only variable which normally impacts on these data are on occasions when storm events cause a sharp rise in throughput caused by the increases in volume from surface areas and roofs which discharge via the biological waste water system due to risk considerations.

The site is fully compliant with the requirement under the Protection of the Environment Act 2003, for existing plants, which operate under IE licences, to implement Best Available Techniques (BAT) in the treatment of emissions.

This means that the element of the treatment process to be utilised by the IE43 extension process is available and compliant with the regulations.

Similarly the inorganic system is also compliant with this requirement and the requirements under Article 8 of Directive 2000/76/EC and specified in Annex IV of Directive.

The annual AER (annual environmental report) to the EPA as well as the routine monitoring reports show that the site is well within the discharge limits and achieves the desired removal efficiencies.

11.5.4 BAT Status of the Biological Wastewater Treatment Plant

In the case of wastewater treatment, the BREF note for the general chemical sector and the BREF note for the Organic Fine Chemicals Sector, of which the pharmaceutical sector is a component have been issued.

The biological wastewater treatment plant at the site and the current quoted treatment efficiencies meet all anticipated organic treatment standards.

The current BOD:COD ratios and the treatment efficiencies and characterisation /acceptance criteria are more stringent than those anticipated in the BREF document.

A benchmarking exercise against BAT looks at the entire wastewater treatment system and procedures comprising:

- wastewater screening criteria and upfront pre-treatment,
- scale of operation,
- osmotic and pH stability,
- support analytical capability,
- physiochemical pre-treatment,
- modularity, adaptability and appropriateness of the treatment train,
- operator expertise and involvement,
- production of valid and meaningful monitoring data,
- mechanical reliability and maintenance, and
- energy efficiency.

The Lilly plant implements all of these screening techniques and operational parameters for process control. The operational data logs and the laboratory support systems demonstrate that these techniques are actively used on site and the emission monitoring shows that the site is compliant with the licence as granted.

In terms of the treatment system employed, multi stage activated sludge with contact tanks and pre-denitrification as necessary, the type of plant and the design parameters chosen are well within conservative values for this technology which are listed in all the BREF Notes as appropriate technology.

The biological wastewater treatment plant at Lilly achieves the performance values required but more importantly meets the emission limit values specified and the receiving environment is monitored to ensure that no adverse effects are noted or caused.

Therefore it can be stated with confidence that the system employed on the Lilly site is compliant with all possible interpretations of BAT with respect to normal design parameters as it uses the same acclimated bacteria of any biological variant system in a conservatively designed plant and utilizes all of the relevant process screening and control parameters to maintain process control and record relevant data.

In the case of API control, the pre-screening process is designed to ensure that recalcitrant material is not discharged to the biological treatment plant.

No adverse cross media effects are anticipated as the site can implement the widest possible set of choices for off gas control from aerosol suppression to odour control to fume incineration as necessary.

Similarly, all residual wastewater sludges are incinerated so that all potential pathways to the external environment for recalcitrant materials are controlled.

The IE43 extension wastewater will increase the ratio of highly biodegradable wastewater and will further enhance the stability of the wastewater treatment process.

11.6 Storm Water Management

Storm water management is addressed in Chapter 14 *Soils, Geology, Hydrology and Hydrogeology* (operational phase) and in Chapter 4 *Construction Activities* (construction phase).

11.7 Residual Impact of Treated Wastewater on Receiving Waters

Treated wastewater is discharged through a pipeline to a diffuser about 500m offshore near Sandy Cove Island in the outer Kinsale harbour. Refer to **Figure 11.3**. The receiving waters are used for water sports and fishing and there are beaches within 2km of the emission point.

At present the annual volume of treated wastewater discharged is circa 40% of the licence limit. This will rise to approximately 50% when the IE43 extension is fully operational.

Wastewater dispersion at the outfall location provides a dilution factor of approximately 100,000 as determined by the most recent dye dispersion tests

This has been borne out by results of a modelling study, completed in 2011, by the National University of Ireland, Galway. The study modelled the near field dilution and dispersion of the treated wastewater emissions from the wastewater diffuser at Sandy Cove.

The modelling was performed to investigate whether the receiving surface water body would be compliant with EC Environmental Objectives (Surface Waters) Regulations (*S.I. No. 272/2009*) if the treated wastewater emissions load were discharged at the potential worst case limits permitted under the IE License (P0009-03) conditions.

These potential worst case limits were based on the calculated emissions loads that would result if each licensed parameter was discharged in the treated wastewaters at their respective licensed Emissions Limit concentrations and if these wastewaters were also discharged at the maximum total daily emission volume allowed by the license.

The results of the modelling indicate that none of the emissions exceeded the relevant EQS at a distance of 100m from the diffuser. Most emission limits were an order of magnitude less than that needed to exceed the EQS.

Ongoing monitoring has also been conducted since 1978 in the Bandon Estuary and Kinsale Harbour by the Department of Zoology, National University of Ireland, Galway. A copy of the most recent benthic survey report is provided in the 2010 AER which can be viewed on the EPA website, www.epa.ie. The monitoring is of the benthic (the bottom layer) and littoral environments (area covered with salt water at high tides, and exposed to the air at low tides) including the area around the wastewater outfall from the facility. The monitoring comprises:

- Assessments of the hydrography, including in temperature, dissolved oxygen and salinity;
- Physical sedimentary analysis encompassing grain size distribution patterns;
- Chemical analysis of sediment organic carbon;
- Biological analysis of the sediment microflora; and
- Investigation of the faunal communities of Kinsale Harbour.

The monitoring has found no evidence that the wastewater emissions are having any noticeable effect on the receiving waters of Kinsale harbour. No change in this status would arise as a result of the introduction of the proposed IE43 extension project.

11.8 References

Environmental Protection Agency (2008) *BAT Guidance Note on Best Available Techniques for the Manufacture of Organic Chemicals (1st Edition)* EPA, Wexford

Environmental Protection Agency (2006) *BREF for Organic Fine Chemicals* EPA, Wexford

Eli Lilly (2015) *Annual Environmental Report*

Eli Lilly EPA Industrial Emission Licence P0009-03

Eli Lilly EPA Industrial Emission Licence P0009-04

12 Waste

12.1 Introduction

This chapter describes waste generation and management in the Lilly plant, provides an estimate of wastes likely to arise as a result of the proposed IE43 Biotech Manufacturing Facility Extension and assesses the likely impacts of the waste generated as a result of the proposed development.

Lilly has a well-developed existing waste management, minimisation and auditing strategy. This system is aimed not only at managing waste, but also at determining the most environmentally beneficial methods for controlling the generation of all wastes, and for reusing, recovering or disposing of them.

12.2 Methodology

For this chapter, information was obtained in respect of site waste management from records kept by Lilly. Lilly submits an Annual Environmental Report (AER) to the Environmental Protection Agency (EPA) in accordance with the Industrial Emissions (IE) licence in operation for the site. Lilly keeps a detailed record of all wastes produced on site, their management and final disposal. This information is included in the AER. The AER report is available online on the EPA website (www.epa.ie)

The site operates under IE licence reference P0009-03 but has a proposed determination for a revised licence (P0009-04) in progress at present. This EIS is based on the conditions applied to the revised licence.

12.3 Receiving Environment

12.3.1 Existing Waste Characteristics

Lilly maintains a full record of all waste resulting from activities at the Kinsale plant. From this data yearly summaries of the waste streams arising on site are produced, which are reported to the EPA in the AER. Wastes generated at Lilly are categorized as either hazardous or non-hazardous for disposal, in accordance with the EU European List of Wastes (LoW) and the Basel Convention. Lilly undertakes monitoring of certain wastes, as required by *Schedule C.4 Waste Monitoring* of the IE licence P0009-03.

12.3.1.1 Hazardous Waste

The wastes, classified as hazardous for disposal, include the following:

- solvent waste,
- product contaminated solid wastes from production buildings,
- product contaminated solid wastes from laboratories,

- unwashed plastic and metal drums previously containing hazardous substances,
- catalyst materials,
- waste activated carbon,
- waste electrical and electronic equipment (WEEE),
- tank cleaning residues,
- waste mineral oils,
- paint,
- gas cylinders, and
- Genetically Modified Microorganism (GMM) waste.

Lilly has identified and quantified the hazardous waste streams, and their compositions, from on-site production processes. **Table 12.1** indicates the quantities of hazardous waste produced on site in 2015.

12.3.1.2 Non-Hazardous Waste

Non-hazardous wastes generated on site include the following:

- general refuse and food waste,
- cardboard, paper and plastics,
- wood, plastic and metal drums,
- wastewater treatment plant sludge,
- scrap metal,
- construction and demolition material,
- waste cooking oil, and
- glass, soft drink cans.

Refer to **Table 12.2** for quantities of non-hazardous waste produced on site in 2015 (Eli Lilly, AER 2015). Lilly actively pursues means of reuse, recovery and recycling throughout the facility. Most of the non-hazardous wastes are taken off site and recycled and reused. Residual materials are landfilled off-site. There is no waste disposed of by on-site landfilling.

Different waste handling and control systems are in place to address the types of waste generated on site. Wastes are carefully segregated so that treatment or recycling processes are optimised. Dedicated tanks, containers, and skips, appropriately identified and labelled for particular wastes, are located at several points around the site. Each type of waste is then stored, treated or recycled as appropriate.

Table 12.1: Hazardous Waste Management Streams 2015

Waste material	LoW Code	Main source	Quantity Tonnes	Further treatment	Recovery, reuse recycling
Phosphoric and phosphorous acid	06 01 04*	Production	2.97	Incineration in Belgium	Energy recovery
Other acids	06 01 06*	Production	0.182	Incineration in Belgium	Energy recovery
Sodium and potassium hydroxide	06 02 04*	Production	0.241	Incineration in Belgium	Energy recovery
Aqueous washing liquids and mother liquors	07 05 01*	Production	731.12	Incineration in Belgium and UK	Energy recovery
Organic halogenated solvents washing liquids and mother liquor	07 05 03*	Production	68.426	Incineration in Belgium	Energy recovery
Other organic solvents washing liquids and mother liquor	07 05 04*	Production	358.998	Incineration in Belgium & UK	Energy recovery
Other organic solvents washing liquids and mother liquor	07 05 04*	Production	5329.86	Incineration on site	Energy recovery
Halogenated filter cakes and spent absorbents	07 05 09*	Production	4.219	Incineration in Belgium	Energy recovery
Other filter cakes and spent absorbents	07 05 10*	Production	4.007	Incineration in Belgium	Energy recovery
Solid wastes containing dangerous substance	07 05 13*	Production	66.64	Incineration in Belgium, UK & Germany	Energy recovery
Waste paint and varnish containing organic solvents and other dangerous substances	08 01 11*	Production	2.283	Incineration in Belgium & Germany	Energy recovery
Wastes not otherwise specified	13 08 99*	Production	1.417	Incineration in Belgium & Germany	Energy recovery

Waste material	LoW Code	Main source	Quantity Tonnes	Further treatment	Recovery, reuse recycling
Packaging wastes containing residues of or contaminated with dangerous substance	15 01 10*	Production	16.625	Incineration in Germany and Belgium	Energy recovery
Packaging wastes containing residues of or contaminated with dangerous substance	15 01 10*	Production	3.846	Metal recycling in Ireland	Recovery of metal
Absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances	15 02 02*	Production	2.003	Incineration in Germany & Belgium	Energy recovery
Discarded equipment containing chlorofluorocarbons, HCFC, HFC	16 02 11*	Production	0.565	Metal recycling in Ireland	Recycling
Discarded equipment containing hazardous compounds (16) other than those mentioned in 16 02 09 to 16 02 12	16 02 13*	Production	8.015	Metal recycling in Ireland	Recycling
Organic wastes containing dangerous substances	16 03 05*	Production	2.51	Incineration in Belgium	Energy recovery
Linings and refractories from non-metallurgical processes containing dangerous substances	16 11 05*	Production	13.286	Incineration in Belgium	Energy recovery
Gases in pressure containers (including halons) containing dangerous substances	16 05 04*	Production	0.092	Incineration in Germany	Energy recovery
Laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals	16 05 06*	Production	1.019	Incineration in Belgium	Energy recovery
Discarded equipment containing hazardous components (16) other than those mentioned in 16 02 09 to 16 02 14	16 02 13*	Production	0.043	Metal recycling in Ireland	Recycling
Inorganic wastes containing dangerous substances	16 03 03*	Production	5.782	Incineration in Belgium	Energy recovery

Waste material	LoW Code	Main source	Quantity Tonnes	Further treatment	Recovery, reuse recycling
Organic wastes containing dangerous substances	16 03 05*	Production	0.138	Incineration in Germany	Energy recovery
Batteries and accumulators included in 16 06 01, 16 06 02 or 16 06 03 and unsorted batteries and accumulators containing these batteries	20 01 33*	All areas	0.173	Metal recycling in Ireland	Recycling
Lead Batteries	16 06 01*	All areas	1.731	Metal recycling in Ireland	Recovery
Fluorescent tubes	20 01 21*	All areas	0.371	Recovery in Ireland	Recovery
Wastes not otherwise specified	13 08 99*	All areas	2.7	Incineration in Belgium	Energy recovery
Wastes not otherwise specified	13 08 99*	All areas	0.142	Recovery in Ireland	Recovery
Wastes whose collection and disposal is subject to special requirements in order to prevent infection	18 01 03*	Production	0.596	Physico-chemical treatment	Energy recovery

* Denotes the waste is hazardous.

Table 12.2: Non-Hazardous Waste Management Streams in 2015

Waste material	LoW Code	Main source	Quantity Tonnes	Recovery, reuse recycling
Mixed municipal waste	20 03 01	All areas	148.02	Landfill
Mixed municipal waste	20 03 01	All areas	4.74	Energy recovery
Biodegradable kitchen and canteen waste	20 01 08	Canteen	17.079	Composted off-site
Edible oil and fat	20 01 25	Canteen	1.06	Recovery
Spent activated carbon	19 09 04	Production	0.8	Recycling
Saturated or spent ion exchange resins	19 09 05	Production	6.2	Recycling in Belgium
Bulky waste	20 03 07	All areas	31.824	Landfill
Bulky waste	20 03 07	All areas	3.536	Recycling in Ireland
Bulky waste	20 03 07	All areas	33.06	Recovery in Ireland
Mixture of concrete, bricks, tiles and ceramics	17 01 07	Construction on site	1195.83	
Iron and steel	17 04 05	Construction on site	155.186	Recycling in Ireland
cables other than those mentioned in 17 04 10	17 04 11	Construction on site	2.12	Recycling in Ireland
Absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 15 02 02	15 02 03	Production	62.2	Incineration in Ireland
Waste packaging	15 01 06	All areas	68.5	Recycling in Ireland
Wooden pallets	15 01 03	All areas	113.8	Recycling
Paper and cardboard	20 01 01	General office waste	8.415	Recycling
Metals	20 01 40	Construction on site	176.3	Recovery
Organic sludge	07 05 12	Effluent treatment plant	106.8	Recycling

Waste material	LoW Code	Main source	Quantity Tonnes	Recovery, reuse recycling
Waste printing toner	08 03 18	Offices and laboratories	0.2	Recycling
Glass	20 01 02	All areas	3.624	Recycling
Edible oil and fat	20 01 25	Canteen	0.4	Recovery
Discarded equipment other than those mentioned in 16 02 09 to 16 02 13	16 02 14	All areas	3.1	Recycling
Linings and refractories from non-metallurgical processes other than those mentioned in 16 11 05	16 11 06	Production	11.5	Recycling
Discarded electrical and electronic equipment other than those mentioned in 20 01 21, 20 01 23 and 20 01 35	20 01 36	All areas	2.7	Recycling
Wood other than that mentioned in 20 01 37	20 01 38	Construction on site	88.94	Recycling
Metals	20 01 40	All areas	28.82	Recycling
Alkaline batteries	16 06 04	All areas	0.3	Recycling

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12.3.1.3 Liquid Waste Water

There a number of liquid waste streams generated on-site including:

- Process wastewater – primary, secondary and aqueous liquid waste arising directly and indirectly from manufacturing including solvents
- Utility wastewater – steam and hot water generation, purified water production and cooling systems
- Sanitary/foul wastewater – canteen, washrooms and toilets (similar in composition to normal domestic sewage)
- Surface run-off
- Contaminated surface run-off
- Incinerator quench water

The treatment of process, utility, sanitary and incinerator quench wastewaters is discussed in Chapter 11 *Effluent Generation and Treatment*. Surface water run-off management is discussed in Chapter 14 *Soils, Geology, Hydrogeology and Hydrology*.

12.3.1.4 Solvent Waste

The process wastewater streams consist of primary, secondary and aqueous waste water streams. Primary and secondary process waste streams contain over 80% and less than 20% solvent respectively. These process waste streams are incinerated in units with heat recovery potential. Aqueous process waste water streams contain less than 2% solvent and may be treated in the on-site biological wastewater treatment plant (WWTP), refer to Chapter 11 *Effluent Generation and Treatment*.

Solvent wastes and wastes containing solvents are produced on site in significantly greater quantities than any other waste on site. These solvent wastes are mother liquor or distillate streams from production processes. The mother liquor streams could contain un-reacted materials and product residues.

Lilly's policy has been to be self-sufficient in the management of wastes on site, particularly solvent wastes. Since the start of production operations in 1981, much effort has been focused on reducing the dependence on off-site disposal.

Currently Lilly has three management options for solvent wastes. Solvent waste can be:

- treated by incineration on site,
- treated by incineration off-site, and
- treated in the biological wastewater treatment plant (WWTP) on site.

Further detail on the generation and treatment of solvent waste effluent on site is described in Chapter 11 *Effluent Generation and Treatment*.

Table 12.3 Categorisation of Solvent Wastes for Disposal on Site

	Solvent content of the waste	Management option	Comment
Primary wastes	> 80%	Incineration	high calorific value
Secondary wastes	< 20%	Incineration	low calorific value
Aqueous wastes	< 2%	wastewater treatment plant, subject to treatability, API content; otherwise incineration	very low calorific value

12.3.2 Existing Waste Management

This section details the waste treatment arrangements for solid and liquid wastes generated on site. The control and abatement of air emissions generated on site is described in Chapter 10 *Air Quality and Climate*.

12.3.2.1 Biological Wastewater Treatment Plant

The on-site biological WWTP can accept aqueous (process), sanitary and potentially contaminated surface water (including rain water in bunds). This is discussed in further detail in Chapter 11 *Effluent Generation and Treatment*.

12.3.2.2 Inorganic Wastewater Treatment Plant

The inorganic WWTP treats the quench water and scrubber blow down from the incineration process. Refer to **Figure 11.2 Inorganic Treatment Plant**. This is discussed in further detail in Chapter 11 *Effluent Generation and Treatment*.

12.3.2.3 Incineration On Site

John Zink (KEU)

The on-site incinerator is used to treat liquid solvent wastes generated by production processes. The John Zink (KEU) unit is used for liquid wastes only. Both primary and secondary wastes are treated in the John Zink (KEU) incinerator. Natural gas is used to heat up the system following shut down, and, as an auxiliary fuel, to maintain the combustion temperature if insufficient energy is available from the waste feed. The combustion gases leaving the chamber are routed to a waste heat boiler where high pressure steam is generated. A portion of this steam is used to supply the incineration plant itself. The remainder of the steam is supplied to the site steam supply. The off-gases are then quench cooled before entering the gas cleaning plant. The quench water is discharged to a treatment system. This is also described in Chapter 11 *Effluent Generation and Treatment*. Boiler ash/slag is collected separately and shipped offsite as a hazardous waste stream.

The John Zink (KEU) has a licensed capacity of 75m³/day with a nominal thermal capacity of 8MW. The current annual throughput of the John Zink (KEU) incinerator is circa 5.7 million litres of primary waste and 8.2 million litres of secondary waste, which equates to approximately 50% of the licensed capacity of the unit.

Fume Thermal Oxidiser

There are two Reeco regenerative thermal oxidisers (RTO) units on site as part as the air abatement and control systems. These units treat the solvent laden air extracted from some of the manufacturing processes on site. The RTOs are an IE licensed emission point (refer to label A2-1 on **Figure 10.1**). Refer to Chapter 10 *Air Quality and Climate* for further discussion on air emissions on site.

12.3.2.4 Incineration Off Site

Where solvent waste volumes exceed on site incineration capacity this excess material is shipped off site for incineration. This occurs particularly when the incinerator is offline for maintenance over an extended period.

Solvent wastes, which have high solids content such as tank residues, are also sent off site for incineration.

All solid hazardous waste is removed off site for incineration.

12.3.2.5 Off-Site Waste Contractors

Lilly uses only contractors with the necessary permits and / or licences to transport, treat or recover waste. Movement of material off site is carefully controlled and documented in accordance with the statutory requirements. The wastes produced on site, and their means of treatment or disposal are reported to the EPA each year in the Annual Environmental Report (AER). This report is available on line at the EPA website – www.epa.ie.

Solvent waste, to be sent off site is transported in road tankers. Smaller quantities of liquid waste are exported in UN approved drums. Solid waste is exported in UN approved packaging conforming to ADR/IMDG requirements.

12.3.3 Existing Waste Control Systems

Waste management and control is important to all treatment, recycling and minimisation programmes. At the Lilly site several waste control systems exist. The system used depends on the type of waste to be managed.

In the case of new products, prior to a new product being introduced to the site, the product development information is reviewed, handling of all new waste streams discussed and control procedures developed. Options for recovery and minimisation are again reviewed prior to scale-up to manufacturing. Environmental concerns raised during the product development stage are addressed prior to manufacturing. Waste streams are verified and tested where appropriate to ensure that onsite treatment and abatement facilities can address product development needs.

Manufacturing is controlled through careful adherence to specific manufacturing procedures. These procedures ensure that the production, treatment and disposal of process wastes are strictly managed and controlled.

12.3.3.1 Waste Minimisation

Waste minimisation efforts have been successful through the reduction in volumes of solvent through the outsourcing of older more energy intensive processes. Solvent usage is now approximately one quarter of that used 15 years ago. Better segregation and recycling of non-hazardous waste has been achieved through the operation of a dedicated site non-hazardous waste facility. This is key to meeting site and corporate waste reduction goals.

Waste minimisation efforts at Lilly are ongoing in order to minimise the environmental impact of its operations. This is also reflected in the Lilly corporate policies.

Specific corporate policy objectives in relation to waste include:

- Recovery and recycling of the maximum practical amount of hazardous and non-hazardous waste materials.
- Minimisation of non-hazardous waste to landfill.
- Reduction in fugitive emissions across the site.
- Improvements and reduction in the dependency on the fume duct system through effective condensation, scrubbing and other appropriate process modifications.

12.3.3.2 Cleaner Technology

The use of clean technologies on site has resulted in improved efficiency in the use of materials and energy, and in the reduction of waste generated on site. Cleaner technologies implemented on site include:

- The installation of a larger backup Regenerative Thermal Oxidiser (RTO).
- The installation of a bio-filter unit at the wastewater treatment plant to remove odours or volatile organics emanating from the plant.
- The replacement of older steam traps in the solvent recovery area with more efficient types.
- In the majority of cleaning steps, the substitution of organic solvents by aqueous cleaning agents, resulting in a significant reduction in the use of organic solvents.
- Changing the plant fuel source from HFO and LPG to natural gas.
- Undertaking an energy audit and implementing the findings.
- Optimising water usage and recycling water in the incinerator.
- Addition of a heat recovery boiler to the John Zink (KEU) thermal oxidiser.
- Upgrading of the biological wastewater treatment plant.
- Membrane filtration capability to remove active ingredients from process waste streams.
- Installation of a CHP Plant for efficient energy generation.

12.4 Characteristics of the Proposed Development

12.4.1 Waste Generated by the Proposed IE43 Extension

As with the existing IE43, the proposed IE43 extension will generate increased volumes of solid and liquid wastes from the direct or indirect biotech manufacturing process. Wastes arising from biotech manufacture are characterised by waste that contains or has been in direct contact with genetically modified microorganisms (GMM). This bio-waste is inactivated by chemical or heat treatment or sent directly to bio-waste containers for off-site disposal.

Based on the existing IE43 facility **Table 12.4** and **12.5** describes and estimates the annual volumes of hazardous and non-hazardous wastes generated by the proposed IE43 extension (for off-site disposal).

Table 12.4: Estimated IE43 Non-Hazardous Solid & Liquid Wastes for Offsite Disposal

Generic Waste Name	Waste Description	Organic/ Inorganic	Physical State	Packaging	Estimated IE43 Max Waste Quantity (kg/yr)
Obsolete Raw Materials (Ex-Biotech)	Obsolete or rejected nutrients, buffers, reagents	Both	Liquid	Drum	2,400
Obsolete Raw Materials (Ex-Biotech)	Obsolete or rejected nutrients, buffers, reagents	Both	Solid	Dums/ Boxes / FIBC	2,400
Autoclaved Waste (Ex Biotech)	PPE, wipes, labbing, packaging, containers	Inorganic	Solid	Dums/ Boxes / FIBC	24,000
Decontaminated Waste (Ex-Biotech)	Used filters, resins, reagent packs, PPE, absorbent materials	Inorganic	Solid	Drum	48,000
Non Cell Contact Waste (Ex-Biotech)	Used PPE, wipes, absorbent materials, packaging, consumables	Inorganic	Solid	Dums/ Boxes / FIBC	120,000
Estimated Annual Total (kg):					196,800

Table 12.5: Estimated IE43 Hazardous Solid & Liquid Wastes for Offsite Disposal

Generic Waste Name	Waste Description	Organic/ Inorganic	Physical State	Packaging	Estimated IE43 Max Waste Quantity (kg/yr)
Anti-foam C Emulsion	Obsolete Anti-foam C material	Organic	Liquid	Drum	20
MEM Amino acid	MEM Amino acid	Organic	Liquid	Dums	200
Trypan Blue Stain	Obsolete Trypan Blue material	Organic	Liquid	Dums	20
Used containers and wipe with flammable residue (Ex Biotech)	Unclean containers with corrosive residue	Inorganic	Solid	Drum / Boxes	12,000
GMM Consumable Waste (Ex-Biotech)	PPE, wipes, tubing, packaging, containers, used filters, resins, reagent packs, absorbent, materials	Inorganic	Solid	Dums/ Boxes / FIBC	24,000
Triton X100 surfactant	Triton X residue in empty containers	Organic	Liquid	Dums/ Boxes / FIBC	200
Estimated Annual Total (kg):					48,440

12.4.2 Solvent Waste Management

Where possible 'clean' primary and secondary process waste solvent streams are segregated at source and sent for recovery. This may take place at the on-site solvent recovery facility or shipped off-site for recovery.

As referred to in Section 12.3.1.3, other liquid wastes are discussed further in Chapter 11 *Effluent Generation and Treatment* for the treatment of aqueous, utility, sanitary and incinerator quench waste water. Surface water run-off management is discussed in Chapter 14 *Soils, Geology, Hydrogeology and Hydrology*.

12.4.3 Solid Waste Management

The solid waste material from the proposed IE43 extension (see Tables 12.4 and 12.5 above) will either be incinerated off-site or recycled where suitable. All solid hazardous waste is removed off site for incineration. Materials which are incinerated off site will be exported to appropriately licensed facilities.

The solid waste generated by production processes in the IE43 biotech manufacturing facility extension can be linked to the following functions:

- Weighing and dispensing,
- Cell culture and primary recovery,
- Purification.

Weighing and Dispensing

The packaging material associated with the raw material dispensing will include empty plastic drums and any over-packing material. The over-packing will be considered for recycling.

Cell Culture and Primary Recovery

Cell culture and primary recovery wastes will include used disposable/once-use components such as pipettes, sample bags, sample flasks, culture flasks, media bags, filter disks and filter cartridges. These wastes will be bagged and drummed for offsite treatment and disposal. All cell contaminated solid waste will be incinerated in licensed facilities.

Purification

The purification stage wastes will include used disposable/once-use components such as buffer solution bags, product solution bags, single-use connections and assemblies and filter cartridges. These wastes will be bagged and drummed. These items will not have come in contact with cells and will not need autoclaving. Some of these solid waste materials may be considered for recycling, if feasible.

This packaging solid waste from the proposed IE43 extension is estimated to amount to circa 40 tonnes per annum, when the plant is fully operational, of which it may be feasible to recycle circa 20-30 tonnes per annum.

12.4.4 Other Wastes

There will also be general wastes from offices and break areas in the proposed IE43 extension, which will typically include paper, cardboard, plastics, ink cartridges and general refuse. These wastes will be segregated and sent off site for recycling. Refer to **Table 12.2**.

12.5 Evaluation of the Impacts

12.5.1 Construction Impacts

During construction there will be waste generated directly and indirectly related to the construction of the proposed IE43 extension. This will include excavated material, building materials removed from the existing IE43 structure as well as waste building supplies. Where possible the excavated materials will be stockpiled on site to be used for future construction activities. Asphalt material removed for the administration block extension and the internal road realignment will be taken off site to be recycled by a registered waste contractor. Refer to Chapter 14 *Soils, Geology, Hydrogeology and Hydrology* for further detail.

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 IE43 extension 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 segregated and disposed of off-site. Sanitary wastewater generated from the construction compound will be treated at the on-site biological wastewater treatment plant and treated effluent will be discharged at the licensed offshore outfall in the outer Kinsale harbour near Sandy Cove Island. Refer to Chapter 11 *Effluent Generation and Discharge*.

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

12.5.2 Operational Impacts

During operation, the proposed IE43 extension will generate increased volumes of waste on site, as outlined in Section 12.4 above. The existing site infrastructure has capacity to manage the effluent wastewaters generated on site including the wastewater treatment plants and incinerator. Refer to Chapter 11 *Effluent Generation and Treatment*.

There will be increased volumes of solid waste that will need to be managed on site and disposed off-site by licensed waste contractors. These additional volumes will be accepted by the existing licensed waste contractors as is the case for the existing IE43 facility. The nature and volume of waste generated by the proposed extension is expected to be similar to that generated for the existing IE43 and will be as outlined in Section 12.4 above.

No significant impacts 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, as detailed in Section 12.3.

12.6 Mitigation Measures

12.6.1 Construction Mitigation Measures

A Construction Environmental Management Plan (CEMP) will be prepared prior to commencement of construction. This is discussed in further detail in Chapter 4 *Construction Activities*.

The wastes generated onsite during construction will be managed according to the CEMP. It is envisaged that all waste generated during the construction phase will be collected and disposed or recycled offsite or where possible treated using the existing waste and effluent management systems employed on site.

12.6.2 Operational Mitigation Measures

The existing waste management systems on site will be employed to manage and minimise the additional volumes of waste generated during the operation of the proposed IE43 extension, see Section 12.3.2.

12.7 Residual Impacts

Lilly will continue its current policy of minimising, reusing and recovering waste, where possible. There is not expected to be a significant environmental impact from the wastes arising from the operation of this plant. The residual impacts of the liquid wastes not described here (aqueous process, utility, sanitary, potentially contaminated run-off and incinerator quench waste water) are discussed in Chapter 11 *Effluent Generation and Treatment* and Chapter 14 *Soils, Geology, Hydrogeology and Hydrology* (surface run-off).

12.8 References

Eli Lilly (2015) Annual Environmental Report 2015

Eli Lilly EPA Industrial Emission Licence P0009-03

Eli Lilly EPA Industrial Emission Licence P0009-04

European Commission (2001) *Commission Decision of 16th January 2001 amending Decision 2000/532/EC as regards the list of wastes*, (2001/118/EC) Official Journal of the European Communities, Brussels.

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13 Biodiversity

13.1 Introduction

Dixon Brosnan Environmental Consultants have conducted an appraisal of the potential impacts of the proposed development on terrestrial and aquatic ecology. This chapter describes and evaluates the habitats with their representative flora and fauna and addresses the impacts of the development on the ecology of the site and the surrounding area.

This chapter initially sets out the methodology followed (**Section 13.2**) and describes the receiving environment (**Section 13.3**). The main characteristics of the proposed development which are of relevance for biodiversity are described (**Section 13.4**). The likely significant impacts of the proposed development on biodiversity are described (**Section 13.5**), measures are proposed to mitigate likely significant impacts (**Section 13.6**), and residual impacts are described (**Section 13.7**).

13.2 Methodology

This appraisal is based on surveys of the proposed site and surrounding area and a review of desktop data. An ecological survey was carried out on July 18, 2016. This assessment follows the structure and protocols detailed in the following:

- Advice notes on current practice in the preparation of Environmental Impact Statements (EPA, 2003)
- Guidelines on the information to be contained in Environmental Impact Statements (EPA 2002)
- Advice notes for preparing environmental impact statements (EPA, draft September 2015)
- Revised guidelines on the information to be contained environmental impact statements (EPA, draft September 2015).
- Guidance on integrating climate changes and biodiversity into environmental impact assessment (EU Commission, 2013).

The appraisal of impacts follows the protocols outlined in guidelines for Assessment of Ecological Impacts of National Road Schemes (National Roads Authority, 2009) and Guidelines for ecological impact assessment in the United Kingdom (IEEM (2006)). Potential impacts on designated Natura 2000 sites (SAC/cSAC/SPA) are specifically addressed in the Appropriate Assessment (AA) Screening Report, which has been submitted as part of this application.

13.2.1 Desktop Study

A desktop study was used to identify features of ecological value occurring within the proposed development site and those occurring in close proximity to it. A desktop review also allows the key ecological issues to be identified early in the appraisal process and facilitates the planning of appropriate surveys. Sources of information utilised for this report include the following:

- National Parks & Wildlife Service (NPWS) - www.npws.ie,
- Environmental Protection Agency (EPA) – www.epa.ie,
- National Biodiversity Data Centre – www.biodiversityireland.ie,
- Bat Conservation Ireland - <http://www.batconservationireland.org>,
- Birdwatch Ireland.

13.2.2 Surveys

Surveys were carried out at the site on July 18, 2016. The habitats to be affected are common in the surrounding landscape and are of low ecological value. Thus the likelihood of additional ecological impacts occurring, which have not been identified in this EIS, is considered very remote. The following surveys were carried out:

- Habitats were mapped according to the classification scheme outlined in the Heritage Council publication *A Guide to Habitats in Ireland (Fossitt, 2000)* and following the guidelines contained in *Best Practice Guidance for Habitat Survey and Mapping (Heritage Council, 2011)*.
- The proposed development area was surveyed for invasive species.
- All bird species recorded during walkover surveys and habitat surveys were recorded. As the habitats noted on site consist primarily of low value grassland, no specialised surveys for birds were considered necessary.
- A general mammal survey was carried out in conjunction with the site walkover and habitat surveys. No roosting habitat or high value commuting or feeding habitat for bats was recorded and therefore no specialised bat surveys were considered necessary.

13.3 Receiving Environment

13.3.1 General Landscape

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 Ballyvrin Road, and to the west by the R605 regional road. Fields adjoin the eastern boundary of the site. Dunderrow village is located to the north west of the 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 through the site and discharges into the Bandon Estuary at Doon Creek. The Bandon Estuary is situated to the west of Dunderrow and extends southwards to the sea at Kinsale Harbour.

13.3.2 Designated Conservation Areas

Special Areas of Conservation (SACs) and candidate SACs are protected under the Habitats Directive 92/43/EEC and the European Communities (Birds and Natural Habitats) Regulations 2011, as amended. Special Protection Areas (SPAs) are protected under the Birds Directive 2009/147/EC and European Communities (Birds and Natural Habitats) Regulations 2011, as amended. Collectively, these sites are referred to as Natura 2000 or European sites. Natural Heritage Areas (NHAs/pNHAs) are national designations under the Wildlife Act 1976, as amended.

The site of the proposed development does not form part of any Natural Heritage Area (NHA/pNHA), Special Protection Area (SPA), Special Area of Conservation (SAC) or candidate Special Area of Conservation (cSAC), Nature Reserve, or National Park.

The proposed development site is located within 15km of a number of designated sites (including Natura 2000 sites) as shown in **Figure 13.1**. All designated sites, along with their distance from the site of the proposed development, are listed in **Table 13.1**.

Potential impacts on designated Natura 2000 sites (SAC/cSAC/SPA) are specifically addressed in a report for Appropriate Assessment Screening which has been submitted as part of this application. In terms of other environmental designations, the nearest pNHA is at a distance of 2.9 km from the proposed development with a total of eight pNHAs located within 15 km.

The Bandon River Below Innishannon and the Bandon River Above Innishannon pNHAs are located upstream of the Eli Lilly site. Garretstown Marsh and Garrylucas Marsh pNHAs are considered of value for brackish marsh and fens/flushes respectively. James Fort pNHA has been designated on the basis of terrestrial habitats (i.e. grassland and walls). The Sovereign Islands pNHA, Courtmacsherry Estuary pNHA and Old Head of Kinsale pNHA overlap with the Sovereign Islands SPA, Courtmacsherry Bay SPA/Courtmacsherry SAC and Old Head of Kinsale SPA respectively. These sites are designated primarily for their bird populations. However a range of important estuarine habitats also occur within Courtmacsherry Estuary.

Table 13.1: Designated Sites within 15 km of the Eli Lilly Site

Site	Code	Distance from Lilly site	Distance from outfall in Kinsale Harbour
SAC			
Courtmacsherry Estuary SAC	001230	9.0km SW	10.9km W
SPA			
Sovereign Islands SPA	004124	10.1km SE	3.8km E
Courtmacsherry Bay SPA	004219	9.9km SW	10.9km W
Old Head of Kinsale SPA	004021	12.2km S	6.8km S
pNHA			
Sovereign Islands	000105	10.1km SE	3.8km E
Bandon Valley Below Innishannon	001515	2.9 km W	9.6km NNE

Bandon Valley Above Innishannon	001740	7.5km NW	13.3km NNW
Garrylucas Marsh	000087	9.6km S	4.8km SSW
James Fort	001060	5.1km SE	2.2km N
Garrettstown Marsh	001053	8.3km S	5.7km SW
Courtmacsherry Estuary	001230	9.9km SW	10.9km W
Old Head Of Kinsale	000100	12.0km S	6.1km S

13.3.3 Habitats

Habitat mapping was carried out in line with the methodology outlined in the Heritage Council publication Best Practice Guidance for Habitat Survey and Mapping (Heritage Council, 2011). All habitats within the study area were classified to level 3 of the classification scheme outlined in A Guide to Habitats in Ireland (Fossit, 2000) and cross-referenced with habitats listed under Annex I of the Habitats Directive. Parts of the site were previously surveyed by DixonBrosnan as part of the preparation of the EIS for the existing IE43 Biotech Manufacturing Facility (ARUP, 2011) and any relevant information from previous surveys has been included where relevant.

A current habitat map is included as **Figure 13.2** and the recorded habitats are described below in **Table 13.2**. The ecological value of habitats is defined by the classification scheme outlined in the Guidelines for Assessment of Ecological Impacts of National Road Schemes (National Roads Authority, 2009).

Table 13.2: Terrestrial Habitat Values

Habitat	Description	Ecological value (NRA guidelines)
Recolonising bare ground (ED3)	Large areas of the proposed development area are covered by the habitat type recolonising bare ground (ED3). Species noted include Willowherb sp. (<i>Epilobium</i> sp.), Ragwort (<i>Senecio jacobaea</i>), Purple-loosestrife (<i>Lythrum salicaria</i>), Common Birds-foot-trefoil (<i>Lotus corniculatus</i>), Docks (<i>Rumex</i> spp.), Greater Plantain (<i>Plantago major</i>), White Clover (<i>Trifolium repens</i>), Centaury (<i>Centaurea erythraea</i>), Selfheal (<i>Prunella vulgaris</i>), Gorse (<i>Ulex europaeus</i>), Cat's-ear (<i>Hypochaeris radicata</i>), Dandelion (<i>Taraxacum officinale</i> agg.), Prickly Sow-thistle (<i>Sonchus asper</i>), Spear thistle (<i>Cirsium vulgare</i>), Smooth Hawksbeard (<i>Crepis capillaris</i>), Scentless Mayweed (<i>Tripleurospermum inodorum</i>).	Local importance (Low value)
Built & artificial surfaces BL3	A limited number of species were noted growing within this habitat including Bramble (<i>Rubus fruticosus</i> agg.), Spear thistle (<i>Cirsium vulgare</i>), Sycamore (<i>Acer pseudoplatanus</i>), Alder (<i>Alnus glutinosa</i>), Willowherb sp. (<i>Epilobium</i> sp.), Butterfly Bush (<i>Buddleja davidii</i>),	Local importance (Low value)

Habitat	Description	Ecological value (NRA guidelines)
	Bindweed (<i>Calystegia</i> sp.) and Laurel (<i>Prunus laurocerasus</i>).	
Treeline WL2 (See Figure 13.2 for details).	Two sections of treeline (Treeline WL2 (A) and Treeline WL2 (B) are dominated by Cypress (<i>Cupressus</i> sp.) with occasional Ash (<i>Fraxinus excelsior</i>). Treeline WL2 (B) will be cut back for line of sight purposes and to make way for a new entrance. Along the road in association with the treeline is an earth bank (Earth bank BL2), which supports laurel (<i>Prunus laurocerasus</i>). This earth bank will be removed. Treeline WL2 (C) will be removed during the construction phase. Species present in the northern section include Alder (<i>Alnus glutinosa</i>), Hawthorn (<i>Crataegus monogyna</i>), Elm (<i>Ulmus</i> sp.), Holly (<i>Ilex aquifolium</i>), Bramble (<i>Rubus fruticosus</i> agg.), Ivy (<i>Hedera helix</i>), Stinging nettle (<i>Urtica dioica</i>), Crab-apple (<i>Malus sylvestris</i>), Bracken (<i>Pteridium aquilinum</i>), Foxglove (<i>Digitalis purpurea</i>), Ragwort (<i>Senecio jacobaea</i>), Blackthorn (<i>Prunus spinosa</i>), Bindweed (<i>Calystegia</i> sp.), Herb-robert (<i>Geranium robertianum</i>), Honeysuckle (<i>Lonicera periclymenum</i>). The southern section is made up of Alder (<i>Alnus glutinosa</i>), Hawthorn (<i>Crataegus monogyna</i>), Elm (<i>Ulmus</i> sp.), Holly (<i>Ilex aquifolium</i>), Bramble (<i>Rubus fruticosus</i> agg.), Ivy (<i>Hedera helix</i>), Stinging nettle (<i>Urtica dioica</i>), Spear thistle (<i>Cirsium vulgare</i>), Ragwort (<i>Senecio jacobaea</i>), Honeysuckle (<i>Lonicera periclymenum</i>).	Local importance (Low value)
Hedgerow WL1	A small, low growing section of hedgerow occurs within the proposed development area and supports Alder (<i>Alnus glutinosa</i>), Elm (<i>Ulmus</i> sp.), Bramble (<i>Rubus fruticosus</i> agg.), Gorse (<i>Ulex europaeus</i>), Bracken (<i>Pteridium aquilinum</i>) and Stinging nettle (<i>Urtica dioica</i>).	Local importance (Low value)
Spoil & bare ground ED2	The site of the proposed staff carpark is dominated by gravel, earth and rock. Species noted include Creeping thistle (<i>Cirsium arvense</i>), Spear thistle (<i>Cirsium vulgare</i>), Creeping buttercup (<i>Ranunculus repens</i>), Prickly sow-thistle (<i>Sonchus asper</i>), Willowherb sp. (<i>Epilobium hirsutum, parviflorum & angustifolium</i>), Ragwort (<i>Senecio jacobaea</i>), Herb-robert (<i>Geranium robertianum</i>), Purple-loosestrife (<i>Lythrum salicaria</i>), Figwort sp. (<i>Scrophularia nodosa & auriculata</i>),	Local importance (Low value)

Habitat	Description	Ecological value (NRA guidelines)
	Common Birds-foot-trefoil (<i>Lotus corniculatus</i>), Docks (<i>Rumex spp.</i>), Greater Plantain (<i>Plantago major</i>), White Clover (<i>Trifolium repens</i>), Centaury (<i>Centaureum erythraea</i>), Selfheal (<i>Prunella vulgaris</i>).	
Eroding River FW1/Tidal River CW2	A stream flows in an approximate northeast-southwest direction through the Lilly site as shown on Figure 14.2. This stream originates in the hills of Clogheen and Tuckene, several kilometres to the northeast of the site, and enters the River Bandon at Doon Creek, approximately 1km to the southwest of the site. A section of the stream, approximately 120m, was diverted south-eastwards as part of the planning application for the existing IE43 manufacturing facility. Refer to Figure 1.2. This stream originates in the hills of Clogheen and Tuckene, several kilometres to the northeast of the site, and enters the River Bandon at Doon Creek, approximately 1km to the southwest of the site. The stream discharges to the tidal section of the main Bandon River and thus discharges downstream of sensitive salmonid spawning habitats and freshwater pearl mussel populations which occur within the freshwater sections of the river. The tidal section of the Bandon River is classified as Tidal River CW2. Although this habitat correspond approximately to the annexed habitat estuaries (1130) it is not designated as a Natura 2000 site. A small tributary stream has been culverted throughout the length of the plant site and is of negligible ecological value.	Local importance (Low value)

13.3.4 Flora

The site of the proposed development lies within Ordnance Survey National Grid 10km squares W55 and W65. The National Parks and Wildlife Service (NPWS) rare plant database has recorded two plants as historically present within W55, namely Penny Royal (*Mentha pulegium*) and Lesser Snapdragon (*Misopates orontium*). Within grid square W65 Tufted Salt Marsh Grass (*Puccinellia fasciculata*) was recorded. None of these species were noted nor are they expected to occur in the type of habitats recorded during site surveys.

13.3.5 Invasive species

Non-native plants are defined as those plants which have been introduced outside of their native range by humans and their activities, either purposefully or accidentally. Invasive non-native species are so-called as they typically display one or more of the following characteristics or features: (1) prolific reproduction through seed dispersal and/or re-growth from plant fragments; (2) rapid growth patterns; and, (3) resistance to standard weed control methods.

Where a non-native species displays invasive qualities and is not managed it can potentially: (1) out compete native vegetation, affecting plant community structure and habitat for wildlife; (2) cause damage to infrastructure including road carriageways, footpaths, walls and foundations; and, (3) have an adverse effect on landscape quality.

Japanese Knotweed (*Fallonia japonica*) has been recorded from grid square W65 within which the proposed development is located. However, this species was not noted within the proposed development area or in proximity to it during site surveys.

Occasional Buddleia (*Buddleja davidii*) was noted within recolonising bare ground habitat. This species is classed as Amber: Uncertain risk by the Invasive Species Ireland classification scheme (www.invasivespeciesireland.com). In the context of this site, it is unlikely to spread from within the site and invade established farmland outside the site boundary.

13.3.6 Mammals

The NPWS species record database details the following protected mammal species as occurring within the 10km Grid square W65: Otter (*Lutra lutra*), Red Squirrel (*Sciurus vulgaris*), Hedgehog (*Erinaceus Europaeus*), Pygmy Shrew (*Sorex minutus*) and Stoat (*Mustela erminea hibernica*).

The only protected mammal recorded within the survey area was Irish Hare which are common within the overall site. No signs of otter were recorded along the stream within the site boundary. Some common rodent species and species such as fox and rabbit occur.

13.3.6.1 Bats

Bats are protected by law in the Republic of Ireland under the Wildlife Act 1976 and subsequent amendments. In addition to domestic legislation bats are also protected under the EU Habitats Directive (92/43/EEC). The lesser horseshoe bat is listed in Annex II of the EU Habitats Directive, while all bat species are listed in Annex IV of the same Directive. It is an offence to disturb, injure or kill bats or disturb or destroy their roosts.

There are no records of Lesser Horseshoe Bat (*Rhinolophus hipposideros*), which is listed on Annex II of the Habitats Directive, in proximity to the Eli Lilly site.

The National Biodiversity Centre has records for eight bat species within a 10km radius of the site as follows: Daubenton's Bat (*Myotis daubentonii*), Common Pipistrelle (*Pipistrellus pipistrellus*) Soprano Pipistrelle (*Pipistrellus pygmaeus*), Nathusius Pipistrelle (*Pipistrellus nathusii*), Brown Long-eared Bat *Plecotus auritus*, Leislers Bat (*Nyctalus leisleri*), Whiskered Bat (*Myotis mystacinus*) and Natterers Bat (*Myotis nattereri*).

The proposed development areas do not provide suitable feeding habitat for bat species and the loss of small sections of treeline/hedgerow will be insignificant in the context of the local landscape as they do not have significant potential as commuting routes between habitats. No mature trees with potential as bat roosts will be affected and buildings within the overall site are modern and unlikely to support bat roosts.

13.3.7 Reptiles and Amphibians

No habitat suitable for amphibians was recorded.

13.3.8 Birds

The habitats within the proposed development area consist primarily of recolonising bare ground with some treeline and hedgerow habitat. Rook (*Corvus frugilegus*), Jackdaw (*Corvus monedula*), Magpie (*Pica pica*), Woodpigeon (*Columba palumbus*), Swallow (*Hirundo rustica*), Wren (*Troglodytes troglodytes*), Robin (*Erithacus rubecula*), Blue Tit (*Parus caeruleus*) and Blackbird (*Turdus merula*) were recorded during site surveys.

Certain bird species are listed by BirdWatch Ireland as Birds of Conservation Concern in Ireland. Red List bird species are of high conservation concern, and Amber List species are of medium conservation concern. Swallow is included on the Amber List. Overall there are no habitats of particular value for birds within the proposed development area and there are large areas of comparable habitat within the surrounding landscape.

13.4 Characteristics of Proposed Development

The existing IE43 biotech manufacturing facility houses a biologics production train (T1). The proposed IE43 biotech manufacturing facility extension development will allow for a second biologics train (T2) to increase capacity for existing Lilly molecules and future products. The proposed IE43 extension footprint is presented in **Figure 3.3** of this EIS.

The proposed development will also include realignment of internal site roads, services and hard standing and additional staff car parking. The existing site entrance on the Ballyvrin road will be for construction traffic during the construction phase of the proposed IE43 extension. The additional temporary entrance will be closed once construction is complete.

It is not expected that blasting will be required. All excavated material will be retained on site and used in landscaping or in construction. The majority of the excavated material will be bedrock that can be re-used as engineering fill.

The bridge crossing over the stream, constructed to facilitate the IE42 construction works, will be used to access the area to be used as a construction compound on the southern side of the stream. Refer to **Figure 4.1**

The project will take approximately 30-36 months to construct. Once operational, the plant will be run 24 hours a day, 7 days a week in line with the existing facility.

13.4.1 Emissions to Water

Emissions to the aquatic environment could potentially impact on the aquatic environment. Further details on such emissions are provided in Chapter 11 *Effluent Generation and Discharge* and Chapter 14 *Soils, Geology, Hydrology and Hydrogeology* of this EIS and are summarised below:

13.4.1.1 Storm Water Discharges

Rainwater run-off from areas, with little or no potential for contamination by process materials, such as roads and roofs, is collected in the storm water drainage system and drains into the containment pond.

The inlet flow and outlet flow from the containment pond passes through chambers, in which there is continuous monitoring for Total Organic Carbon (TOC) and pH and a daily visual inspection as specified by the EPA Industrial Emissions (IE) licence. Run-off collected in the containment pond is discharged into Doon Creek. Refer to **Figure 14.2**.

Rainwater run-off from bunded areas and some process building roofs is collected and routed to the biological wastewater treatment plant (WWTP) and discharged accordingly, see **Section 13.4.1.2** below.

13.4.1.2 Treated Waste Water Discharge

Treated waste water is discharged through a pipeline to a diffuser about 500 m offshore near Sandy Cove Island in the outer Kinsale Harbour. Because the Lilly site has been subject to Industrial Emissions (IE) licensing, the effluent discharges within the parameters of the existing licence have been adjudicated upon by the EPA to ensure that no significant adverse environmental impact will or can arise from such discharges. The proposed IE43 extension project falls within the same category of licensable activity under IE licensing, and can be accommodated within the scope of the current IE licence. There is already sufficient organic and hydraulic treatment capacity available in the Lilly wastewater treatment plant to accommodate the project and to ensure that the wastewater receives the necessary treatment to conform to BAT and that there will be no significant residual environmental impact.

A modelling study, was completed in 2011, by the National University of Ireland, Galway. The study modelled the near field dilution and dispersion of the treated wastewater emissions from the effluent diffuser at Sandy Cove.

The modelling was performed to investigate whether the receiving surface water body would be compliant with EC Environmental Objectives (Surface Waters) Regulations (S.I. No. 272/2009) if the treated wastewater emissions load were discharged at the potential worst case limits permitted under the current IE License conditions. These potential worst case limits were based on the calculated emissions loads that would result if each licensed parameter was discharged in the treated wastewaters at their respective licensed Emissions Limit concentrations and if these wastewaters were also discharged at the maximum total daily emission volume allowed by the license.

The results of the modelling indicate that none of the emissions exceeded the relevant EQS at a distance of 100m from the diffuser. Most emission limits were an order of magnitude less than that needed to exceed the EQS.

Ongoing monitoring has also been conducted since 1978 in the Bandon Estuary and Kinsale Harbour by the Department of Zoology, National University of Ireland, Galway. A copy of the most recent benthic survey report is provided in the 2010 AER which can be viewed on the EPA website, www.epa.ie.

The monitoring is of the benthic (the bottom layer) and littoral environments (area covered with salt water at high tides, and exposed to the air at low tides) including the area around the effluent outfall from the facility. The monitoring comprises:

- Assessments of the hydrography, including in temperature, dissolved oxygen and salinity;
- Physical sedimentary analysis encompassing grain size distribution patterns;
- Chemical analysis of sediment organic carbon;
- Biological analysis of the sediment microflora; and
- Investigation of the faunal communities of Kinsale Harbour.

The monitoring has found no evidence that the effluent emissions are having any noticeable effect on the receiving waters of Kinsale harbour. No change in this status would arise as a result of the proposed development which will also operate in line with the provisions of the IE licence.

13.4.2 Emissions to Air

All process waste gas streams from this development will be discharged directly to atmosphere via filters as there will be no major point source air emissions. The products, which will be manufactured in the IE43 biotech manufacturing facility will be aqueous based and will not contribute to any significant increase in air emissions. There will be minor emission points in the form of emergency relief vents and building air extracts. It is envisaged that there will not be any drying operations in the IE43 biotech manufacturing facility and therefore there will not be any dust emission points from the facility. The limits on emissions to air from the plant, set out in the IE Licence will continue to be met.

13.5 Potential Impact of the Proposed Development

13.5.1 Do Nothing' Impact

Most of the habitats to be affected have been significantly modified from the natural state by human activity. Some encroachment of scrub could occur on areas that are being recolonised by vegetation. In the absence of development, no significant changes to the habitats noted on site are likely to occur.

13.5.2 Magnitude, Probability and Significance of Impacts

When describing changes/activities and impacts on ecosystem structure and function, important elements to consider include magnitude, duration and probability of occurrence (IEEM, 2006).

Magnitude refers to the 'size' or 'amount' of an impact, determined on a quantitative basis if possible. Duration refers to the time for which the impact is expected to last prior to recovery or replacement of the resource or feature. This should be defined in relation to ecological characteristics (for example species' lifecycles) rather than human timeframes. Appropriate criteria for the assessment of magnitude and duration for this project are provided in **Tables 13.3 and 13.4** below.

Table 13.3: Criteria for Determining the Magnitude of Ecological Impacts

Magnitude	Examples
Very High	e.g. The proposal (either on its own or with other proposals) will result in – The total loss of or very major alteration to key elements/features of the baseline conditions such that post-development/character/composition/attributes will be fundamentally changed and may be lost from the site altogether.
High	e.g. The proposal (either on its own or with other proposals) will result in – Major alterations to key elements/features of the baseline (predevelopment) conditions such that post-development/character/composition/attributes will be fundamentally changed.
Medium	e.g. The proposal (either on its own or with other proposal) will result in – The loss of or alteration to one or more key elements/features of the baseline conditions such that post-development/character/composition/attributes of baseline would be partially changed.
Low	e.g. The proposal (either on its own or with other proposals) will result in – A minor shift away from baseline conditions. Change arising from the loss/alteration will be discernible but underlying character/composition/attributes of baseline conditions would be similar to predevelopment circumstances/patterns.
Negligible	e.g. The proposal (either on its own or with other proposals) will result in – A very slight change from baseline condition. Change barely distinguished approximating to the “no change” situation.

Table 13.4: Criteria for assessment of duration

Duration	Criteria
Permanent	Effects continuing beyond one human generation (c.25 years) are expected. There is likely to be a substantial improvement after this period, whereby these would be described as "very long term effects."
Temporary	Long term-(15-25 years) Medium (5-15 years) Short term (0-5 years)

13.5.2.1 Probability of occurrence

It is important to consider the likelihood that a change/activity will occur as predicted and also the degree of confidence in the assessment of the impact on ecological structure and function. The following scale (IEEM, 2006) is often utilised in ecological assessment:

- Certain/near-Certain: probability estimated at 95% chance or higher.
- Probable: probability estimated above 50% but below 95%.
- Unlikely: probability estimated above 5% but less than 50%.
- Extremely Unlikely: probability estimated at less than 5%.

13.5.2.2 Significance of impacts

Based on the above and the value of habitats and species a matrix of significance can be used to determine specific impacts. This matrix is shown below in **Table 13.5**.

Table 13.5: Impact Significance Matrix

Impact Significance		Ecological Value				
		Very High	High	Medium	Low	Negligible
Magnitude	Very High	Major	Major	Major	Moderate	Minor
	High	Major	Major	Moderate	Minor	Negligible
	Medium	Major	Moderate	Minor	Minor	Negligible
	Low	Moderate	Minor	Minor	Negligible	Negligible
	Negligible	Minor	Negligible	Negligible	Negligible	Negligible

13.5.3 Potential Impacts on Terrestrial Habitats

The potential for impacts on semi-natural habitat will be negligible due to the low value of the habitats affected. Levels of dust during construction are predicted to be low and effectively managed by mitigation. The impact on vegetation in adjoining habitats from wind-blown dust is predicted to be negligible. Based on the criteria outlined by the IEEM, as described above, the predicted impacts are detailed in **Table 13.6**.

Table 13.6: Impacts on Habitats

Habitat	Ecological value (NRA guidelines)	Predicted Impact
Recolonising bare ground (ED3)	Local importance (Low value)	Negligible
Built & artificial surfaces BL3	Local importance (Low value)	Negligible
Treeline WL2/ Hedgerow WL1	Local importance (Low value)	Negligible
Spoil & bare ground ED2	Local importance (Low value)	Negligible

13.5.4 Potential Impacts on Aquatic Habitats

A small stream (Eroding River FW1) is located within the site boundary, but outside the proposed development area. This stream discharges to a tidal section of the Bandon River.

Impacts on this stream could potentially arise through increased silt levels and/or hydrocarbons in surface water run-off. Construction works on the riverbank could result in silt reaching the river and if appropriate controls are not in place, could result in de-stabilisation of the riverbank. Some soils may be more likely to erode than others, especially sandy or silty soils which need to be treated with greater care.

High silt levels can impact in particular on salmonid spawning habitat. Excessive siltation can cause eggs and fry to be smothered. Spawning salmonids are likely to avoid traditional spawning areas due to excessive silt deposits. Adult fish may also be affected by increased silt levels as gills may become damaged by exposure to elevated suspended solids levels. Aquatic invertebrates may be smothered by excessive deposits of silt from suspended solids. In areas of stony substrate, silt deposits may result in a change in the macroinvertebrate species composition, favouring less diverse assemblages and impacting on sensitive species. Aquatic plant communities may also be affected by increased siltation. Submerged plants may be stunted and photosynthesis may be reduced. Significant impacts on fish stocks could impact on otter due to a reduction in prey availability. Spills of hydrocarbons can have direct toxicological impacts on habitats and fauna.

It is noted that the stream within the site boundary is of low ecological value and discharges to a tidal section of the Bandon River. Habitats and species within the tidal sections of watercourses are generally robust and adapted to fluctuating levels of suspended solids. Therefore, the potential for significant impacts during construction is limited. The impact on the stream is predicted to be minor to negligible. The impact on the tidal section of the Bandon River is predicted to be negligible.

Treated waste water is discharged through a pipeline to a diffuser about 500 m offshore near Sandy Cove Island in the outer Kinsale Harbour. During operation changes in discharge volumes or increased discharges of nutrients or other chemicals could impact on water quality.

There is already sufficient organic and hydraulic treatment capacity available in the Lilly wastewater treatment plant to accommodate the project. The plant will continue to operate under an Industrial Emissions (IE) Licence which specifies limits that ensure that no significant adverse environmental impact will or can arise from the discharge. The impact on water quality and aquatic ecology due to the discharge of treated effluent is predicted to be negligible.

13.5.5 Potential impacts on designated sites

Potential impacts 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. This report provides information to enable Cork County Council to perform its statutory function to undertake screening for AA. The conclusion of this report is that the likelihood of the proposed development having a significant effect on any European sites (in view of their conservation objectives) either individually or in combination with other plans or projects, and on the basis of objective information, can be excluded. Therefore it is the opinion of the author of the report that the proposed development can be screened out and therefore Appropriate Assessment (Stage 2) is not required.

Three of the proposed Natural Heritage areas (The Sovereign Islands pNHA, Courtmacsherry Estuary pNHA and Old Head of Kinsale pNHA) overlap with Natura 2000 sites. As noted above in the conclusion from the Appropriate Assessment screening report, significant effects on these sites have been excluded. The James Fort pNHA is designated for terrestrial habitats for which no potential impacts have been identified. The Bandon River below Innishannon and the Bandon River above Innishannon pNHAs are located upstream of the site and no impact on these sites is predicted. Garretstown Marsh and Garrylucas Marsh pNHAs are located a considerable distance from the Eli Lilly site (5.7km and 4.8km respectively) and in the absence of significant impacts on water quality or defined hydrological pathways, the impacts on these pNHAs is predicted to be negligible.

13.5.6 Potential Impacts on Fauna

13.5.6.1 Protected Mammals

No significant loss of habitat for mammal species is predicted. Whilst increased noise and disturbance is predicted to occur during construction and to a lesser degree during operation, the impact is predicted to be negligible.

The development areas do not provide suitable feeding habitat for bat species and the loss of small sections of treeline/hedgerow will be insignificant in the context of the local landscape. No mature trees with potential as bat roosts will be affected. Overall the impact on bats is predicted to be negligible.

13.5.6.2 Birds

The small sections of hedgerow/treeline which will be removed have some potential to provide suitable habitat for breeding birds. Overall, the loss of habitat for breeding birds within the development site is considered a permanent, minor impact.

The habitats within the development area are utilised by birds for feeding although it is generally of limited local value. Some disturbance/displacement of feeding birds may occur during construction due to increased noise and disturbance. However, this will be short-term in duration. The impact is therefore predicted to be a short-term, minor impact. During the operational phase, the levels of activity will stabilise and birds in the surrounding landscape will be expected to habituate to any increased noise and disturbance. The impact on birds in habitats adjoining the proposed development site is therefore predicted to be permanent and negligible during operation.

13.5.6.3 Impacts on other fauna

No habitat suitable for reptiles was recorded and common frog was not recorded. The site is only likely to support common invertebrate species. Given that small areas of relatively common habitats will be affected, any impact on these species will be negligible.

13.5.7 Climate change and biodiversity

The EU Commission guidance document on integrating climate change and biodiversity into environmental impact assessment (EU Commission, 2013) aims to improve the way in which climate change and biodiversity are integrated into Environmental Impact Assessment. Key principles specified by the document when considering impacts include the following:

- Consider climate change at the outset,
- Analyse the evolving environmental baseline trends,
- Taking an integrated approach,
- Seek to avoid biodiversity and climate change effects from the start,
- For biodiversity, EIA should focus on ensuring 'no net-loss',
- Assess alternatives that make a difference in terms of climate change and biodiversity,
- Use ecosystem-based approaches and green infrastructure as part of the project design and/or mitigation measures,
- Assess climate change and biodiversity synergies and cumulative effects which can be significant.

The potential impacts from the proposed development on climate have been specifically addressed by Chapter 10 *Air Quality and Climate* of this EIS. This chapter concluded that “the emissions from the Lilly plant with the IE 43 facility operational are not expected to have a significant effect on the global climate” and that “No significant interactions between the impacts on biodiversity resulting from this development and climate change have been identified.”

In relation to biodiversity, it is important to adopt an “ecosystem” approach which considers all of the different ecological elements and how they interact with each other. The site of the proposed development consists of a mixture of low value habitats with limited connectivity to the surrounding landscape.

The small sections of hedgerow and treeline to be removed do not form important connective elements in the context of the local landscape.

As detailed in Chapter 7 *Landscape and Visual*, the proposed planting scheme will include the planting of trees on a berm and a new section of hedgerow. Trees to be utilised include Hawthorn, Oak, Alder, Beech, Sweet Chestnut and Field Maple. This will ensure that local biodiversity is maintained and enhanced where possible thus minimising impacts on local ecology.

13.5.8 Cumulative Impacts

Cumulative impacts on fauna could potentially occur due to increased noise and activity levels. In-combination impacts from noise/disturbance are likely to be most pronounced during construction. This is a short term impact which will be localised. During operation a localised increase in traffic and noise is predicted. As this proposed development is not predicted to significantly increase long term noise and disturbance levels over background levels no significant cumulative impacts have been identified.

No significant impact on water quality and thus no significant impacts on aquatic ecology are predicted. The stream diversion has already taken place and will not impact cumulatively with other construction related impacts. There are no other significant developments in this rural area and no other cumulative impacts have been identified with respect to construction or operation of the proposed IE 43 extension.

13.6 Mitigation Measures

The likely success of the proposed mitigation measures is high, either in their current form or as they will be adapted on-site to achieve the desired result. The mitigation measures have been drawn up in line with current best practice and include an avoidance of sensitive habitats at the design stage. It is clear that the mitigation measures are designed to achieve a lowering or reducing of the risk of impact to acceptable levels. Whilst the proposed methods of mitigation may be amended and supplemented the risk that the mitigation measures will not function effectively in preventing significant ecological impacts is low. The following mitigation measures will be implemented.

13.6.1 Construction Phase Mitigation Measures

Chapter 4 Construction Activities details the construction methodology for the proposed development and the associated environmental controls to minimise construction impacts.

This will be developed further prior to construction into a detailed Construction and Environmental Management Plan (CEMP) by the appointed Contractor. The following standard best practice construction measures will be implemented during the construction phase.

13.6.1.1 Protection of Habitats

To prevent incidental damage by machinery or by the deposition of spoil during the site clearance stage, any trees /habitats earmarked for retention will be securely fenced early in the construction phase. The fencing will be clearly visible to machine operators.

To prevent Japanese Knotweed from outside the site being inadvertently brought in to the site, the contractor will be required to inspect vehicles before using them on site, and will pay particular attention to caterpillar tracks and where trucks and dumpers are stowed. The supplier of fill will be required to provide a guarantee that the fill to be imported does not contain knotweed. In addition, the fill will be inspected for signs of knotweed, prior to importation to site. The UK Environmental Agency's publication *Managing Japanese knotweed on development sites - The Knotweed Code of Practice* (EA 2013), states that inspection of topsoil brought into the site, should be carried out using the guidance in appendix I-IV of the code BS 3882:2007 *The British Standard Specification for topsoil and requirements for use*. This Standard was replaced subsequently by BS3882:2015 *Specification for Topsoil*. The inspection of fill will be carried out according to this Standard.

13.6.1.2 Protection of Water Quality

The employment of good construction management practices will serve to minimise the risk of pollution of soils, groundwater or surface water during construction. The Construction Industry Research and Information Association (CIRIA) in the UK has issued a guidance note on the control and management of water pollution from construction sites, *Control of Water Pollution from Construction Sites, Guidance for Consultants and Contractors*, CIRIA, 2001.

As most of the construction works will take place within the existing operational site, most of the run-off during construction will be discharged via a hydrocarbon interceptor to the existing Lilly site storm water drainage system which discharges to the stream via the containment pond and the site monitored surface water discharge point. Where necessary, additional berms, swales, hydrocarbon interceptors and settlement ponds with filters will be utilised to minimise any impacts from surface water run off during construction. The entire system will be subject to a daily visual inspection as well as routine maintenance. Refer also to the Jacobs report *Temporary Surface Water Control System* which accompanies the planning application for further details.

13.6.1.3 Air Quality

Construction activities have the potential to generate dust emissions, particularly during the site clearance and excavation stages. The potential for dust to be emitted depends on the type of construction activity being carried out in conjunction with ambient conditions, including rainfall, wind speed, wind direction and the distance to potentially sensitive locations. Most of the dust would be deposited close to the potential source and any impacts from dust deposition would typically be within a hundred metres or so of the construction area. It is noted that there are not sensitive habitats in proximity to site works that could be significantly affected by fugitive dust emissions. A dust minimisation plan will be prepared and implemented by the building contractor during the construction phase of the project. Refer to Chapter 4 *Construction Activities* for further details of dust mitigation measures.

13.6.1.4 Waste Management

A construction and demolition waste management plan will be developed and maintained by the main contractor prior to construction works commencing on site. The Plan will meet the requirements of the DoEHLG *Best Practice Guidelines on the Preparation of Waste Management Plans for Construction & Demolition Projects*.

13.6.1.5 Landscaping and invasive species

A small number of buddleia plants were recorded within the proposed development. These plants will be dug out for disposal at landfill prior to the commencement of site works.

As detailed in Chapter 7 *Landscape and Visual* a mixture of trees will be used in the final planting scheme. This will ensure that local biodiversity is maintained and enhanced where possible thus minimising impacts on local ecology.

13.6.2 Operational Phase Mitigation Measures

The detailed measures and standard operating procedures in place on site currently will be extended to cover the proposed IE43 extension facility. All underground process pipes and drains will have secondary containment and all chemical storage tanks will be bunded. Storage areas, production facilities and roadways will have impervious surfaces, which will drain to collection systems.

Storm run-off from collection systems will drain to the containment pond where it will be monitored before being discharged to Doon Creek. It will be contained if the monitoring detects contamination. The external areas around the IE43 extension facility, where there would be potential for spills or leaks, will be bunded to contain and divert spills and firewater. Bund run-off will drain to the biological WWTP for treatment.

The storm water system for IE43 extension will be designed using the same parameters as the existing IE43 design with the addition of attenuation as required. Refer to Chapter 14 *Soils, Geology, Hydrology & Hydrogeology* for further details. There is enough capacity in the proposed system to cater for flows from the proposed IE43 extension. The water discharges, via the containment pond, to the stream after passing through the monitoring.

13.6.3 Bird Mitigation Measures

The Wildlife Act 1976, as amended, provides that it is an offence to cut, grub, burn or destroy any vegetation on uncultivated land, or any such growing in any hedge or ditch from the 1st of March to the 31st of August. Exemptions include the clearance of vegetation in the course of road or other construction works or in the development or preparation of sites on which any building or other structure is intended to be provided. Nonetheless, it is recommended that vegetation be removed outside of the breeding season.

13.7 Residual Impacts

Overall the development will impact primarily on low value and highly modified habitats. No particular difficulties in the effective implementation of the prescribed mitigation measures have been identified. There will be a net loss of small sections of hedgerow and treeline. The impacts on habitats are predicted to be negligible. The impact on the stream which adjoins the site is predicted to be localised, temporary and minor to negligible. The impact on aquatic habitats during operation is predicted to be negligible.

With the exception of localised impacts and short-term impacts during construction, no significant impacts on fauna are envisaged. No impact from the spread of invasive species will occur. Any impact on air quality will be negligible. The impact on designated sites and their conservation objectives is predicted to be negligible.

14 Soils, Geology, Hydrology and Hydrogeology

14.1 Introduction

This chapter of the EIS consists of an appraisal of the proposed IE43 Biotech Manufacturing Facility Extension hereafter referred to as the proposed IE43 extension, under the heading of soils, geology, hydrology and hydrogeology.

This chapter initially sets out the methodology followed (**Section 14.2**), describes the receiving environment (**Section 14.3**), and summarises the main characteristics of the proposed development which are of relevance for soils, geology, hydrology and hydrogeology (**Section 14.4**). The likely significant impacts of the proposed development on soils, geology, hydrology and hydrogeology are described (**Section 14.5**), measures are proposed to mitigate likely significant impacts (**Section 14.6**), and residual impacts are described (**Section 14.7**). The chapter concludes with a reference section (**Section 14.8**).

14.2 Methodology

14.2.1 Introduction

This appraisal is based on a desk study, in which a review was undertaken of published information, studies and site investigations which have been carried out at the Lilly site at various times, as well as a geotechnical site investigation that was carried out for the existing IE43 facility, in December 2010.

This chapter has been prepared having regard to the following guidelines:

- Revised Guidelines on the Information to be Contained in Environmental Impact Statements (Environmental Protection Agency, Draft September 2015);
- Advice Notes for Preparing Environmental Impact Statements (Draft September 2015);
- Guidelines on the Information to be contained in Environmental Impact Statements (EPA 2002);
- Advice Notes on Current Practice in the Preparation of Environmental Impact Statements (EPA 2003);
- Geology in Environmental Impact Statements – a Guide (Institute of Geologists of Ireland (IGI) 2002);
- Environmental Impact Assessment of National Road Schemes – A Practical Guide (NRA) 2008a);

- Guidelines on Procedures for Assessment and Treatment of Geology, Hydrology and Hydrogeology for National Road Schemes (NRA 2008b,c);
- Guidelines for the Preparation of Soils, Geology and Hydrogeology Chapters of Environmental Impact Statements (IGI 2013);
- Good practice guidelines on the control of water pollution from construction sites (Construction Industry Research and Information Association (CIRIA) 2001).

14.2.2 Desk Study

The information in this section comes from a number of different sources, including:

- Walkover surveys,
- Site Investigations and previous studies,
- Flood Risk Assessment, carried out by RPS. Refer to **Appendix 14.1.**, This Flood Risk Assessment was undertaken in line with the requirements set out in the Department of the Environment, Heritage and Local Government/ Office of Public works guidelines, “*The Planning System and Flood Risk Management Guidelines for Planning Authorities*”, (Guidelines) and the particular requirements of a site specific Flood Risk Assessment as outlined in Appendix A of the Technical Appendices to those guidelines
- Public information sources (listed below).

14.2.3 Site Investigations and previous studies

The previous site investigations and study sources of information include:

- Geotechnical Site Investigation Report by IGSL (February 2011).
- Hydrogeological Groundwater Development Investigation by WYG (January 2012). Refer to **Appendix 14.2.**

14.2.4 Public Sources of Information

The public sources of information used in this chapter are as follows:

- Historical Maps, Ordnance Survey of Ireland,
- Published geological, soil, groundwater, surface water, aquifer, recharge and aggregate potential maps obtained from the Geological survey of Ireland (GSI),
- Waste and IPPC licensed facility maps (EPA Geoportal),
- EPA online Envision Map Viewer (www.epa.ie),

- Review and analysis of relevant reports from the Lee CFRAM Study, January 2014 (available to download from <http://www.leecframs.ie/>,
- Aerial photography and mapping from Google Maps and Bing,
- Potential flooding information from the OPW Catchment Flood Risk Assessment and Management (CFRAM) (www.myplan.ie).

14.3 Receiving Environment

14.3.1 Geology

14.3.1.1 Regional Bedrock Geology

The bedrock underlying the Lilly site is of Lower Carboniferous age and is thought to form part of the Kinsale and Courtmacsherry Formations. The Kinsale Formation consists mainly of calcareous mudstone or muddy limestone, while the Courtmacsherry Formation comprises calcareous mudstone, calcareous siltstone and limestone. Refer to the Geological Survey of Ireland bedrock geology map presented in **Figure 14.1**. These formations are known collectively as the Cork Group and were deposited in deep waters in the Munster basin some 360 million years ago. After deposition, the mudstones were subject to faulting and folding. Because of the lack of outcrop in this area, there is little information on the extent of folds or faults. However in general, the faults and fold axes tend to strike eastnortheast-west southwest.

14.3.1.2 Local Bedrock Geology

Geotechnical investigatory works were undertaken in December 2010 for the existing IE43 facility (IGSL 2011). The scope of this investigation also included the area covered by the proposed IE43 extension.

The rock cores taken during the site investigation confirm that bedrock in the area of the proposed IE43 extension consists of a complex sequence of laminated siltstone, calcareous siltstone, shale and mudstone.

14.3.1.3 Mineral / Aggregate Resources

There are no pits or quarries adjacent or within the vicinity of the proposed development. The GSI online maps indicate the nearest active quarry to the proposed development is Dromkeen Quarry, approximately 6km north east of the site.

Pre-1946, there are records on OSI Six-inch mapping of a number of small pits and quarries in the vicinity, the closest being a small quarry approximately 2km south of the site.

14.3.1.4 Geological Heritage Sites

The Geological Survey of Ireland (GSI) in partnership with the Department of Environment, Heritage and Local Government designed the Irish Geological Heritage Programme, which aims to identify, document and protect the wealth of geological heritage in Ireland. Certain geologically valuable sites are designated as Geological Heritage Sites (GHSs).

There are no GHSs within 2km of the proposed IE43 extension development.

14.3.2 Soils

According to the Teagasc Soils map, acid brown earths and brown podzolics dominate in this area. Brown podzolic soil is generally well drained, with good moisture holding capacity. The lime-deficient acid brown earth is also free draining with good moisture holding capacity. The soil originates from glacial drift of sandstone-limestone mix, and is generally of good structure.

14.3.2.1 Site Specific Soils

The previous geotechnical investigation revealed the ground comprised of indigenous soils comprising grey brown and reddish brown, sandy gravelly clay with medium to high cobble content. It is thought that these soils represent heavily over-consolidated ablation till with local fluvio-glacial outwash deposits. The glacial till matrix is predominantly clay in nature but silt dominant till is also known to occur at the site which was as identified during the earthworks phase of IE42.

14.3.2.2 Regional and Local Potential for Contaminated Land

A desktop review was carried out of the Environmental Protection Agency (EPA) website for both existing and historic licensed and illegal waste activities to identify any potential contaminating activities near the proposed development.

The following licensed activities were reviewed:

- Waste licences and permits/certificates of registration
- Integrated Pollution Control (IPC) and Industrial Emission (IE) Licences
- Potential illegal dumping and historical landfills and potential contamination in surrounding sites

There are no waste licences, waste permits or waste certificates of registration facilities within 2km of the site.

Lilly currently operates under an Industrial Emissions (IE) licence (licence registration number P0009-03). According to EPA records, there are no other IPC or IE licensed sites (active or surrendered) within 2km of the Lilly site.

A revised IE licence (P0009-04) is currently in the proposed determination stage and is expected to be in place by year end.

IE43 extension will be included in this revised licence. Lilly have assessed the proposed development against the conditions of P0009-04 which are in line with current regulatory requirements.

There are no known historic landfills located within 2km of the Lilly site. According to the EPA publication, *The Nature and Extent of Unauthorised Activities in Ireland* (2005) unauthorised waste activity has not been noted at or within 2km of the site.

The main land use of the surrounding area is agriculture. The main source of agricultural pollution is farmyard runoff percolating to ground in surface runoff and land spreading with fertilisers.

Nitrate levels in groundwater samples analysed as part of a 2012 hydrogeological report by WYG (**Appendix 14.2**) were found to be below drinking water standards and faecal contamination was low. Therefore, there does not appear to be a land spreading issue affecting the nitrate groundwater concentrations beneath the site. Refer to **Appendix 14.2** for the WYG report (2012).

14.3.2.3 Landslide Risk and Slope Stability

A review of the landslide information on the GSI Landslides Database does not indicate landslide potential on or near the site. The site slopes gently south to southeast.

14.3.3 Hydrology

14.3.3.1 Introduction

A stream flows in an approximate northeast-southwest direction through the Lilly site as shown on **Figure 14.2**. This stream originates in the hills of Clogheen and Tuckene, several kilometres to the northeast of the site, and enters the River Bandon at Doon Creek, approximately 1km to the southwest of the site. In 2016, a section of the stream, approximately 120m in length, located south of IE43 was diverted south-eastwards under the planning permission granted for the existing IE43 manufacturing facility. Refer to **Figure 1.2**.

A small tributary stream has been culverted throughout the length of the plant site. The culverted stream flows in an approximately north-south direction through the site and discharges into the larger stream at the south eastern site perimeter.

14.3.3.2 Flood Risk

A flood risk assessment (FRA) has been completed in respect of the proposed development, refer to **Appendix 14.1**. This report states that there are no recorded reports of flood events, according to the OPW Flood Hazard Mapping website.

The national CFRAM (Catchment Flood Risk Assessment and Management) programme undertaken by the Office of Public Works (OPW) in Ireland commenced in c.2011 and produced a series of Preliminary Flood Risk Assessments (PFRA) which cover the entire country, (<http://www.cfram.ie/pfra/interactive-mapping/>).

The South Western CFRAM Project has been updating the PFRA published for the South Western River Basin District. The area surrounding the proposed development was not included in the CFRAM project; therefore the PFRA mapping available for the area has been used to inform this FRA. The PFRA mapping indicates that the existing Lilly site is unlikely to be at risk of flooding associated with the stream which discharges to the Bandon River. Refer to **Appendix 14.1** for further details

It is understood however, from discussions with Lilly personnel, that there was minor flooding within Eli Lilly property south of the stream due to a blockage within the channel early in 2012.

There are also reports of flooding downstream of the site during an event in June 2012. It is understood that this flooding resulted from a blockage and capacity limitations at a bridge crossing the Regional Road R606. This bridge is located less than 1km downstream of the proposed development. It was also noted that the channel upstream of the R606 culvert was not well maintained prior to this flood event. However, stream and bank maintenance was carried out following the event.

It is therefore considered in the FRA that there may be a fluvial flood risk in the vicinity of the proposed IE43 extension development.

In recent years, a series of studies were commissioned by the Office of Public Works to establish extreme flood levels around the Irish coastline. The mapping published as part of this study was reviewed with regard to the proposed development. The published mapping does not include the lands in the vicinity of the proposed IE43 extension development. Given the existing and proposed development levels, the risk of coastal flooding at the proposed IE43 extension development is considered insignificant.

Similarly, the FRA does not consider groundwater flooding or pluvial flooding to be a significant risk at the Lilly facility.

14.3.3.3 Water Framework Directive

The Water Framework Directive (WFD) (2000/60/EC) established a framework for the protection of all waters including rivers, lakes, estuaries, coastal waters, groundwater, and their dependent wildlife/habitats.

One of the key aims of the WFD is achieving “good status” for all waters by a set deadline. The EPA database provides information on the current status of all waterbodies in Ireland including lake, river, transitional and coastal waterbodies.

As discussed above, the stream that flows in an approximate northeast-southwest direction through the Lilly site flows into the Bandon River at Doon Creek. Doon Creek flows into a section of the Bandon River called the Lower Bandon Estuary, a transitional water body monitored as part of the WFD. The Lower Bandon Estuary has a Transitional Waterbody Score that indicates it is:

“At risk of not achieving good status” (EPA database, 2016).

Treated wastewater (effluent) from the Lilly treatment plants is discharged through a pipeline to a diffuser about 500 m offshore near Sandy Cove Island in the outer Kinsale harbour. Refer to **Figure 11.3**. The receiving waters are used for water sports and fishing and there are beaches within 2km of the emission point.

Sandy Cove is located within the defined Coastal Waterbody of Kinsale Harbour. Kinsale Harbour, as reported by the EPA, has a Coastal Waterbody Score that indicated it is:

“Strongly expected to achieve good status” (EPA database, 2016).

14.3.3.4 Bathing Waters

Directive 2006/7/EC concerning the management of bathing water quality came into force in 2006 and repealed the existing Directive. The 2006 Directive focused on the protection of public health, a proactive approach to the management of bathing water quality and greater public participation. It establishes more stringent microbiological standards for two new parameters, intestinal Enterococci and *Escherichia coli*.

The 2006 Directive also established a new classification system for bathing water quality based on four classifications ‘poor’, ‘sufficient’, ‘good’ and ‘excellent’ and generally requires that a classification of ‘sufficient’ be achieved by 2015 for all bathing waters. The Bathing Water Directive is implemented in Ireland through the Bathing Water Quality Regulations, 2008 (S.I. No. 79 of 2008).

Local authorities are required on or before 24 March each year to identify bathing waters in relation to the forthcoming bathing season and to notify the EPA of the bathing waters so identified. A Local Authority is required to identify as bathing waters, all elements of surface water where the Local Authority expects a large number of people to bathe and where such water lies within the functional area of the authority or is immediately contiguous to the functional area of the Local Authority. Local authorities are also required to ensure that appropriate measures have been taken in relation to public participation in the identification process. In 2015 a total of 137 bathing waters were identified by the relevant Local Authorities.

The nearest designated bathing waters to the effluent outfall are Garretstown and Garrylucas, White Strand which are located approximately 6 km west of the outfall. Garrylucas, White Strand is classified as having Excellent Water Quality and Garretstown as having Good Water Quality (EPA, 2015).

14.3.4 Hydrogeology

14.3.4.1 Introduction

The site is located within the South Western River Basin District which covers all of Cork City, most of counties Cork and Kerry, parts of Limerick, South Tipperary and Waterford respectively. The main aquifers in the southwest Cork region are isolated sand and gravel deposits. These predominantly occupy narrow stretches along the rivers, including the Bandon River.

The Geological Survey of Ireland has devised a system for classifying the aquifers in Ireland based on the hydrogeological characteristics, size and productivity of the groundwater resource. The three main classifications are Regionally Important Aquifers (RI), Locally Important Aquifers (LI) and Poor Aquifers (P).

The Geological Survey of Ireland aquifer classification for the Lilly site and surrounds is *Locally Important Aquifer (LI) – bedrock which is Moderately Productive in Local Zones*. Refer to **Figure 14.3**.

Groundwater movement in the bedrock is concentrated in fractures and fissures, and along bedding planes. These occur predominantly close to the bedrock surface. Groundwater movement beneath the site has been interpreted as being in a south westerly direction. Groundwater in the bedrock appears to be confined by the overlying low permeability glacial till.

14.3.4.2 Groundwater Vulnerability

The vulnerability of a groundwater body is the term used to describe the ease with which the groundwater in the area can be contaminated by human activities. The vulnerability is determined by many factors including the travel time, the quantity of contaminants and the capacity of the deposits overlying the bedrock to attenuate contaminants.

These factors in turn are based on the thickness and permeability of the subsoil deposits, e.g. groundwater in bedrock which has a thick cover of low permeability clay is less vulnerable than the groundwater in bedrock which is exposed at the surface. The criteria for determining groundwater vulnerability, as developed by the Geological Survey of Ireland are shown in **Table 14.1** below. The Extreme vulnerability class is further sub-divided into Extreme (X) – rock near Surface or Karst and Extreme (E) - subsoils <3m thick.

Table 14.1: GSI Groundwater Vulnerability Mapping Guidelines (DoELG 1999)

Vulnerability Rating	Hydrogeological Conditions				
	Subsoil Permeability (Type) & Thickness			Unsaturated Zone	Karst Features
	High Permeability (sand/gravel)	Moderate permeability (e.g. sandy subsoil)	Low permeability (e.g. clayey subsoil, clay, peat)	(sand/gravel aquifers only)	(<30m radius)
Extreme (E)	0 – 3.0m	0 – 3.0m	0 – 3.0m	0 – 3.0m	-
High (H)	>3.0m	3.0 – 10.0m	3.0 – 5.0m	>3.0m	N/A
Moderate (M)	N/A	>10.0m	5.0 – 10.0m	N/A	N/A
Low (L)	N/A	N/A	>10.0m	N/A	N/A
Notes: (1) N/A = not applicable (2) Precise permeability values cannot be given at present (3) Release point of contaminants is assumed to be 1-2m below ground surface					

The Geological Survey of Ireland groundwater vulnerability maps show that the main vulnerability rating of the bedrock aquifer on site ranges from '*High (H) to Rock at or near Surface or Karst*', indicating an overburden thickness of 3m to 10m. Refer to **Figure 14.4**.

14.3.4.3 Groundwater Use

The site has two water supply sources. There is a municipal supply of potable water as well as a groundwater supply which is pumped from a number of wells at various locations around the site. The plant currently requires up to 1500m³/day of water for operation. Up to 1000m³ per day can be supplied from the municipal supply.

Approximately half of the groundwater well water is treated by filtration to drinking water standards. This is used for general washing, scrubber and cooling tower make-up. Twenty five per cent of the treated water is further treated and is used for production activities. It is also used in the laboratories and as boiler make up water. The remaining raw water is used in cooling towers and as quench water for the incinerators.

In 2015, approximately 445,859m³ (1200m³/ day) water was consumed at the site of which approximately 271,974m³ (745m³/day) was from the groundwater supply and 173,885m³ (477m³/day) was from the municipal supply.

Permission was granted with the IE43 development in 2012 for the abstraction of up to 1500m³/day of groundwater. As part of the development of the existing IE43 building, Lilly commissioned five additional groundwater wells on-site to facilitate the abstraction of up to 1500m³/day of groundwater . Although the five additional wells have been commissioned, they have not been drawn down to date. It intended that the wells will be drawn down in the next year or so.

As part of the development of the existing IE43 development, White Young Green (WYG) carried out a hydrogeological development investigation in 2012 at the request of Lilly on the groundwater resources beneath the Lilly site. Refer to **Appendix 14.2**. The investigation found that the long term sustainable groundwater yield of the wells on site, indicates that c. 1800m³/day of groundwater can be supplied to site.

Pumping tests were undertaken on the existing wells and test wells at the Lilly site. The long term sustainable groundwater yield of each well tested was determined from the constant rate pumping test results plotted on a semi-log graph of drawdown and time and are outlined in **Table 14.2** below. The parameters used in calculating the sustainable yield of a well included;

- The maximum permissible drawdown (obtained from information on the well construction and groundwater strikes).
- Pumping test data in relatively steady state conditions.
- Maximum drought period for an area.

Table 14.2: Sustainable Yield Calculations (WYG Report, 2012)

Test Production Well	Predicted 200 day drought drawdown level (m)	Discharge Rate (m ³ /day)	Predicted Specific Capacity after 200 days (m ² /day)	Maximum permissible drawdown (m)	Drought Period Sustainable Yield Calculation (m ³ /day)
W1	6.9	352	51	6	306
W9	7.6	115	15.13	8	121
W16	36	144	4	29	116
W17	36	310	8.61	26	224
W19	30	345	11.5	15	173
W20	37	345	9.32	22	205
W21	37.5	720	19.2	25	480
W22	24	288	12	14	168
Total		2619			1793

Table 14.2 indicates that c.1,800m³/day can be extracted from the aquifer on a sustainable basis in drought conditions. In early 2004, there were six production wells operating at the site supplying in the region of 1,000m³/day to 1,500m³/day.

The water levels in the stream flowing along the south of the site were measured at two locations over the five day pumping test at pumping rates up to 3,000m³/day. No change was detected to the water levels in the stream. This indicates that there is no evidence of hydraulic connection between the stream and the groundwater on-site. The monitoring of the groundwater levels in the bedrock wells on-site did not show any significant influence on the water table indicating the drawdown influences were not extensive beneath the whole site. It also concluded that the drawdown from the additional wells would be unlikely to impact on the groundwater resource and the water levels of the stream.

Nevertheless, a number of measures and controls were proposed in the previous 2011 IE43 EIS in order to protect surface water and groundwater sources from the drawdown of the additional wells. These measures are repeated in this EIS for clarity as the wells will be drawn down in the next year or so. These measures are described in Section 14.6 *Mitigation Measures* below.

As part of the planning condition for the original IE43 development, Lilly was conditioned to provide a water storage facility on site with 24 hour capacity. This condition was easily achieved as there are already two existing raw water storage tanks on site, T1 & T2 that act as feed tanks for water supply on site. These tanks provide 24 hour storage capacity. Each of these tanks has a raw water storage capacity of 1800m³, providing a combined water storage capacity of 3600m³. Thus these tanks currently provide in excess of 24 hour storage capacity based on the current total water demand for the operational site of up to 1500m³/day.

There are no discharges to the ground or groundwater on site and a comprehensive series of measures are in place to protect the groundwater under the site.

14.3.4.4 Groundwater Monitoring

The current IE Licence (P0009-03) conditions require monitoring of the groundwater wells on site. Monitoring is undertaken as follows:

Table 14.2: Groundwater Monitoring under IE Licence P0009-03.

Parameter	Monitoring frequency	Analysis Method / Technique
pH	Biannually ^{note 2}	pH electrode / meter
COD	Biannually	Standard method
Conductivity	Biannually	Standard method
Major cations	Biannually	Standard method
Major anions	Biannually	Standard method
Individual heavy metals	Biannually	Standard method
Trace Organics ^{note 1}	Biannually	Standard method

Note 1: Screening for priority pollutants list substances (such as CLP40, USEPA volatile and/or semi volatile).

Note 2: Six-monthly.

14.3.5 Onsite Drainage

14.3.5.1 Introduction

The storm water drainage collection system is described below. Process effluent is described in Chapter 11, *Effluent Generation and Treatment*.

14.3.5.2 Uncontaminated Storm Water Run-off

Rainwater run-off from areas with little or no potential for contamination by process materials, such as roads and roofs, is collected in a storm water drainage system. This drainage system drains into a containment pond located in the south western area of the site. Refer to **Figure 14.5 On-Site Surface Water Management System**.

The inlet flow and outlet flow from the containment pond passes through chambers, in which there is continuous monitoring for the flow rate, total organic carbon (TOC) and pH. The IE licence (P0009-03) requires weekly monitoring at the storm water outfall for pH and TOC and a daily visual inspection. Therefore the risk of contaminated storm water discharging to the stream is minimised.

After passing through the containment pond, the storm water outfalls to the stream which flows in an approximate northeast-southwest direction through the Lilly site as shown on **Figure 14.2**. This stream flows into Doon Creek which forms part of the Bandon River.

Storm Water Separation

The storm water drainage system was re-configured when the IE30 development came on-stream in 2005 so that the storm water run-off from the western part of the site can be separated from the run-off from the eastern part of the site. A diversion chamber was constructed, upstream of the containment pond, on each of the main collector drains, which serve the two parts of the site. There is the provision to route either main drain into the existing containment pond or to permit either main drain to bypass the containment pond if necessary.

Normally storm water run-off from the entire site drains through the containment pond. In the event of a fire or incident in part of the site, storm water run-off from the other parts can be diverted around the pond, while run-off from the affected area can continue to flow into the pond. This reduces the total flow to the pond and increases the available containment capacity for potentially contaminated water. Refer to Section 14.3.5.4 below for further details on fire water containment.

14.3.5.3 Bund Run-Off

Rainwater run-off from bunded areas and some process building roofs is collected and routed to the biological wastewater treatment plant as potentially contaminated run-off. This is considered necessary as the bunds are acting as secondary containment of the materials stored in the bunded tanks. The biological wastewater treatment plant is described in Chapter 11, *Effluent Generation and Treatment*.

14.3.5.4 Fire-Water Containment

Chemicals are used in all process areas on site and are stored in tank farms, and warehouses.

In the tank farm, each tank is bunded to 110% of the tank volume to contain any chemicals in the case of leaks or fire. As discussed above, rainwater from bunded areas is routed to the biological wastewater treatment plant.

Activation of sprinkler, deluge and foam fire-fighting systems could potentially create contaminated firewater that may run-off from the location of the fire into the storm water drainage system. As discussed above, the storm water system drains into the containment pond. The containment pond can retain potentially contaminated fire water which is collected by the storm water drainage system. The pond has a capacity of 6,110m³ and is lined with high-density polyethylene. This volume was based on an approximately 2-hour flow rate from the following sources:

- Firewater from the most severe fire in any one area of the Lilly site.
- Site drainage from storm rainfall coincident with the fire.

As described previously, the outflow from the pond is automatically monitored for TOC and pH. In the event that the pre-set limit for TOC or pH is exceeded, the outlet valve from the pond will close automatically.

This outlet valve can be closed, remotely, from the environmental control room or security centre, or manually at the valve. In the unlikely event of contamination of the pond, the pond's contents can be pumped to the inlet to the biological wastewater treatment plant (WWTP) or the final effluent holding tank/wet well, depending on the need to treat the pond water. Therefore the risk of contaminated storm water discharging to the stream is minimised.

14.3.5.5 Storm Water Attenuation

The existing surface water drainage network serving the existing IE43 building conveys run off from this area to an attenuation tank located to the south west of the building. The existing attenuation tank provides for storage of runoff associated with the existing IE43 development during periods of heavy rainfall, attenuating flows discharging to the stream.

14.3.5.6 Treated Wastewater Receiving Waters

Treated wastewater from the treatment plants is discharged through a pipeline to a diffuser about 500 m offshore near Sandy Cove Island in the outer Kinsale harbour. Refer to **Figure 11.3**. Refer to Chapter 11 *Effluent Generation and Discharge*. The receiving waters are used for water sports and fishing and there are beaches within 2km of the emission point.

14.4 Characteristics of the Proposed Development

For the proposed IE43 extension and associated works, this section addresses the characteristics of the proposed development in relation to soils, geology, hydrology and hydrogeology during both the construction and operational phases.

14.4.1 Construction Phase

14.4.1.1 Introduction

The process block extension will extend outwards from the southern façade of the existing IE43 facility. The headblock extension will extend outwards from the north eastern façade of the existing IE43 administration block. Additional staff car parking will be provided via new car parks within the site. Internal site roads, services, hard standing and landscaping are also proposed as part of the development. Refer to **Figure 3.1 Site Location Plan** and **Figures 3.3 to 3.5** which show the extent of the proposed development. The construction of these elements will require ground preparation works such as excavation works, removal of made ground and reuse of excavated material as landscaping. These are described further below.

In addition to the areas required beneath the footprint of the proposed development, there will be a number of areas required within the Lilly site to facilitate the construction phase of the IE43 extension. This will include separate car parking and access/egress points for Lilly staff and construction staff.

A contractor's laydown area will be located south of the IE43 process block extension, north of the recently diverted stream. Contractor facilities will be located south of IE42 and IE30, north of the existing stream. A contractor's compound will be located south of the contractor facilities, south of the existing stream. Vehicular access across the stream to the contractor's compound will be via the existing bridge across the stream. The construction of these elements will require minimal excavation as most of these areas are already hard standing. These are described further below. In addition, a full description of all of the construction works for the proposed development may be referred to in Chapter 4 *Construction Activities*.

14.4.2 Ground Preparation Works

As described previously in Chapter 4 *Construction Activities*, the eastern part of the Lilly site generally slopes downwards in a south-easterly direction from higher ground adjacent to the local road towards the stream, which crosses the site. The cross-fall extends to the land to the east of production building IE42.

The area of the proposed IE43 process block extension is currently at 29.000m (site datum) as this area formed part of the ground works scope for the exiting IE43. This will be the formation level for the lower ground floor slab of the proposed IE43 process extension. The area of the proposed IE43 headblock extension will have the same ground levels as the existing building (38.700m (site datum)). Therefore the only excavation required for these two areas will be locally for foundations and services.

The majority of the material arising from the excavations for the headblock and process block extensions will be reused as landscaping material on existing berms located along the eastern and south eastern boundaries of the site or as engineering fill for the proposed development.

Only very small volumes of material (approximately 900m³ tarmac/asphalt) which are unsuitable for reuse on site will require offsite disposal. This material will be removed off site for recycling and reuse or disposal at a licenced site.

Materials required for the construction works will be sourced locally where possible. Materials required from quarries will only be sourced from quarries which are listed on the register maintained by the local authority. The environmental impacts associated with registered quarries have already been assessed by the local authority under Section 261 of the Planning and Development Act 2000, as amended. Approximately 8,000m³ engineering fill will be required to be imported.

All traffic movements associated with the import and export of materials have been included in the construction traffic impact assessment. Refer to Chapter 8 *Roads and Traffic* of this EIS for further details.

Any additional engineering fill required will be sourced from material already stockpiled on site.

No material will require excavation for the establishment of the construction compounds. These sites are currently hardstanding.

No soil contamination is expected. In the unlikely event that any evidence of soil contamination is found during work on site, the appropriate remediation measures will be employed. Any work of this nature would be carried out in consultation with, and the approval of the EPA and the Environmental Department of Cork County Council.

14.4.3 Construction Site Drainage

Construction Site Drainage is described in Section 4.9.3 of *Construction Activities*. That section outlines the proposed construction site drainage which will be put in place to minimise impacts on surface and groundwater. Refer also to the Jacobs report *Temporary Surface Water Control System* which accompanies the planning application for further details.

14.4.4 Water Supply during construction

It is envisaged that the construction activities for the proposed IE43 extension will require approximately 50m³ per day of water. There is sufficient capacity within the municipal supply and groundwater supply for this increase.

14.4.5 Operational Phase

14.4.5.1 Water Supply

It is envisaged that the IE43 extension process activities will require approximately 109,500m³ of raw water per year (300m³ per day), thereby increasing overall Lilly site water consumption to 657,000m³ per annum (1800m³ per day).

In order to supply the increased water demand it is proposed to increase water sourced from well water by up to c. 1800m³ per day. It is not anticipated that the demand for council water will exceed 1000m³/day.

As discussed previously in Section 14.3.4.3, the results of the study carried out by WYG on behalf of Lilly indicate that there is sufficient capacity within the aquifer (c. 1800m³ per day) to facilitate this increase. In addition, the drawdown from the additional wells (commissioned as part of existing IE43 development) is unlikely to impact on the groundwater resource and the water levels of the stream. The measures and controls proposed previously for the IE43 EIS in order to protect surface water and groundwater sources from the drawdown of the additional wells are repeated in this EIS for clarity as the wells will be drawn down in the next year or so. These measures are described in Section 14.6 below.

Also, as discussed in Section 14.3.4.3, the two existing raw water storage tanks on site, T1 & T2 will continue to provide in excess of 24 hour storage capacity based on the projected total water demand for the operational site of up to 1800m³/day.

14.4.5.2 Drainage

Eli Lilly commissioned a flood risk assessment (FRA) for the site which considers the proposed IE43 extension and associated works. Refer to **Appendix 14.1**. As outlined above in Section 14.3.3.2, it is considered that there may be a fluvial risk (existing stream) to the proposed development. The proposed development is located within Flood Zone C and while the meteorological conditions required to generate a flood risk to the proposed development will not occur frequently, there still is a risk which needs to be considered.

The proposed development therefore includes a concrete wall adjacent to the stream bank. The proposed top of wall level is 31.5 m (site datum). This will provide protection to the site should an event of greater magnitude occur.

A section of the existing surface water drainage network runs through the footprint of the proposed IE43 extension. As part of the works this section of sewer will be diverted to the south of the site. In addition to diverting this line, the existing attenuation tank downstream will also be replaced.

Surface water runoff associated with the extension, delivery yard, access road and proposed car park to the north will be conveyed within the existing and diverted line to the proposed attenuation tank. Forward flow from the attenuation tank to the existing network downstream will be limited to the pre-development runoff rate or 'greenfield' runoff rate.

There is an existing surface water drainage network within the existing IE43 car park. As part of the proposed works the existing network will be extended to provide capacity for the additional car spaces. An attenuation tank will also be provided to store runoff from the existing and additional parking areas. The forward flow from this attenuation tank to the downstream network will be limited to greenfield runoff rate. This will result in a reduction in the rate of forward flow from this car park when compared with the existing scenario.

By limiting the forward flow from each attenuation tank to predevelopment runoff rates, there will not be a change in the rate of runoff discharged from the site. Drawing IE43-A01-04-000084, prepared as part of the planning submission, illustrates the layout of the proposed surface water drainage network and the location of the proposed attenuation tanks.

Process water generated by the proposed development will connect into the existing process water drainage system. There will be no discharges to ground.

14.5 Evaluation of the Impacts

14.5.1 Construction Impacts

Potential sources of pollution of soil, geology, surface waters or groundwater during the construction phase are leaks or spills of fuels, lubricants and paints. Some work below the existing ground level will be required, as outlined above. The foundations will be constructed above the water table and therefore will not impact on groundwater.

Small or minimal groundwater inflow(s) is therefore anticipated during excavation works. Construction Site Drainage is described in Section 4.9.3 of *Construction Activities*. This section outlines the proposed construction site drainage which will be put in place controls to minimise impacts on surface and groundwater. These are standard construction controls which can easily be implemented and will ensure that no significant impacts on surface water or groundwater will arise during the construction phase

Piling may be required in some areas such as in the vicinity of the old stream bed north of the recently diverted stream.

The excavation associated with the proposed IE43 extension will potentially create the risk that silt or mud may enter the stream, which runs past the southern part of the proposed IE43 extension site, either directly or carried in surface water run-off. Refer to Construction Site Drainage which described in Section 4.9.3 of *Construction Activities*.

There is sufficient capacity within the existing water supply for the additional 50m³ per day required during the construction phase.

14.5.2 Operational Impacts

14.5.2.1 Potential Contamination

The handling, use and storage of the small quantities of solvents and hazardous chemicals required for the proposed IE43 extension 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.

There is little risk that spills or leaks will enter the ground and groundwater or into the streams which flow through and past the site.

14.5.2.2 Groundwater Abstraction

In order to supply the increased water demand it is proposed to increase water sourced from well water by up to c. 1800m³ per day. It is not anticipated that the demand for council water will exceed 1000m³/day. 1,800m³/day can be extracted from the aquifer on a sustainable basis in drought conditions.

14.5.2.3 Flooding Risk

It is considered that there may be a fluvial flood risk in the vicinity of the proposed development.

A hydraulic model of the existing channel and river bank was generated as part of the FRA to quantify the flood risk to the proposed development. This model found that the maximum water levels in the stream, in the vicinity of the proposed development would be approximately 29.26 m (site datum). This is approximately 0.44 m below the proposed finished floor level of 29.7 m (site datum).

Following review of the available information and the development of the hydraulic model, it is considered that the site of the proposed development is located within **Flood Zone C**. Flood Zone C is defined in the Guidelines as the Flood Zone where the probability of flooding is lowest (less than 0.1% or 1 in 1000) and would be considered suitable for the proposed development.

The proposed development therefore includes a concrete wall adjacent to the stream bank. The proposed top of wall level is 31.5 m (site datum). This will provide protection to the site should an event of greater magnitude occur

The design of the surface water drainage system for the proposed development has ensured that flows to the stream will not be increased, as a result of the proposed development and that surface water discharges will be at greenfield rates. Therefore it is considered that there will not be an impact on flooding elsewhere as a result of the proposed development.

In terms of potential impacts therefore, the main potential impact is that the capacity of the existing channel may be reduced significantly if not maintained regularly.

14.5.2.4 Geophysical Risk

While the project involves the construction of short lengths of relatively low concrete walls, these pose no significant engineering challenges. Given the ground conditions on the site and the nature of the proposed IE43 extension project, the risk of a landslide or other geophysical risk is regarded as negligible.

14.5.3 Potential Cumulative Impacts

There are no planned developments on site or in the surrounding area that may have a cumulative effect on the soils, geology, hydrology or hydrogeology as a result of this proposed development.

As production demands change in response to the pharmaceutical market the site may need to be developed in the future to have the capacity to meet these demands. Additional warehousing, administration and laboratory facilities may all need to be considered in the future. With such developments, the design focus will be to maximise efficiencies in terms of land on site and the present infrastructure while minimising the impact on natural resources such as groundwater. The WYG hydrogeological report (refer to **Appendix 14.2**) has shown that the proposed IE43 extension will not require additional raw water (in excess of 1000m³/day) from municipal sources as there is more than adequate groundwater resources within the site to meet current and future demands.

14.6 Mitigation Measures

14.6.1 Construction Mitigation Measures

Refer to Section 4.14.6 of Chapter 4 *Construction Activities*.

This section outlines the employment of good construction management practices which will serve to minimise the risk of pollution of soils, groundwater or surface water during construction.

14.6.2 Operational Mitigation Measures

The detailed measures and standard operating procedures in place on site currently will be extended to cover the proposed IE43 extension. All underground process pipes and drains will have secondary containment and all chemical storage tanks will be bunded to 110% of capacity as is site practice.

Storage areas, production facilities and roadways will have impervious surfaces, which will drain to collection systems. Storm run-off from collection systems will drain either to the environmental controls area for treatment of run-off, or to a sump where it will be monitored before discharge. It will be contained if the monitoring detects contamination. The external areas around the proposed IE43 extension, where there would be potential for spills or leaks, will be bunded to contain and divert spills and firewater. The water discharges via the containment pond to the stream after passing through the monitoring chamber.

As outlined previously, the proposed development is located within Flood Zone C and while the meteorological conditions required to generate a flood risk to the proposed development will not occur frequently, there still is a risk which needs to be considered. The proposed development includes a concrete wall adjacent to the stream bank. The proposed top of wall level is 31.5 m (site datum). This will provide protection to the site should an event of greater magnitude occur. In order to ensure that flood damage is minimized the following measures are also recommended:

- Suitable building materials and finishes that are less likely to be damaged and easier to restore will reduce the amount of time would take to return the facility to operation.
- All chemicals, solvents, fuels or other materials that may cause environmental contamination should they come in contact with flood waters will be stored within a bunded area within the proposed development.

The design of the surface water drainage system for the proposed development has ensured that flows to the stream will not be increased, as a result of the proposed development and that surface water discharges will be at greenfield rates. (Refer to Sections 14.4.5.2 and 14.5.2.3 above). Therefore it is considered that there will not be an impact on flooding elsewhere as a result of the proposed development.

It can be seen from the hydraulic model that a reduction in capacity has an impact on estimated water levels. The channel may become overgrown with vegetation if not maintained. In order to minimise the risk of the channel capacity being reduced, a channel maintenance programme will be put in place in consultation with Inland Fisheries Ireland (IFI).

As detailed in the previous 2011 IE43 EIS, flows in the stream will be monitored for up to 12 months prior to drawdown and the following measures and controls (as detailed previously in the IE43 EIS) will be put in place, from the outset to protect surface and groundwater sources in the long term. These will include:

- Two gauging stations, one upstream and the other downstream of the wells, will be installed on the stream and monitoring of flow rate and water level undertaken for up to 12 months prior to commissioning of the additional abstraction wells. These will be used to establish the baseline data on the stream level and flows prior to commissioning the wells.
- The sustainable yield for each well was established during the development phase. The abstraction from each well will be automatically capped at a percentage of its sustainable yield.
- There is a number of groundwater monitoring wells on the site. The groundwater levels in monitoring wells across the site will be monitored on an ongoing basis.
- The groundwater level and discharge flow volumes will be monitored in each well to ensure that there is no excessive drawdown of the groundwater.
- The water levels in the stream will be monitored on an ongoing basis for at least 5 years using the gauging stations described above. The requirement for monitoring after this period will be reviewed with Inland Fisheries Ireland and Cork County Council.
- Pumping from the wells will be controlled to ensure that there will be no impact on the water levels in the stream.
- The mitigation measures outlined above will be implemented to ensure that there are no adverse impacts on the stream or the local groundwater due to the groundwater abstraction activities.
- In the event of an effect being detected on the stream or the local groundwater that cannot be resolved by managing the groundwater abstraction on site, increased water supply will be obtained from Cork County Council.

The development is not expected to have a significant impact on soils, geology, hydrology, hydrogeology.

14.7 Residual Impacts

It is anticipated that with the implementation of the mitigation measures above, neither the construction, nor the operation phases of the project will result in any significant negative impacts on the soils, geology, surface water or groundwater of the site.

14.8 References

An Fóras Taluntais (1980) Soil Map of Ireland

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<http://dcenr.maps.arcgis.com/apps/MapSeries/index.html?appid=a30af518e87a4c0ab2fbde2aaac3c228> Accessed 8 July 2016

IGSL (2011) Eli Lilly IE43 Geotechnical Site Investigation Report (Project No. 15026)

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15 Cultural Heritage

15.1 Introduction

15.1.1 Introduction

This chapter of the EIS consists of an appraisal of the proposed IE43 Biotech Manufacturing Facility Extension hereafter referred to as the proposed IE43 extension, under the heading of archaeological, architectural and cultural heritage.

This chapter initially sets out the methodology followed (**Section 15.2**), describes the receiving environment (**Section 15.3**), and summarises the main characteristics of the proposed development which are of relevance for archaeological, architectural and cultural heritage (**Section 15.4**). The likely significant impacts of the proposed development on archaeological, architectural and cultural heritage are described (**Section 15.5**), measures are proposed to mitigate likely significant impacts (**Section 15.6**), and residual impacts are described (**Section 15.7**). The chapter concludes with a reference section (**Section 15.8**).

The proposed development is located within the Eli Lilly facility, located at Ballythomas West, Dunderrow, Kinsale, Co Cork.

There are a total of 42 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 a 2km radius of the proposed development. One of these (CO111-089), a redundant record, lies within the construction footprint of the proposed development. These records provide evidence for human settlement and activity in the area dating back to the Bronze Age.

Some terms used in this report are explained hereunder.

15.1.2 Archaeological Heritage

Archaeological heritage can be described as the study of past human societies through their material remains and artefactual assemblages. The Valetta Treaty (or the European Convention on the Protection of the Archaeological Heritage, 1992) defines archaeological heritage as “all remains and objects and any other traces of humankind from past times” this includes “structures, constructions, groups of buildings, developed sites, moveable objects, monuments of other kinds as well as their context, whether situated on land or under water”.

15.1.3 Architectural Heritage

Architectural heritage is defined in the Architectural Heritage (National Inventory) and Historic Monuments (Miscellaneous Provisions) Act, 1999 as structures and buildings together with their settings and attendant grounds, fixtures and fittings, groups of such structures and buildings, and sites, which are of architectural, historic, archaeological, artistic, cultural, scientific, social or technical interest.

15.1.4 Cultural Heritage

Cultural Heritage is an expression of the ways of living developed by a community and passed on from generation to generation, including customs, practices, places, objects, artistic expressions and values. Cultural Heritage is often expressed as either Intangible or Tangible Cultural Heritage (ICOMOS, 2002). Environmental Protection Agency Guidelines (2003), define cultural heritage as including archaeological heritage, architecture, history, landscape and garden design, folklore and tradition, geological features, language and dialect, religion, settlements, inland waterways (rivers), and place names.

15.1.5 Study Area

In order to obtain a comprehensive assessment of the Cultural Heritage Environment, a study area within approximately 2km radius of the proposed development site including construction footprint was examined.

15.2 Methodology

15.2.1 Methods

The methodology used to complete this section of the EIS comprised the following:

- A review of the relevant legislation and guidelines;
- A desktop assessment of the proposed development site and study area;
- A survey or inspection of the proposed development site;
- An evaluation of the likely significant impacts of the proposed development on the archaeological, architectural and cultural heritage of the proposed development site and study area; and
- Proposed mitigation measures to be undertaken to prevent or reduce any potential impacts on the archaeological, architectural and cultural heritage.

15.2.2 Legislation and Guidelines

In Ireland, the primary means of protecting cultural heritage assets are the National Monument (Amendments) Acts 1930 to 2004, the Heritage Act 1995, the relevant provisions of the National Cultural Institutions Act 1997, the Architectural Heritage (National Inventory) and Historic Monuments (Misc. Provisions) Act 1999 and the Local Government (Planning and Development) Act 2000, as amended. Policies for both the archaeological and architectural heritage are relayed in a series of specific published guidelines. This chapter is prepared having regard to the following guidelines:

Guidelines on the information to be contained in Environmental Impact Statements, 2002 (Environmental Protection Agency) and Draft Revised Guidelines, 2015.

Advice Notes on Current Practice in the Preparation of Environmental Impact Statements, 2003 (Environmental Protection Agency) and Draft Revised Advice Notes, 2015.

Guidelines on the information to be contained in Environmental Impact Statements, 2003, EPA.

Advice Notes on Current Practice (in preparation of Environmental Impact Statements), 2003, EPA.

Framework & Principles for the Protection of the Archaeological Heritage, 1999 (Department of Arts, Heritage, Gaeltacht & the Islands).

Policy & Guidelines on Archaeological Excavation, 1999 (Department of Arts, Heritage, Gaeltacht & the Islands).

Architectural Heritage Protection, Guidelines for Planning Authorities, 2004. (Department of the Environment, Heritage and Local Government).

Comprehensive guidelines on the treatment of the archaeological and architectural heritage during the planning and design of national road schemes were published by the National Roads Authority in 2005. These were also used as a guide in the compilation of this EIS.

Guidelines for the assessment of Archaeological Heritage Impacts of National Road Schemes, 2005a (NRA).

Guidelines for the assessment of Architectural Heritage Impacts of National Road Schemes, 2005b (NRA).

15.2.3 Desktop Study

The desktop study provided a cultural heritage overview of the proposed development site and study area and used the following sources.

15.2.4 Record of Monuments and Places (RMP)

This record was established under Section 12 (1) of the National Monuments (Amendment) Act 1994.

It lists all monuments and places believed to be of archaeological importance in the County. The numbering system consists of two parts: the first part is the county code (CO for Cork) followed by the Ordnance Survey map number (six-inch to the mile scale); the second part is the number of a circle surrounding the site on the RMP map, e.g. CO111-085 refers to circle 085 on OS sheet 111 for County Cork. The circle is intended to show the recorded monument or place and is sometimes referred to as the zone of archaeological potential or zone of notification but the circles do not define the exact extent of the monument or place. The diameter of the circle can vary depending on the size and shape of the site but it averages out at approximately 180m. The RMP for County Cork was published in 1998. There are a number of RMP sites within the study area. Refer to Section 15.3 below for further details.

15.2.5 Sites and Monuments Record (SMR) Database of the Archaeological Survey of Ireland at the NMS

The purpose of the Archaeological Survey of Ireland (ASI) is to compile a baseline inventory of the known archaeological monuments in the State. The archive and database resulting from the survey are being continually updated. Archaeological sites which are added to the database are proposed to be included in the next published edition of the RMP and will then be afforded its protection. Sites previously listed in the RMP which, following investigation, are now considered to be of no archaeological potential are de-listed from the database and generally described as redundant records. This database, complete with maps is now available for consultation via the National Monuments Service (NMS) website at www.archaeology.ie. There are a number of SMR sites within the study area. Refer to Section 15.3 below for further details.

15.2.6 Archaeological Inventory

The inventories for each county are follow-ons by Archaeological Survey of Ireland to the RMPs. They give a written description of each archaeological site in the county.

The Archaeological Inventory of County Cork - East Cork, Volume 2 (Power, Byrne, Egan, Lane and Sleeman) was published in 1994 and a follow up volume, Volume 5 (Ronan, Egan and Byrne), was published in 2009.

15.2.7 Files of the NMS, Department of Arts, Heritage, Regional, Rural and Gaeltacht Affairs (DAHRRGA)

The NMS was consulted to retrieve information on lists of RMP sites that have been afforded added protection such as;

- National Monuments in the ownership or guardianship of the state – None in the study area;
- Monuments subject to Preservation Orders and Temporary Preservation Orders – None in the study area; and

- Monuments listed in the Register of Historic Monuments – None in the study area.

15.2.8 The National Museum of Ireland Archives

These files were consulted for townlands within the study area. The topographical files contain the reports, including correspondence, present location and occasionally, illustrations of archaeological material recovered throughout the country. No stray finds are reported in the files for the proposed development site or adjoining townland.

15.2.9 County Development Plan for Cork (2014)

The Cork County Development Plan (CDP) (2014) outlines Cork County Council's objectives with regard to the preservation of the archaeological, architectural and cultural heritage of the County. The CDP outlines the Council's objectives regarding the protection of the archaeological heritage, including the protection of monuments listed in the Sites and Monuments Record and Record of Monuments and Places, by preservation in situ, or in exceptional cases, preservation by record. It aims to safeguard 'sites and settings, features and objects of archaeological interest generally'. The zones of archaeological potential identified in the RMP are to be protected, as are underwater archaeology and historic towns. The CDP states that the significance of medieval archaeology, industrial and post medieval archaeology, battlefield and siege sites, as well as structures shown on the 1st and 2nd edition Ordnance Survey 6 inch maps are to be assessed prior to any development. It states that where development may have an impact on the archaeological heritage, an archaeological assessment will be required, and appropriate mitigation measures shall be put in place.

The CDP states that preservation in situ is the preferred option, and that there must be compelling reasons to justify preservation by record. Development that does not compromise sub-surface archaeological remains will be encouraged, and development that does not have a visual or physical impact on the setting of a monument will be favoured.

According to the plan, previously unidentified archaeological sites that are uncovered during construction works must be investigated and recorded.

The rich and varied architectural heritage of the County is protected through the inclusion of buildings in the Record of Protected Structures (RPS), as required in the Planning and Development Act 2000 (Part IV).

This record includes all structures or parts of structures which are in the opinion of the Council of 'special, architectural, historical, archaeological, artistic, cultural, scientific, social or technical interest'. This designation is to ensure that changes or alterations to the included buildings or their settings will be carried out in such a way that their existing special character and setting is retained and enhanced. The objectives of the Council for the RPS include:

- The identification of structures for protection according to criteria set out in Architectural Heritage Protection – Guidelines for Planning Authorities (2004, 2011), as well as the extension of the RPS to form a comprehensive schedule for the County;
- The protection of structures and parts of structures, listed in the RPS, as well as their curtilage and attendant grounds;
- Ensuring that development proposals for protected structures are appropriate and of high quality;
- Ensuring best conservation practises are promoted; and
- Ensuring high quality architectural design of new development relating to or impacting on structures and their settings included in the RPS.

The National Inventory of Architectural Heritage (NIAH) for County Cork includes approximately 6,500 items of architectural importance in the County. The structures identified as being of international and national importance are included on the RPS. Other structures of regional importance, were considered for inclusion in the record. Cork County Council recognises the important contribution that all historic structures, including those not on the record, make to County Cork's heritage. The Council will seek the enhancement of these elements in recognition of their "quality, character and local distinctiveness" (Cork County Development Plan 2014, Vol. 1, p.194) and will "give regard to and consideration of all structures which are included in the NIAH for County Cork, which are not currently included in the Record of Protected Structures, in development management functions" (ibid. 195). In addition to these objectives, the Council will seek to enhance all historic structures, features and landscapes not included in the RPS as well as non-structural elements such as designed gardens, garden features, masonry walls, railings, follies, gates, bridges and street furniture.

There are no protected structures within the proposed development site. There is one that falls within the 2km study area; White Castle (RPS no 00717) in Ardclloyne located approximately 1.8km away.

The County Development Plan (2014) outlines how the rich and diverse cultural heritage of the County will be promoted and protected by Cork County Council "as an important economic asset". The Plan includes "language, the arts, creative industries, enjoyment of the natural, historic and built environment, events and festivals, use of tourist attractions, libraries, museums, archives and galleries, industrial heritage, the diversity of the faith communities and places of worship, local cultural traditions and sport and recreation" as culture that helps to define the perception of the County and provides a sense of identity. The Plan acknowledges the importance of folklore, oral cultural heritage, historic heritage sites, including battle sites, historic rights of way and Irish place names.

15.2.10 NIAH Architectural Inventory of Architectural Heritage (NIAH)

The National Inventory of Architectural Heritage was set up under the Convention for the Protection of the Architectural Heritage of Europe or the Granada Convention of 1985.

It was established on a statutory basis under Section 2 of the Architectural Heritage (National Inventory) and Historic Monuments (Miscellaneous Provisions) Act 1999.

The work of the NIAH involves identifying and recording the architectural heritage of Ireland, from 1700 to the present day, in a systematic and consistent manner. It is divided into two parts; The Building Survey and Historic Garden Survey (www.buildingsofireland.ie). The main function of both is to identify and evaluate the State's architectural heritage in a uniform and consistent manner, so as to aid to its protection and conservation. The National Inventory of Architectural Heritage carried out a survey of the buildings of County Cork between 2006 and 2011.

Under Section 53 of the Planning and Development Act 2000, as amended, all structures considered of regional, national or international Importance within the survey are recommended for inclusion in the Record of Protected Structures by the Minister for Arts Heritage and the Gaeltacht.

If this is not adopted by the local authority, the reasons must be communicated to the Department. The Building and Historic Garden Survey for County Cork is available online.

No buildings or gardens included in the Inventory are located within the proposed development site. A number of buildings are located within the 2km study area, the nearest of which is Dunderrow House (Reg. No. 20911130) approximately 200m to the north of the Lilly complex.

15.2.11 Database of Irish Excavation Reports (www.excavations.ie)

This website provides a database of summary accounts of archaeological excavations and investigations undertaken in Ireland between 1970 and 2015. Until 2010, these accounts were also published in book form. The database was queried for any investigations undertaken in the proposed development site and Study Area. A number of archaeological investigations were undertaken in the Eli Lilly site and are outlined below in Section 15.3.

15.2.12 Site-specific publications

All available published information on the study area was consulted. This included historical journals, local history publications etc., all of which are listed.

15.2.13 Cartographic Sources

The following maps were consulted:

- The Down Survey Parish and Barony maps (1654-1659);
- Ordnance Survey 6-inch maps: the three editions of the 6-inch to one mile scale maps were consulted, the first edition published in 1841-1842, the second edition published in 1902, and the third edition published in 1939 onto which the RMP was superimposed in 1998. Refer to **Figures 15.1-15.3**; and

- The 25-inch to one mile scale map, from which the second edition 6-inch map was derived in 1902 was also consulted.

15.2.14 Aerial Photographs

Ordnance Survey of Ireland online aerial photographs (dated 1995, 2000 and 2005) (www.osi.ie) and Google maps online aerial photographs are available for viewing (www.google.ie).

These were examined to identify any previously unrecorded features of archaeological/cultural heritage significance that may only be visible from the air. The growth and expansion of the facility was apparent on the images. No archaeological features were apparent on the photographs.

15.2.15 Site Inspection

The primary purpose of a site inspection is to assess the physical environment in which the proposed development will take place and identify any possible features of cultural heritage significance which have not been previously recorded. Current land use, local topography and environmental conditions are assessed to gain an overall picture of the area. The proposed development site was visited in July 2016.

15.3 Receiving Environment

The area to be developed is located within the Lilly site boundary. The Lilly site itself is located approximately 5km northwest of Kinsale, on the R605 road from Kinsale to Inishannon, Co Cork. It occupies the entire townland of Ballythomas West and a portion of the adjoining townland of Ballythomas East. The plant comprises a series of buildings and car parks, compounds and yards.

The Lilly pharmaceutical manufacturing plant in Dunderrow was opened in 1981 and it has been gradually expanded during the past three decades. The following archaeological investigations have been carried out within the Lilly complex in recent years.

- **June 2000** (Planning Ref: S/00/1140) archaeological monitoring of extension to an existing warehouse (IE1). No features or finds of archaeological significance were revealed.
- **May 2001** Archaeological monitoring under licence (01E1111) in southwest area of complex. No features or finds of archaeological significance were revealed.
- **November 2001** (Planning Ref. S/01/3362) archaeological monitoring (01E1111) of construction of an electrical distribution building and material store, extension to Drum and an environment treatment building. No features or finds of archaeological significance were revealed.
- **July 2002** (Planning Ref: S/01 5197) archaeological monitoring (01E1111) of construction of an office building & laboratory. No features or finds of archaeological significance were revealed.

- **December 2002** an archaeological assessment in advance of development of clean manufacturing facility. GeoArc Ltd (Planning Ref: C/03/0053) identified anomalies which were investigated under licence (03E0573) in April 2003.
- **April 2003** archaeological testing (03E0573) investigated anomalies identified during geophysical investigation which were confirmed as old field boundaries and previous field cultivation activities.
- **August 2003** Archaeological monitoring (03E0573) following testing in April 2003. No finds or features of archaeological nature were noted during monitoring.
- **May 2004** Archaeological section of EIS for proposed development of various buildings (IE35 & IE16 expansion).
- **October 2007** Archaeological testing (07E860) in advance of the construction of IE42 biotech manufacturing facility. No features or finds of archaeological significance were revealed.
- **December 2007 to April 2008** Archaeological monitoring (07E860) of five fields within the IE42 construction site. No features or finds of archaeological significance were revealed.
- **January 2011** Geophysical survey (10R0171) was carried out by Target Geophysics on two small areas at the northern end of the site in advance of construction of IE43. A number of anomalies of limited archaeological potential were identified.
- **May 2011** Archaeological testing (11E0115) of identified geophysical anomalies revealed no features or finds of archaeological significance.
- **July 2011** Archaeological and cultural heritage section of EIS for IE43.
- **November 2011** Geophysical survey (11R150) of a field in the north-eastern corner of Ballythomas East revealed a subsurface circular enclosure approximately 30m diameter (this has been included as a ringfort in the SMR database by the ASI – referred to as CO111-099).
- **November 2012** Archaeological wading and metal detector survey (12D11 and 12R50) of a stream on the townland boundary between Ballythomas West (at the north) and Ballythomas East (at the south). No features or finds of archaeological significance were revealed.
- **November 2012** Archaeological testing (12E129) of the proposed diverted line of the stream in Ballythomas East above. No features or finds of archaeological significance were revealed.
- **September 2015** Archaeological testing (15E425) and a metal detector survey (15R121) in advance of the construction of a warehouse IE27 at the north-western corner of the facility. No features or finds of archaeological significance were revealed.

- **June 2016** Archaeological monitoring (16E276) of the area surrounding the stream diversion in Ballythomas East revealed a levelled fulacht fiadh. During the subsequent excavation under an extension to the above licence a horizontal water mill was identified and also excavated (Cotter 2016). The stream diversion was carried out under planning reference 11/06594 relating to the construction of IE43.

The existing IE43 manufacturing facility commenced construction in 2012, to the east of IE42, another large biotech production building. The land now beneath the existing IE43 building was used as a construction zone during the building of IE42 and, as part of that project, was archaeologically monitored between December 2007 and April 2008 under licence 07E0860. No archaeological features were revealed.

When IE43 was itself developed extensive ground reduction was undertaken to bedrock levels within its footprint and in adjoining ground.

Cartographic sources indicate the area of the Lilly complex including the proposed development site has been under agricultural use since the mid-19th century.

The 1842 6" OS map, (**Figure 15.1**), the 25-inch map of 1897-1904 (**Figure 15.2**) (from which the second edition of the 6-inch map was derived) and the 1939 6-inch map (**Figure 15.3**) show the area laid out as generally reasonably sized, rectangular fields.

There are only very minor changes to field boundaries apparent from the mid-19th century until the late 20th century when the manufacturing complex was established.

There are 42 recorded archaeological sites included in the RMP and SMR database within the 2km study area (**Table 15.1** and **Figure 15.4**) of which eight are in the Lilly complex or immediately adjoining land. Two of these are redundant records, one (CO111-090) within the construction footprint of the proposed development in Lilly lands in Ballythomas East and the other (CO111-090) a short distance northeast in Ballyvrin Lower.

The other six are a fulacht fia (CO111-035) and ringfort (CO111-099) in Ballythomas East, a bullaun stone (CO111-034) and a souterrain (CO111-085) in Ballythomas West, a graveyard in Horsehill More (North) (CO111- 033) and a battlefield (CO111- 100) in Ardclloyne, Ballincurra, Ballythomas East, Ballythomas West, Ballyvrin Upper, Ballyvrin Lower and Horsehill More (North and South). Two other archaeological sites were recently identified and excavated within the south-eastern part of the Lilly complex which have not yet been included in the SMR database. These are a fulacht fia and a horizontal water mill, both in Ballythomas East and situated just south of the stream defining the townland boundary between Ballythomas West and East.

The fulacht fia (CO111-035) in Ballythomas East is included in the Archaeological Inventory of Co Cork (Power 1994) and is described as follows:
In reclaimed land to E of stream. No visible surface trace.

The ringfort in the same townland (CO111-099) was identified as a circular enclosure during a geophysical survey of undeveloped lands within the Lilly complex in 2011 (Nichols 2011). The enclosure, measuring approximately 30m diameter, was revealed with an entrance facing southeast and has been included as a ringfort in the SMR. This land remains undeveloped within the complex.

The bullaun stone (CO111-034) in Ballythomas West is now located in the reception area of a Lilly administration building. It is included in the Archaeological Inventory of Co Cork (Power 1994) and is described as follows:

Bullaun stone in NW corner of field in pasture. Circular flat stone with central hollow (diam. 0.47m; D 0.21m).

The souterrain (CO111-085) also in Ballythomas West was found during the initial phase of development of the Lilly facility. It is described in the Archaeological Inventory of Co Cork (ibid) as follows:

Souterrain Discovered 1980 during construction of industrial complex. Two earth-cut chambers linked by creepway. Entrance gained through collapsed roof of chamber 1; original entrance (Wth 0.6m) infilled at NE end of chamber. Chamber 1 roughly circular in plan (2.4m N-S; 2.2m E-W; H 1.6m). Creepway (L 1.5m; Wth 0.7m; H 0.4m) leads S to chamber 2; L-shaped in plan; main axis E-W (L 2.5m; Wth 1.9m; H 1m). Blocked construction shaft to E of creepway; visible in SE face of chamber 1 and N of chamber 2 (UCC).

The graveyard in Horsehill More (North) (CO111- 033) is located immediately northwest of the Lilly complex and is described in the Archaeological Inventory of Co Cork (ibid) as follows:

Graveyard On N side of Dunderrow crossroads; circular graveyard (diam. c. 65m); S half of boundary truncated by roadway, from which it is separated by stone wall; otherwise bounded by stone-faced earthen bank (for plan see Henchion 1971, 111). In occasional use; Henchion (ibid.) records 55 inscriptions; earliest headstones dates from 1730; Roche chest tomb has date 1665 on side panel (ibid.).

No longer any visible trace of C of I church erected here in 1812 (Brady 1863, vol. 1, 90) and described by Lewis (1837, vol. 1, 572) as 'a small handsome edifice, with a lofty square tower' (part of S wall visible in photo facing p 110, Henchion 1971); on site of ancient parish church of Dunderrow. Church here was in repair in 1639 (Brady ibid.) but by 1810 church in graveyard described as 'unsafe and not capable of receiving such repairs as may be safe and permanent' (Day 1913, 170).

The battlefield complex (CO111-100) includes the townlands of Ballythomas West and Ballythomas East, in which the Lilly complex is located as well as the adjoining townlands of Ardclloyne, Ballinacurra, Ballyvrin Lower, Ballyvrin Upper, Horsehill More (North) and Horsehill More (South).

The battlefield site is associated with the Battle of Kinsale of 1601 when the Gaelic Irish and English crown forces engaged in open battle concluding a three month siege of the town. The site is not described in the SMR database nor in the Archaeological Inventory of County Cork (1994 and 2009).

The battle was one of the more significant encounters in the Nine Year War fought between the Gaelic lords of Ulster and their allies against the crown forces of Elizabeth. It marked a decisive point in medieval Irish history after which the old Gaelic society went into decline, never to recover.

The Spanish forces, allied to the Gaelic lords of Ulster, landed in Kinsale in September 1601 and quickly found themselves pinned down by the English crown forces who surrounded the town and held the harbour. The English were, in turn, surrounded by the, largely northern, Gaelic forces. The siege lasted three months ending in a significant defeat for the Gaelic Irish. Although no above ground traces of the battle or its associated siege works survive in the landscape today it is thought likely that substantial contemporary earthworks and defences would have extended across the surrounding landscape.

The location of the military encounter between the Gaelic forces and the English was long thought to have been at Millwater Ford (Shiels 2004, 346-7) approximately 1.6km southeast of the Lilly complex.

Close to this location the numerically superior Gaelic forces of approximately 6,000 men and 800 horses were routed by an English force of approximately 1,500-2,000 men and 400-500 horses.

The Kinsale Battlefield Project was set up in 2001 with the aim of locating sites associated with and leading up to the battle in 1601. To date desk based analysis re-examining historical and cartographic sources has been undertaken including a re-evaluation of the Trinity College painting which appears to present a contemporary picture of the battle. Metal detection surveys have also been carried out at three locations.

This led to the discovery of 21 pieces of unfired lead shot in Abbeylands, adjoining Camphill, and three lead shots in Rathbeg, both a short distance north of Kinsale town, suggesting the respective locations of the lord deputy's camp and the earl of Thomond's second camp (Shiels 2009, 139-141 and O'Keeffe and Shiels 2008, 12).

Following further analysis Shiels has concluded that the battle itself may not have taken place in the area of Millwater Ford but may have taken place near the village of Dunderrow (Shiels 2007, 6).

This analysis is based on the premise that the earl of Thomond's first camp was located at Liscahane More, where a metal detection survey was attempted but due to ground conditions could not be successfully undertaken (Shiels 2009, 141 and Shiels 2007, 6). Shiels (2004, 347) proposes that the Gaelic tercios (or defensive square positions) formed during the encounter between the two forces could be detected by extensive metal detection survey followed by strategic test pitting.

The retreat of the Gaelic forces "which would have spread equipment and projectiles over a wide area" makes attempts to locate these retreating positions more difficult (Shiels 2004, 347). Shiels suggests that it is possible that some part of the military encounter may have occurred within the Eli Lilly facility although to date no such evidence has been found despite numerous archaeological investigations within the facility.

The two archaeological sites within the Lilly property which are not yet included in the SMR database, were identified during archaeological monitoring of ground works adjoining the area of a stream diversion just inside Ballythomas East townland in June 2016 in an area of rough ground (**Figure 15.5**). A fulacht fia was first identified in boggy ground to the southeast of the stream and during the excavation of this the remains of a horizontal water mill were uncovered at the south-western end of the fulacht fia. Both were fully excavated and post-excavation work is ongoing (Cotter 2016).

The broader landscape of the proposed development site and study area demonstrates that the earliest evidence for human activity dates to the Bronze Age (circa 2,400-500 BC). Although the island of Ireland has been occupied since the Mesolithic period (circa 7,000-4,000BC) and continuing through the Neolithic period (circa 4,000-2,400 BC) there is no surviving evidence of this period in the study area.

The concentration of Bronze Age sites includes the two aforementioned fulachtaí fia along with eight others, as well as two standing stones.

There is no evidence for the Iron Age (500-BC-AD400) activity in the broader landscape or study area but there are a large number of monuments dating to the medieval period (early medieval - 5th -12th century; high medieval 12th century - circa 1400; and late medieval period - circa 1400 to 16th century) within the study area. This includes the aforementioned souterrain, bullaun stone and ringfort as well as seven other ringforts, another souterrain and bullaun stone, a vertical wheeled water mill and possibly enclosures. The churches and graveyards, burial grounds and fortified house may date to the following centuries.

Table 15.1: Archaeological sites included in the RMP and SMR database within a 2km radius of the proposed development site (Refer also to Figure 15.4 and Figure 15.5)

RMP	Site Type	Townland
CO111-089	Redundant record	Ballythomas East
CO111-099	Ringfort	Ballythomas East
CO111-090	Redundant record	Ballyvtrin Lower
CO111-100	Battlefield	Ardcloyne, Ballincurra, Ballythomas East, Ballythomas West, Ballyvtrin Upper, Ballyvtrin Lower, Horsehill More (North and South)
CO111-036	Ringfort	Ballythomas East
CO111-035	Fulacht fia	Ballythomas East
CO111-034	Bullaun stone	Ballythomas West
CO111-085	Souterrain	Ballythomas West
CO111-033	Graveyard	Horsehill More (North)
CO111-070	Fulacht fia	Killany
CO111-067001-	Ringfort	Killany
CO111-067002-	Souterrain	Killany
CO111-068	Burial ground	Killany

RMP	Site Type	Townland
CO111-069	Fulacht fia	Killany
CO111-066001-	Earthwork	Dunderrow
CO111-066002-	Souterrain	Dunderrow
CO111-065	Ringfort	Dunderrow
CO111-030	Fulacht fia	Knocksmall
CO111-029	Fulacht fia	Knocksmall
CO111-028	Standing stone	Knocksmall
CO111-027	Ringfort	Lissard
CO111-031001-	Enclosure	Clogheen
CO111-031002-	Souterrain	Clogheen
CO111-032	Standing stone	Horeshill More (North)
CO111-088	Fulacht fia	Ballynamona
CO111-086	Enclosure	Ballynamona
CO111-038	Ringfort	Ballynamona
CO111-040	Ringfort	Mellifontstown
CO111-041002-	Church	Mellifontstown
CO111-041001-	Graveyard	Mellifontstown
CO111-039	Ringfort	Mellifontstown
CO111-044	Fulacht fia	Ardmartin
CO111-037	Enclosure	Butlerstown
CO111-091	Water mill- vertical wheeled	Ardcloyne
CO111-071	Fortified house	Ardcloyne
CO111-087	Bee-boles	Ballinacurra
CO111-075001-	Graveyard	Tisaxon Beg
CO111-075002-	Burial ground- Watchman's hut	Tisaxon Beg
CO111-075003-	Church	Tisaxon Beg
CO111-073001-	Fulacht fia	Tisaxon Beg
CO111-073002-	Fulacht fia	Tisaxon Beg
CO111-072	Bullaun stone	Tisaxon Beg

According to Murphy (2002, 10) the village of Dunderrow was built by the Roche family for the employees of their estates.

The Roche family originally came from Castletownroche near Fermoy, Co Cork in the late 15th century and were a major force in the area for almost three hundred years. O'Leary & Murphy (1990, 48) suggest that the name Dunderrow comes from Dún Dear Mhuighe, the fortress of the oak plain. The Dún or 'Doon' being a large mound built by the Danes in the 8th - 9th century and said to have been 'one of the largest Danish entrenchments of its kind in the country'.

It had ‘five circumvallations (fosses or mounds of earth) moated, and could very well have covered up to or over two acres’. Murphy (2002, 10) ascribes the name to a ‘nearby Celtic ringfort or rath, the substantial portion of which is preserved to the present day – Dún Dair Mhuighe, the Fortress of the Oak Plain’. The name Ballythomas derives from Baile Thomáis meaning the townland, town or homestead of Tomáis (Logainm.ie).

The 1st edition Ordnance Survey (OS) map of 1842 (**Figure 15.1**) shows a number of unnamed buildings almost centrally located within the Lilly landownership.

A roadway/avenue runs from the west side of one of these buildings, presumably a house, south-westwards to the Kinsale to Inishannon road and another runs from the north side of the house north-westwards to a secondary road. There are fields to the east and west of the house and some of the field boundaries to the north and west of the house are tree-lined.

A church and graveyard lie just outside the western land boundary at a T-junction. A wider section of road at this junction is attributed as ‘corporation ground’.

The areas of the proposed IE43 extension, temporary site entrance and associated construction areas are shown as fields with an unnamed stream flowing southwest through the land from the eastern boundary of the Lilly lands. The stream flows along the townland boundary between Ballythomas West and Ballythomas East with an irregular unnamed small watercourse a short distance to the southwest which is likely to be the tail race from the horizontal water mill excavated in June 2016 in this area.

The 25-inch map of 1897-1904 (**Figure 15.2**) depicts a similar topography to the 1st edition map. While the layout of the field boundaries remains largely the same there are some other minor changes. ‘Ballythomas House’ is named and depicted within the complex of buildings almost centrally located within the Lilly lands. Some additions and changes are apparent to the buildings and the roadways/avenues remain unchanged. The ground to the south and northwest of the house is depicted as marshy. The junction of the secondary road to the north of the house and the main Kinsale to Inishannon road is marked as ‘Dunderrow Cross Roads’. The areas of the proposed IE43 extension and associated construction areas are shown as fields.

The course of the irregular unnamed watercourse, which is probably associated with the horizontal water mill, has been moved a short distance to the northwest to align with the stream, townland boundary and existing field boundaries. Some of the land through which the stream previously flowed is shown as marshy.

The 3rd edition OS map of 1939 (**Figure 15.3**) depicts a similar topography to the 25-inch map. Ballythomas House is named and depicted with some modifications to the nearby buildings. Watercourses run along the field boundaries to the northeast of the house. The stream is shown running from northeast to southwest along the southern townland boundary with marshy ground adjoining it in places.

The areas of the proposed IE43 extension and associated construction areas are shown as fields.

The Cork County Development Plan (2014) does not list any protected structures or features of architectural merit within the extent of the Lilly land ownership. The nearest protected structure to the proposed development is that of White Castle (RPS no 00717) in Ardclloyne located approximately 1.8km to the southeast of the site. Similarly, there are no architectural conservation areas (ACAs) in the area. The nearest ACAs are in Bandon town.

Nine buildings within the study area are included in the NIAH (**Table 15.2**). The closest of these is Dunderrow House (Reg. No. 20911130) approximately 200m to the north of the Lilly complex.

Table 15.2: Buildings included in the NIAH within a 2km radius of the proposed development site

NIAH No	Name	Location
20911130	Dunderrow House	Horsehill More (North)
20911129	House	Ballyvrrin Lower
20911138	Farm house	Ballynamona
20911139	House	Ballynamona
20911140	House	Ballinacurra
20911142	House	Ballinacurra
20911132	House	Killany
20911134	House	Hollyhill
20911131	House	Dunderrow

15.4 Characteristics of Proposed Development

The extension to the existing IE43 biotech manufacturing facility will include administration and manufacturing accommodation over three floors with intermediate service platforms. The manufacturing element of the IE43 extension (referred to as process block extension) will extend outwards from the southern façade of the existing IE43 facility. The administration element of the IE43 extension (referred to as headblock extension) will extend outwards from the north eastern façade of the existing IE43 administration block. Additional staff car parking for approximately 136 cars will be provided via new car parks. The existing staff car park located just west of the existing Ballyvrrin road site entrance will be extended. A second staff car park will be located east of the existing Ballyvrrin road site entrance, north of IE43. Internal site roads, services, hard standing and landscaping are also proposed as part of the development. Refer to **Figure 3.1 Site Location Plan** and **Figures 3.3 to 3.5** which show the extent of the proposed development. Refer also to **Figure 4.1 Construction Site Logistics Plan** which shows the construction site logistics for the duration of the construction phase

The proposed development site was inspected on the 6th July 2016 in mixed bright sunny weather conditions, refer to **Figures 15.6 and 15.7**. Photographs of the inspected areas were not taken at that time but were taken almost two weeks later.

The area of the proposed IE43 extension was inspected as well as adjoining ground to the north and south where the additional car parking, entrance and associated construction works areas (contractor's car park, contractor's laydown area and contractor's facilities area) will be located during the course of the project. The existing IE43 is a large production building oriented north-northwest by south-southeast with an adjoining administration block at the northern end and an adjoining warehouse to the west. A hard standing (tarmac) area lies to the northeast. A large open hard-surfaced yard lies to the south (**Figure 15.8**) and is flanked to the south and east by a site road which forms part of the existing internal road network and also runs along the eastern side of the aforementioned car park. Ballyvtrin Lower lies to the northeast of the road and Ballythomas East to the southeast. A large manufacturing building, IE42, lies to the southwest. To the north there is a steeply inclined landscaped area, and beyond it a large yard/compound previously used for construction activity.

The proposed manufacturing element of the IE43 extension or process block extension will be located in the large open hard-surfaced yard to the south of the existing IE43 building. The proposed administration element of the IE43 extension (headblock extension) will be within the tarmac area to the northeast.

Both areas were within the construction footprint of IE42 and were archaeologically monitored between December 2007 and April 2008 (07E0860) (Lane 2008). No archaeological features or finds were recovered. Both areas were subject to ground disturbance and ground reduction during the construction of IE43.

In addition to the areas required beneath the footprint of the proposed development, there will be a number of areas required within the Lilly site to facilitate the construction phase of the IE43 extension.

Lilly staff car parking and access/egress to the eastern end of the site will be kept separate from construction traffic during the construction phase. A temporary entrance will be located to the west of the existing Ballyvtrin road entrance. A temporary car park will be located west of the existing staff car park off Ballyvtrin Road. This temporary entrance plus the temporary car park and the western section of the existing car park will be used by Lilly staff during the construction period. The eastern end of the existing staff car park in addition to a number of construction parking areas east of the existing Ballyvtrin Road entrance and north of IE30 and IE43 will be used for construction staff parking. The existing Ballyvtrin Road entrance will be used for construction traffic only. A contractor's laydown area will be located south of the IE43 process block extension, north of the recently diverted stream. Contractor facilities will be located south of IE42 and IE30, north of the existing stream. A contractor's compound will be located south of the contractor facilities, south of the existing stream. Access across the stream to the contractor's compound will be via the existing bridge across the stream. Refer to **Figure 4.1 Construction Site Logistics Plan**.

The temporary entrance and staff car parking to the west of the existing staff car parking will be located in an area of hard standing which was used as a construction car park and laydown during the construction of IE43.

This area (**Figure 15.8**) and another similar area (**Figure 15.9**) further to the northeast which will be used as a car park along the Ballyvrin Road were subject to geophysical survey (10R171) and subsequent archaeological testing (11E0115) in 2011 in advance of the development of the existing IE43 building. No archaeological features or finds were revealed. The exiting staff car park to the north along the Ballyvrin Road was subject to archaeological monitoring in two phases. The western portion was monitored during July and August 2003 (03E0573) (Lane and Brett 2003) and the eastern portion between December 2007 and April 2008 (07E0860). No features or finds of archaeological significance were revealed in either area.

The adjoining ground to the south of IE43, where associated construction works will be undertaken, includes a contractor's laydown area, a contractor's compound and a contractor facilities area. The contractor's laydown area lies to the south of the proposed IE43 extension and to the north of the recently diverted stream. Works associated with the stream diversion process were ongoing, at the time of the inspection, with the new channel for the stream excavated further to the south. During archaeological monitoring and excavation (16E0276) to facilitate this diversion in June 2016 a fulacht fia and water mill were identified and excavated (Cotter 2016).

Ground reduction has now been completed in the area and no archaeological deposits remain in situ. The proposed contractor's compound and contractor facilities area both lie to the west of the laydown area.

The contractors compound is an area which was archaeologically monitored between December 2007 and April 2008 under licence 07E0860 (Lane 2008) as part of the construction of IE42. A small area of burning (measuring 1m by 0.6m) was revealed in this area which upon investigation was determined to relate to tree root burning and was of no archaeological significance. The area was subsequently built up and surfaced with stone forming an open yard (**Figure 15.10**). The contractor facilities area includes an existing site road flanked on the south side by a drain (**Figure 15.11**) and further west an area of hard standing.

15.5 Evaluation of Impacts

The proposed development site lies within the Lilly facility in land which has been subject to numerous archaeological investigations in the past decade followed by development. During archaeological monitoring in the field to the south of IE43 proposed construction laydown area a fulacht fia and horizontal water mill were identified and excavated (Cotter, *ibid*). The deposits were fully resolved during June 2016 and no archaeological deposits remain in situ.

No other archaeological deposits were revealed within the proposed development site or proposed construction areas.

There are six recorded archaeological sites within the Lilly lands and adjoining areas (CO111-085, CO111-034, CO111-033, CO111-035, CO111-099 and CO111-100¹). None of these will be impacted by the proposed development.

Note (CO111-089) lies within the construction footprint of the proposed development but is classified as a redundant record.

There are no protected structures listed in the Cork County Development Plan 2014 within the proposed development site. In addition, there are no structures listed in the National Inventory of Architectural Heritage for Co Cork within the proposed development site.

There are no cultural heritage sites within the proposed development site. No features of archaeological or cultural heritage were noted during the site inspection.

15.5.1 Construction Impacts

The proposed development site is previously disturbed and has been subject to numerous archaeological investigations. No in situ deposits survive within the proposed development area. No construction impacts on archaeological deposits are foreseen.

15.5.2 Operational Impacts

No operational impacts are foreseen.

15.5.3 Potential Cumulative Impacts

No potential cumulative impacts on the archaeological, architectural or cultural heritage are foreseen.

15.6 Mitigation Measures

15.6.1 Construction Mitigation Measures

No construction mitigation is required.

15.6.2 Operational Mitigation Measures

No operational mitigation measures are required.

¹ The battlefield complex (CO111-100) includes the townlands of Ballythomas West and Ballythomas East, in which the Lilly complex is located as well as the adjoining townlands of Ardclloyne, Ballinacurra, Ballyvrin Lower, Ballyvrin Upper, Horsehill More (North) and Horsehill More (South). No evidence of the battlefield complex has been found within the Lilly facility to date despite numerous archaeological investigations within the facility.

15.7 Residual Impacts

As the proposed development site has already been archaeologically investigated and subject to earlier ground reduction there will be no residual impacts on the archaeological, architectural or cultural heritage associated with the proposed development.

15.8 References

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16 Material Assets

16.1 Introduction

This chapter of the EIS consists of an appraisal of the proposed IE43 Biotech Manufacturing Facility Extension hereafter referred to as the proposed IE43 extension, under the heading of material assets.

Material Assets are defined in the EPA Advice notes on current practice in the preparation of EIS (EPA 2003) as “resources that are valued and that are intrinsic to specific places, they may be either human or natural origin and the value may arise for either economic or cultural reasons”. The EPA revised draft Advice notes (2015) state that the “assessment shall be concerned primarily with ensuring equitable and sustainable use of resources”.

Material assets are also appraised in a number of chapters of this EIS including:

Natural resources (soils, geology & water) are examined in Chapter 14, *Soil, Geology, Hydrogeology and Hydrology*. Surface water drainage and process effluent are examined in Chapters 14, *Soil, Geology, Hydrogeology and Hydrology* and Chapter 11, *Effluent Generation and Treatment* respectively. Cultural heritage is examined in Chapter 15, *Archaeological, Architectural and Cultural Heritage* whilst traffic and site access is addressed in Chapter 8, *Roads and Traffic*. Waste produced during the operational phase is addressed in Chapter 12, *Waste*. Construction waste is examined in Chapter 4 *Construction Activities*.

This chapter addresses the following aspects:

- Land use and ownership; and
- Utilities (such as power, water supply, gas).

This chapter initially sets out the methodology followed (**Section 16.2**) and describes the receiving environment (**Section 16.3**). The main characteristics of the proposed development which are of relevance for material assets are described (**Section 16.4**). The likely significant impacts of the proposed development on material assets are described (**Section 16.5**), measures are proposed to mitigate likely significant impacts (**Section 16.6**) and residual impacts are described (**Section 16.7**). The chapter concludes with a reference section (**Section 16.8**).

16.2 Methodology

This chapter has been prepared having regard to the following guidelines:

- Revised Guidelines on the Information to be Contained in Environmental Impact Statements (EPA, Draft September 2015);
- Advice Notes for Preparing Environmental Impact Statements (EPA, Draft September 2015);

- Guidelines on the Information to be contained in Environmental Impact Statements (EPA 2002); and
- Advice Notes on Current Practice in the Preparation of Environmental Impact Statements (EPA 2003).

A desk study was carried out on the existing material assets associated with the site of the proposed development.

Refer to Chapter 4 *Description of Proposed Development* of this EIS for a detailed description of the site and surrounding areas.

16.3 Receiving Environment

16.3.1 Land Use, Zoning and Local Settlement

The Lilly site is located southeast of Dunderrow village in Co Cork. The site is surrounded by farmland and dispersed rural dwellings. The nearest settlements to the site are individual dwellings along the Ballyvrin road and Dunderrow village to the north and northwest of the site respectively. Refer to **Figures 1.2 and 1.3**. Refer to Chapter 7 *Landscape and Visual* for a detailed description of the receiving local landscape.

The western boundary and main entrance of the Lilly facility are located off the R605. The R605 is a National Regional road and is the main road between Innishannon and Kinsale. The local Ballyvrin road borders the northern boundary of the site. The southern and western site boundaries are adjacent to farmland. A stream runs along the southern boundary of the site and flows into the Bandon River Estuary to the west of the site. A section of the stream in the south western corner of the site was diverted as part of the construction for the existing IE43 facility. Refer to **Figure 1.2**.

The current land use within the Lilly site may be broken down into production facilities, environmental facilities, laboratories, warehousing, external storage, utility generation, maintenance workshop, offices, staff facilities and a cafeteria. The existing production facilities and principal buildings are addressed in Chapter 3 *Description of the Proposed Development*.

Section 15.2.14 of the Bandon Electoral Area Local Area Plan (LAP) specifically identifies the role of Lilly within the vision for and context of Dunderrow, with references to further development of the site having direct implications for the proposed extension:

15.2.14. Eli Lilly, a large pharmaceutical firm employing in excess of 450 people has been operating from Dunderrow since 1981. The plant itself is located several hundred metres to the south of the village, and quite distinct from the main body of the village, on the eastern side of the R605. The plant itself is affected by the Seveso II Directive, with a consultation distance of 1,000 meters. Any extension to this existing development will be acceptable in principle subject to the terms of the Directive and the policies and objectives of the County Development Plan.

The lands within the Lilly site are not specifically zoned in the Bandon Electoral Area Local Area Plan (LAP) (2015).

Under the Cork County Development Plan (2014), policy ZU 2-3 states that *“Where lands have not been explicitly zoned, in either the adopted Local Area Plans or the adopted Special Local Area Plans, the specific zoning shall be deemed to be that of the existing use of the lands (if such a use is not an unauthorised use under the Planning Acts) or, if such a use is unauthorised, that of the most recent authorised use of the lands”*.

The Lilly site has been operating as a pharmaceutical facility since early 1981 in compliance with its planning permissions. The proposed IE43 extension project conforms to the zoning objective of the Development Plan in that the zoning is that of the existing use of the land, which is industrial. Further, the LAP has stated that further extension at the Lilly facility would be ‘acceptable in principle’, as long as it conforms to Seveso requirements, as well as planning policy and objectives.

Refer to Chapter 5 *Planning and Policy Context* for further detail.

16.3.2 Utilities

16.3.2.1 Power

The site has a 38kV connection to the national power grid. In 2015, the site consumption of electricity was 59,625 MWHrs/year. 18MWHrs energy was generated on site in 2015. The recently commissioned CHP unit (see section 16.3.2.2 below) will contribute up to approximately 30GWHrs (30,000MWHrs) of electricity generation in the future.

16.3.2.2 Gas and Oil

Natural gas is used on site currently as the fuel for the incinerator, thermal oxidisers and boilers. A new CHP system was installed in 2016 which also uses gas.

In 2015, 7,411,340 m³ gas was consumed over the year (846m³/hr) which comprised usage from the IE4 boilers and KEU incinerator only (the CHP unit was not online in 2015). Therefore it is expected that gas consumption will increase in 2016 due to the addition of the new CHP system.

The CHP unit comprises a 4.4MWe engine/alternator set complete with waste heat recovery boiler. It is located in a new 1860ft² single storey building to the south west of IE42. The CHP engine fuelled by natural gas (LCV = 9,738 kW per hour at 4.4MWe), drives the alternator to supply the site medium voltage network displacing external utility power. Waste heat from the engine exhaust, recovered in the boiler as steam, feeds the site steam header (c. 1800kW), whereas waste heat recovered from the engine jacket, as hot water (c. 1650kW), supplies building hot water systems in IE30, IE42 & IE43.

The net increase in gas consumption for CHP is forecasted as 700m³/h gas (when the CHP unit is running, 1100m³/h gas is consumed but 350m³/h gas is saved at the IE4 boilers.)

Light fuel oil (diesel) is used for the emergency generators, some fork-lift trucks and the firewater pumps. In 2015, the site used 41m³ (year) of light fuel oil.

16.3.2.3 Water Supply, Consumption and Storage

The site has two water supply sources. There is a municipal supply of potable water as well as a groundwater supply which is pumped from a number of wells at various locations around the site. The plant currently requires up to 1500m³/day of water for operation. Up to 1000m³/day can be supplied from the municipal supply. Refer to Section 14.3.4.3 *Groundwater Use* of Chapter 14 *Soils, Geology, Hydrology and Hydrogeology* for further details.

As part of the planning condition for the original IE43 development, Lilly was conditioned to provide a water storage facility on site with 24 hour capacity. This condition was easily achieved as there are already two existing raw water storage tanks on site, T1 & T2 that act as feed tanks for water supply on site. These tanks provide 24 hour storage capacity. Each of these tanks has a raw water storage capacity of 1800m³, providing a combined water storage capacity of 3600m³. Thus these tanks currently provide in excess of 24hrs storage capacity based on the current total water demand for the operational site of up to 1500m³/day.

16.3.2.4 Steam

For the existing IE43 facility, a new branch was installed on the steam generation header from which a new steam line was extended through the site on piperacks to IE43. Refer also to Section 16.3.2.2 above for details in relation to the waste heat produced from the CHP system which feeds the steam header.

16.4 Characteristics of the Proposed Development

16.4.1 Land Use, Zoning and Local Settlement

For the proposed IE43 extension, all of the development works will take place within the Lilly site boundary. No additional land is required by Lilly for this proposed development.

Most of the land to be developed is hardstanding or made ground. The proposed development will require the removal of some vegetation on site. This is addressed in Chapter 13 *Biodiversity*.

There will be no change in land use or zoning arising from the proposed development. The lands that will be developed as part of the proposed IE43 extension are not zoned as part of the Bandon Electoral Area LAP. However the proposed development is “*that of the existing use of the lands*” as stated in the Bandon Electoral Area LAP (2015).

16.4.2 Utilities

There will be an increased demand on utilities to facilitate the operation of the proposed IE43 extension. There will also be an increased demand during construction.

16.4.2.1 Power

During construction, existing electrical services will be utilised with the exception of some portable welding plant. Power demand during the construction phase will require a peak demand of 250kVA/day. There is sufficient capacity within the existing site infrastructure to facilitate the additional load.

During operation, the estimated additional electrical load for the IE43 extension during operation will be 15,000 MWhr/year. There is sufficient capacity within the existing site infrastructure to facilitate the additional load.

16.4.2.2 Gas and Oil

During operation, the proposed IE43 extension development is forecast to increase natural gas demand by circa 252m³/h. There is sufficient capacity within the recently installed CHP system to facilitate the IE43 extension.

During operation, the use of light fuel oil (diesel) will not increase.

16.4.2.3 Water Supply, Consumption and Storage

It is envisaged that the IE43 extension process activities will require approximately 109,500m³ of raw water per year (300m³ per day), thereby increasing overall Lilly site water consumption to 657,000m³ per annum (1800m³ per day).

In order to supply the increased water demand it is proposed to increase water sourced from well water by up to c. 1800m³ per day. It is not anticipated that the demand for council water will exceed 1000m³/day. There is sufficient capacity within the aquifer for the proposed increase. Refer to Section 14.4.5.1 *Water Supply* of Chapter 14 *Soils, Geology, Hydrology and Hydrogeology* for further details.

The construction phase will require an additional 50m³ /day of water.

As discussed previously, the two existing raw water storage tanks on site, T1 & T2 act as feed tanks for water supply on site. These tanks provide 24 hour storage capacity. Each of these tanks has a raw water storage capacity of 1800m³, providing a combined water storage capacity of 3600m³. Thus these tanks will continue to provide in excess of 24hrs storage capacity based on the projected total water demand for the operational site of up to 1800m³/day.

16.4.2.4 Steam

The same steam line for the existing IE43 will be extended for the IE43 extension for operation. There is sufficient capacity within the existing site infrastructure to accommodate the IE43 extension.

16.5 Evaluation of Impacts

16.5.1.1 Land Use, Zoning and Local Settlement

The proposed development is in keeping with the existing land use. No significant impacts are envisaged during the construction and operational phases.

All of the works will be within the Lilly site boundary.

The construction of the proposed IE43 extension and associated works will utilise existing hardstanding on site for the construction compounds and construction staff car parking. No significant impacts are envisaged.

16.5.1.2 Utilities

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 to Chapter 4 *Construction Activities*, Chapter 11 *Effluent Generation and Treatment*, Chapter 12 *Waste* and Chapter 14 *Soils, Geology, Hydrology and Hydrogeology* for further details.

16.5.1.3 Potential Cumulative Impacts

No significant cumulative impacts on the material assets described above are envisaged.

16.6 Mitigation Measures

The design for the IE43 extension targeted reductions in resource use such as water, electricity, fuel, and raw materials, and has aimed to minimise emissions of process effluent, off-gases, noise and waste. The IE43 extension has been designed to share the existing facilities where possible that are in the existing structure. No mitigation measures are proposed.

16.7 Residual Impacts

It is anticipated that there will be no significant residual impacts on material assets as a result of this development.

16.8 References

Eli Lilly, Annual Environmental Report, 2015.

Eli Lilly, Annual Environmental Report, 2014.

Environmental Protection Agency (2015) Revised Guidelines on the Information to be Contained in Environmental Impact Statements, Draft September 2015.

Environmental Protection Agency (2015) Advice Notes for Preparing Environmental Impact Statements Draft September 2015.

Environmental Protection Agency (2002) Guidelines on the Information to be contained in Environmental Impact Statements.

Environmental Protection Agency (2003) Advice Notes on Current Practice in the Preparation of Environmental Impact Statements.

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17 Other Impacts, Interactions and Cumulative Effects

17.1 Introduction

This chapter addresses the cumulative impacts, indirect impacts and main interactions between different aspects of the environment likely to be significantly affected by the proposed development. This chapter also addresses environmental effects which have not been specifically addressed in the individual chapters of the EIS.

Only topics which could be logically linked to the development have been examined in detail. Accordingly, when a topic is not mentioned, the authors have concluded that no potential for impact exists.

17.2 Methodology

Reference was made to the EPA Documents, *Guidelines on the information to be contained in Environmental Impact Statements*, EPA 2002, and *Advice Notes on Current Practice (in the preparation of Environmental Impact Statements)*, EPA 2003 (EPA guidelines) in the preparation of this chapter of the EIS.

The EPA has more recently published *Revised Guidelines on the Environmental Impact Statements Draft* (EPA, 2015) and *Advice Notes for Preparing Environmental Impact Statements Draft* (EPA, 2015) and both these documents were referred to in preparing this chapter.

The EU has also prepared guidelines, *Guidelines for the Assessment of Indirect and Cumulative Impacts as well as Impact Interactions*, published by the Office for Official Publications of the European Communities in May 1999 (EU guidelines).

At the screening stage in the preparation of the EIS for the proposed development, the potential for significant cumulative and indirect impacts and interactions was examined and any such potential impacts were identified. Where the potential for significant cumulative and indirect impacts and interactions was identified, such impacts and interaction of impacts were included in the scope and addressed in the baseline and impact assessment studies for each of the relevant environmental media and aspects of the project. The cumulative and indirect impacts and interaction of impacts are presented in the chapters of the EIS which address the most relevant environmental media.

The matrix and expert opinion approaches, as outlined in the EU Guidelines, were used in the identification of the potential for significant cumulative and indirect impacts and interactions. Refer to **Table 17.1** for the matrix of potential interactions. Modelling and carrying capacity analyses were used to evaluate impacts.

17.2.1 Definitions

There are no generally agreed and accepted definitions for indirect impacts, cumulative impacts or inter-relationship of impacts. The EPA Guidelines (2002) define cumulative impact thus: *The addition of many smaller impacts to create one larger more significant impact.*

The EPA Guidelines (2002) do not define indirect impacts. The EPA Guidelines use the term synergistic impacts. Synergistic impact is defined as: *Where the resultant impact is of greater significance than the sum of its constituents.*

In 2015, the EPA published draft EIS guidelines, *Revised Guidelines on the Information to be Contained in Environmental Impact Statements.*

The draft EPA Revised Guidelines (2015) define indirect effects as being “those that arise off site or are caused by other parties that are not under the control of the developer” and secondary effects as “those that arise as a consequence of a project.”

The EU guidelines use slightly different definitions as follows:

Indirect Impacts: Impacts on the environment, which are not a direct result of the project, often produced away from or as a result of a complex pathway (sometimes referred to as second or third level impacts or secondary impacts).

Cumulative Impacts: Impacts that result from incremental changes caused by other past, present or reasonably foreseeable actions together with the project.

Impact Interactions: The reactions between impacts whether between the impacts of just one project or between the impacts of other projects in the area.

The term ‘impact interactions’ is equivalent to the term ‘inter-relationship of effects’. The EU guidelines accept that their definitions overlap to a certain extent.

The EU guidelines also refer to ‘Cross-Media Impacts’, in which the impact in one environmental medium may also have an indirect impact on another medium

17.3 Effects in Different Environmental Media

17.3.1 Matrix of Effects

Table 17.1 presents the effects matrix. The effects matrix examines the potential for the topic or issue in the left hand column to interact or have an effect on the environmental media listed in the top row of the matrix.

If there is the potential for an effect during the construction phase, this is indicated by a ‘C’. An ‘O’ indicates the potential for an effect during the operational phase and ‘OC’ indicates the potential for an effect during both phases. If there is considered to be no potential for an effect, this is indicated by ‘-’.

The purpose of the effects matrix is to identify potential effects in different media. Actual effects and their significance are dealt with in the most relevant chapter.

Table 17.1: Potential Interaction of Effects Matrix (C = Construction, O = Operational)

	Noise and Vibration	Air Quality	Surface Water & Ground-water	Climate	Landscape And Visual	Archaeological Architectural & Cultural Heritage	Human Beings	Material Assets	Flora and Fauna	Soils & Geology	Road Network & Traffic
Noise and Vibration	-	-	-	-	-	-	C	-	C	-	-
Air Emissions	-	-	-	-	-	-	C	-	-	-	-
Emissions to water	-	-	-	-	-	-	-	-	C	-	-
Landscape and Visual	-	-	-	-	-	-	CO	-	-	C	-
Archaeological Architectural & Cultural Heritage	-	-	-	-	-	-	-	-	-	-	-
Human Beings	-	-	-	-	-	-	-	-	-	-	CO
Material Assets	-	-	O	-	-	-	-	-	-	-	-
Flora & Fauna	-	-	-	-	-	-	-	-	-	-	-
Soils & Geology	C	C	C	-	C	-	-	C	-	-	-
Traffic	-	-	-	-	-	-	CO	-	-	-	-

17.4 Potential Interactions

The potential effects of noise and vibration during construction and operation on human beings and flora and fauna are addressed in Chapter 6 *Population and Human Health* and Chapter 13 *Biodiversity* respectively. Mitigation measures will be implemented to ensure there will be no significant impacts. Similarly, the potential for air quality impacts during construction are addressed in Chapter 10 *Air Quality and Climate*.

The impact of emissions to water on the flora and fauna are addressed in Chapter 13 *Biodiversity*.

The landscape and visual aspects of the proposed development on human beings and soils and geology are addressed in Chapter 6 *Population and Human Health* and Chapter 14 *Soils, Geology, Hydrology and Hydrogeology* respectively. Mitigation measures are set out to ensure no likely significant effects on aforementioned interactions.

No potential interactions were identified for Archaeology and Cultural Heritage on other aspects of the EIS. This is because the proposed development site is previously disturbed and has been subject to numerous previous archaeological investigations. No construction or mitigation impacts are proposed and therefore no potential interactions are foreseen.

The impacts of increased numbers of people being employed on site due to the construction and operation of the proposed development is addressed in Chapter 8 *Roads and Traffic*.

Chapter 16 *Material Assets* identifies the increased water use an impact due to the operation of the proposed facility. These impacts are addressed in Chapter 14 *Soils, Geology, Hydrology and Hydrogeology*.

There are no potential interactions for the impact of flora and fauna on the other aspects discussed in the EIS.

There are potential interactions between soils and geology and air quality, noise and vibration, landscape and visual, material assets and surface water and groundwater. These potential impacts are addressed in in the respective chapters in the EIS. Chapter 14 *Soils, Geology, Hydrology and Hydrogeology* also addresses the impacts of the proposed development on the local hydrology, groundwater and refers to the flood risk assessment carried out on the site.

In Chapter 8 *Roads and Traffic* the potential impacts of the construction and operation of the proposed development on local traffic are discussed.

17.4.1 Amenity

The impact of the proposed development on the amenity of the local area has been addressed in a number of sections in the EIS including Chapter 6 *Population and Human Health*. Chapter 7 *Landscape and Visual* addresses the impacts of the proposed development on the landscape character of the site, on scenic routes, views and prospects and surrounding areas.

17.5 Cumulative Impacts

The cumulative impacts of the proposed development are addressed in the relevant chapters of the EIS, as they are identified. No other planned or permitted development in the surrounding area has been identified that could give rise to significant cumulative environmental effects when considered in conjunction with the proposed development.

17.6 Reference

Directive 97/11EC amending Directive 85/337/EEC on the assessment of the effects of certain public and private projects on the environment, Official Journal of the European Communities, 1997

Planning and Development Regulations, 2001, Statutory Instrument No 600 of 2001, Government Publications Office, Dublin, 2001

Environmental Protection Agency (2015) *Revised Guidelines on the Information to be contained in the Environmental Impact Statements Draft* EPA, Wexford

Environmental Protection Agency (2015) *Advice Notes for Preparing Environmental Impact Statements Draft* EPA, Wexford

Environmental Protection Agency (2002) *Guidelines on the information to be contained in Environmental Impact Statements* EPA, Wexford

Environmental Protection Agency (2003) *Advice Notes on Current Practice (in the preparation of Environmental Impact Statements)* EPA, Wexford

Office for Official Publications of the European Communities (1999) *Guidelines for the Assessment of Indirect and Cumulative Impacts as well as Impact Interactions*

Directive 85/337/EEC on the assessment of the effects of certain public and private projects on the environment, Official Journal of the European Economic Communities, 1985.

18 Summary of Impacts and Mitigation Measures

18.1 Introduction

Lilly intends to ensure that any potential adverse effects of the proposed development on the environment are reduced 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 as much as is reasonably possible.

This chapter summarises the likely residual environmental effects associated with the proposed development. The predicted impacts and recommended mitigation measures are comprehensively detailed in the relevant chapters of the EIS, and are summarised in Table 18.1 below.

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Table 18.1: Assessment of Potential Effects and Mitigation Measures

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
CONSTRUCTION PHASE		
Site Clearance and Preparation		
• Clearance of vegetation • Setting up of temporary staff car parking • Setting up of site office, contractor facilities, temporary staff car park and contractor car park • Importation of construction equipment	• A construction environmental management plan (CEMP) will be prepared prior to construction commencing. The CEMP will comprise all of the construction mitigation measures, which are set out in this EIS, and 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. The plan will have regard to the guidance contained in the handbook published by Construction Industry Research and Information Association (CIRIA) in the UK, Environmental Good Practice on Site Guide, 4th Edition (CIRIA 2015). • Lilly will have a construction management team on the project site for the duration of the construction phase. The team will supervise the construction of the project including monitoring the contractors' performance to ensure that the proposed construction phase mitigation measures are implemented and that construction impacts and nuisance are minimised. • Lilly will liaise with neighbours and the general community during the construction phase to ensure that any disturbance is kept to a minimum and to ensure that all anticipated nuisances are minimised and that the construction activity will have the lowest possible impacts on the neighbours • A dust minimisation plan will be prepared and implemented by the contractor during the construction phase of the project. • In so far as is feasible, all construction materials will be sourced from local suppliers and adequate supplies or sources of these are available within the Cork area. • The selection and specification of construction materials will be informed by local availability of these materials. Within the necessary constraints of performance, durability and cost, construction materials will	Slight Short-term increase in traffic in the vicinity of the site.

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
	be sourced from local suppliers and manufacturers, where possible. Construction materials will be transported from the suppliers via the R605 and via the Ballyvtrin Road (coming from R605 direction only) to the site. - A car-pooling programme will be implemented for construction contractors to minimise the numbers of cars coming to site. - As required by the Safety, Health and Welfare at Work (Construction) Regulations 2013, a Health and Safety Plan will be prepared which will address health and safety issues from the design stages through to the completion of the construction and maintenance phases.	
Generation of Waste		
- Construction waste - Excavated material	- Waste generated during the construction phase will be carefully managed according to the accepted waste hierarchy which gives precedence to prevention, minimisation, reuse and recycling over disposal with energy recovery. - Any material unsuitable for on-site stockpiling will be removed off site to a suitable waste facility. This will be limited bituminous material from internal roads and car parking area at IE43.	Not significant No significant impact predicted. Bituminous material will be sent off site to be recycled.
Site Tidiness		
Untidy site	The following are some of the measures that will be taken to ensure that the site and surroundings are maintained to a high standard of cleanliness: - A regular program of site tidying will be established to ensure a safe and orderly site, - Scaffolding will have debris netting attached to prevent materials and equipment being scattered by the wind,	Negligible No significant impact predicted.

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
	- Food waste will be strictly controlled on all parts of the site, - Loaded lorries and skips will be covered, - Surrounding roads used by trucks to access to and egress from the site will be cleaned regularly using an approved mechanical road sweeper. Roads will be cleaned subject to local authority requirements. Site roads will be cleaned on a daily basis, or more regularly, as required, - Road edges and footpaths will be cleaned using a hand broom with controlled damping, - Wheelwash facilities will be provided with rumble grids to remove excess mud from wheels. These facilities will be located at all exits from the site, - In the event of any fugitive solid waste escaping the site, it will be collected immediately and removed to storage on site, and subsequently disposed of in the normal manner.	
Visual Impact		
- Site establishment will require erection of permanent and temporary fencing. - Erection of signage. - Excavations for pad foundations and services. - Temporary office and welfare facilities. - Construction of buildings including cranes.	- Construction activity will be adequately fenced-off in order to avoid damage or disturbance to landscape elements outside of minimum area required for such works. - Construction works will proceed in a controlled and orderly manner. - Site hoardings, cranes, temporary buildings and plant will be removed once construction has been completed.	Imperceptible to moderate effects Short-term visual effects during construction phase to local residents.
Traffic		

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
Increase in traffic due to construction activities in the form of HGVs, and workforce and general site traffic.	- A Construction Environmental Management Plan (incorporating a traffic management plan) will be prepared and implemented during the construction phase. It will be regularly reviewed and updated where necessary. - Site access for Lilly staff and construction staff will be segregated. There will be a temporary Lilly staff entrance constructed for this purpose. - A Car Pooling and Road Safety Strategy will be employed which all IE43 construction personnel will be obliged to adhere.	Slight effect Temporary and short term impact on local traffic volumes.
Noise and Vibration		
Principal sources of noise: - Earthworks plant and equipment. - Construction plant and equipment. - Construction traffic.	- Whilst the construction phase is not expected to give rise to noise impacts, as a matter of good practice, reference will be made to BS5228 (BSI, 2014) which offers detailed guidance on the control of noise and vibration from demolition and construction activities. However as mentioned earlier, the predicted noise levels during the construction phase are also within the IE licence daytime limit. - In general BS5228 advises the following, where necessary: - Avoid unnecessary revving of engines and switch off equipment when not required; - Keep internal haul routes well maintained and avoid steep gradients; - Use rubber linings in, for example, chutes and dumpers to reduce impact noise; - Minimize drop height of materials, and - Start-up plant and vehicles sequentially rather than all together. - The following more specific measures are also advised:	Slight effect Short-term and slight increase in noise levels during the construction phase. The impact of the construction works will be negligible on noise and vibration.

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
	- In accordance with best practicable means, plant and activities to be employed on site will be reviewed to ensure that they are the quietest available for the required purpose; - Where required, improved sound reduction methods, e.g. enclosures should be used; - Site equipment should be located away from noise sensitive areas, as much as is feasible; - Regular and effective maintenance by trained personnel should be carried out to reduce noise and/or vibration from plant and machinery; - Limiting the hours during which site activities likely to create high levels of noise or vibration are carried out; - Establish channels of communication between the contractor/developer, Local Authority and residents; - Appointing of a site representative responsible for matters relating to noise and vibration; and - Monitoring typical levels of noise and vibration during critical periods and at sensitive locations for comparison with limits and background levels.	
Air Emissions		
- Dust from excavation and site clearance activities - Emissions from exhausts of construction plant and vehicles. - Dust from movements on site in dry windy weather.	- A Construction Environmental Management Plan will be implemented. - A Dust Minimisation Plan will be formulated for the construction phase of the project. The focus of the control procedures will therefore be to reduce the generation of airborne material. The following measures shall be included as a minimum as part of the dust minimisation plan, to reduce dust emissions in the areas surrounding the site during construction: - Vehicle speeds in the construction site will be strictly limited.	Not significant Short term effects

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
Dust from dry surfaces and stockpiles	- During very dry periods, dust emissions from heavily trafficked locations will be controlled by spraying surfaces with water. - A mechanical road sweeper will be used to control mud on roads as required. - Potentially dusty material being removed from the site will be transported in covered trucks, where the likelihood of emitting dust is high, and during dry weather conditions the area of removal will be sprayed with a mobile tanker on a regular basis to control dust emissions. - Exhaust emissions from construction plant and equipment operating within the site, including trucks, excavators, diesel generators and compressors, will be controlled by the contractor by insuring that the equipment is well maintained and is operated in accordance to normal good practice. - If cement is stored in a silo on site, a filter will be fitted to the silo; alternatively ready-mix concrete might be supplied by truck.	
Climate		
Construction vehicles, generators etc., may give rise to CO₂ and NO_x emissions.	There will be minor emissions to the atmosphere during the construction phase. No mitigation measures required.	Negligible No significant impact on climate predicted.
Soils and Geology		
Excavation works below the existing ground level will be required for foundations and services.	- No topsoil will need to be removed where excavation is proposed as this has been removed as part of previous site works and developments. - Re-use surplus material, where possible. Refer to previous section of this table – Site Clearance and Preparation	Negligible No significant impact predicted.

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
Potential impact on soil from leaks or spills from fuel, etc.	The employment of good construction management practices will serve to minimise the risk of pollution of soil. A storm water drainage collection system will be installed. Any potential spills or leaks may be controlled to prevent contamination.	
Hydrology and Hydrogeology		
Potential impact on surface water during heavy precipitation from stormwater runoff which could contain silt, or oils from plant and vehicles.	- A Construction Environmental Management Plan will be prepared and implemented for the duration of the construction phase of the project. - Measures, as recommended in the CIRIA guidance <i>Control of Water Pollution from Linear Construction Projects</i> will be implemented to minimise the risk of spills and contamination of soils and waters - Stormwater runoff within construction compounds will be directed to stormwater system and directed to the containment pond and monitored before being submit. - Plant and vehicles serviced regularly to minimise leaks. - Fuels and lubricant stored in bunded areas. - Refuelling of plant in controlled areas only.	Negligible No significant impact predicted.
Biodiversity		
- Potential disturbance/displacement of birds and mammals due to increased traffic and noise. - Small sections of hedgerow and treeline will be removed.	- No controls or mitigation measures beyond good construction practice required. Most habitats have been previously significantly modified from the natural state by human activity. Measures set out in the Construction Environmental Management Plan will contribute towards minimising the impacts on natural habitats. These include: - Trees/habitats marked for retention will be fenced off to prevent incidental damage - Construction vehicles coming on site will have vehicles inspected to prevent invasive species coming on site such as Japanese knotweed.	No significant effects Short-term effects. Net loss of small sections of hedgerow and treeline. No impact on aquatic habitats predicted.

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
	Tree and hedgerow removal will occur outside the nesting season.	
Archaeological Architectural and Cultural Heritage		
The work associated with the proposed development will involve limited ground disturbance. There will be no direct impacts on the cultural heritage resource.	No mitigation measures required.	No Impact No significant impact on archaeological, architectural and cultural heritage.
Population and Human Beings		
450 contractors (550 peak) will be employed on-site over a 36 months period.	No mitigation required.	Moderate beneficial Employment
Use of Natural Resources		
Construction phase will require: - Potable water - Power - Fuel - Materials such as steel and concrete.	- Equipment will be serviced regularly to ensure efficient operation. - Materials will be carefully stored and handled to avoid waste and damage. - Water use will be controlled to avoid waste. - Water from on-site groundwater wells will be used.	Negligible Resource use will be typical for the type and size of project.

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
OPERATIONAL PHASE		
Visual Impact		
- Visual impact - Impact on landscape character of the local area	- The colours and elevations proposed will be in keeping with the existing IE43 building. - Local natural colour tones will be utilised. - Landscaping berms to the south and east with mixture of native deciduous and evergreen trees.	Imperceptible to moderate effects Most visible from eastern and northern locations. Designated scenic landscape likely not to be significant
Traffic		
There likely be some increase to local traffic.	- A Mobility Management Plan has been prepared and will be implemented. - Shift patterns associated with the proposed IE43 extension will not coincide with traditional road network peak hours. - Lilly has a flexi-time policy for non-shift staff that will be employed for IE43 extension staff.	Not significant Increased traffic generated. The surrounding road network has sufficient capacity.
Noise and Vibration		
All process operations will be contained within the IE43 building extension.	No mitigation measures are deemed necessary	Imperceptible effect. No residual operational impacts are envisaged.

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
Air Emissions		
Operation will give rise to some air emissions. These will be released from existing air emission points of IE43. Emissions will be limited to boiler exhaust and steam.	No mitigation measures are deemed necessary. Proposed emissions will be filtered as appropriate and discharged to the atmosphere.	Imperceptible effect. No residual operational impacts are envisaged.
Climate		
Increased boiler emissions	No mitigation measures are deemed necessary. Lilly will remain with the carbon emission limits of the Greenhouse Gas Emissions Permit GHG023-10352-4	Imperceptible effect. No residual operational impacts are envisaged.
Soils, Geology, Surface Water and Groundwater		
- Stormwater run-off - Groundwater will be extracted for use on the site. - Flood risk	Stormwater run-off - All underground process pipes and drains will have secondary containment and all chemical storage tanks will be bunded to 110% of capacity as is site practice. - Storage areas, production facilities and roadways will have impervious surfaces, which will drain to collection systems. Storm run-off from collection systems will drain either to the environmental controls area for treatment of run-off, or to a sump where it will be monitored before discharge. It will be contained if the monitoring detects contamination. The external areas around the proposed IE43 extension, where there would	Imperceptible effect. No residual operational impacts are envisaged.

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
	be potential for spills or leaks, will be bunded to contain and divert spills and firewater. The water discharges via the containment pond to the stream after passing through the monitoring chamber. - The proposed development includes a concrete wall adjacent to the stream bank. The proposed top of wall level is 31.5 m (site datum). This will provide protection to the site should an event of greater magnitude occur. In order to ensure that flood damage is minimized the following measures are also recommended: - Suitable building materials and finishes that are less likely to be damaged and easier to restore will reduce the amount of time would take to return the facility to operation. - All chemicals, solvents, fuels or other materials that may cause environmental contamination should they come in contact with flood waters will be stored within a bunded area within the proposed development. - The design of the surface water drainage system for the proposed development has ensured that flows to the stream will not be increased, as a result of the proposed development and that surface water discharges will be at greenfield rates. (Refer to Sections 14.4.5.2 and 14.5.2.3 in Chpt 14). Therefore it is considered that there will not be an impact on flooding elsewhere as a result of the proposed development. - It can be seen from the hydraulic model that a reduction in capacity has an impact on estimated water levels. The channel may become overgrown with vegetation if not maintained. In order to minimise the risk of the channel capacity being reduced, a channel maintenance programme will be put in place in consultation with Inland Fisheries Ireland (IFI). Groundwater As detailed in the previous IE43 EIS, flows in the stream will be monitored for up to 12 months prior to drawdown from the groundwater wells. The following mitigation measures will be put in place: - Two gauging stations, one upstream and the other downstream of the wells, will be installed on the stream and monitoring of flow rate and water level undertaken for up to 12 months prior to commissioning of the	

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
	additional abstraction wells. These will be used to establish the baseline data on the stream level and flows prior to commissioning the wells. - The sustainable yield for each well was established during the development phase. The abstraction from each well will be automatically capped at a percentage of its sustainable yield. - There is a number of groundwater monitoring wells on the site. The groundwater levels in monitoring wells across the site will be monitored on an ongoing basis. - The groundwater level and discharge flow volumes will be monitored in each well to ensure that there is no excessive drawdown of the groundwater. - The water levels in the stream will be monitored on an ongoing basis for at least 5 years using the gauging stations described above. The requirement for monitoring after this period will be reviewed with Inland Fisheries Ireland and Cork County Council. - Pumping from the wells will be controlled to ensure that there will be no impact on the water levels in the stream. - The mitigation measures outlined above will be implemented to ensure that there are no adverse impacts on the stream or the local groundwater due to the groundwater abstraction activities. - In the event of an effect being detected on the stream or the local groundwater, which cannot be resolved by managing the groundwater abstraction on site, increased water supply will be obtained from Cork County Council.	
Biodiversity		
- Leaks and spills from bunds and storage areas - Stormwater runoff	- Standard construction and design will ensure all addition chemical storage tanks are bunded. - See Soils, Geology, Surface Water and Groundwater above.	Imperceptible effect No residual impacts envisaged.

Source / Scale of Effect	Control and Mitigation	Residual Impacts, Significance Level, Environmental Consequence
Archaeological, Architectural and Cultural Heritage		
	No mitigation measures will be required	No impact
Human Beings		
- Health and Safety Impacts - Employment	- The Health and Safety policy, procedures and work practices of the proposed development will be in conformance to all relevant health and safety legislation both during its operational stages. The proposed development will be designed and constructed to best industry standards, with an emphasis being placed on the health and safety of employees, local residents and the community at large. 150 additional staff will be recruited when the proposed extension is fully operational.	No impact Positive effect with additional jobs being created.
Use of Natural Resources		
- Natural gas consumption - Water consumption - Power, utilities and steam consumption	- The development has been designed to a high level of energy efficiency, to minimise the consumption of gas and electrical power and share the existing facilities within the existing structure where possible. - Water will be sourced from both the local mains and on-site groundwater well. The use of mains water will not exceed 1000m³ per day. - There is sufficient capacity on-site for additional demands on power, utilities and steam.	Slight Adverse Impact